Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Diagnostics

Changes to the development pipeline
FY 2016 update

New to Phase I

4 NMEs:
RG6107 C5 inh MAb - PNH
RG6114 mPI3K alpha inh – HR+ BC
RG7854 TLR7 agonist (3) – HBV
RG7907 HBV Capsid (2) – HBV

1 NME in-licensed (Hanmi):
RG6185 pan-RAF inh – oncology

1 NME in-licensed (BioNTech):
RG6180 personalised cancer vaccine – oncology

1 NME with ownership transfer to Chugai:
RG7304 now displayed as **CHU**

1 NME added by Chugai:
CHU Glypican-3/CD3 biMAb – solid tumours

New to Phase II

2 NMEs transitioned from Ph1:
RG6125 Cadherin-11 MAb – RA
RG7916 SMN2 splicer (2) – SMA

Ipatasertib indications specified:
1 NME:
RG7440 ipatasertib – CRPC
2 AIs:
RG7440 ipatasertib – 1L TNBC
RG7440 ipatasertib – TNBC neoadj

1 opt-in deal signed:
NOV TLR4 MAb – autoimmune diseases

New to Phase III

5 AIs:
RG3645 Lucentis 0.3mg PFS - DME
RG7421 Cotellic + Tecentriq + Zelboraf – BRAF mut-positive melanoma
RG7446 Tecentriq + enzalutamide – CRPC
RG7446 Tecentriq - RCC adj

RG6013 emicizumab - Q4W in hemophilia A

New to Registration

3 AIs:

RG1569 Actemra – giant cell arteritis (EU/US)
RG7159 Gazyva – 1L FL (EU)
RG3645 Lucentis – diabetic retinopathy w/o DME (US)

Added to 2L mUC entry:
RG7446 Tecentriq – 1L cis-ineligible mUC

1 AI filed by Chugai:
CHU Actemra – large-vessel vasculitis

Removed from Phase I

2 NMEs:
RG7841 Ly6E ADC – solid tumours
RG7893 Nav1.7 inh – pain

Removed from Phase II

2 AIs:
RG3502 Kadcyla – HER2+ NSCLC
RG7604 taselisib – 2L sq NSCLC

Removed from Phase III

Removed from Registration

1 AI following FDA approval:
RG3645 Lucentis – myopic CNV

Status as of 1 February 2017

Roche Group development pipeline

Phase I (42 NMEs + 26 AIs)

RG6016	LSD1 inh	SCLC
RG6047	SERD (2)	ER+ (HER2-neg) mBC
RG6058	TIGIT ± Tecentriq	solid tumours
RG6061	HIF1 alpha LNA	solid tumours
RG6078	IDO inh	solid tumours
	IDO inh + Tecentriq	solid tumours
RG6114	mPI3K alpha inh	HR+ BC
RG6146	BET inh	solid + heme tumours
RG6180	personalised cancer vaccine	oncology
RG6185	pan-RAF inh	oncology
RG7155	emactuzumab + Tecentriq	solid tumours
	emactuzumab + CD40 iMAb	solid tumours
RG7159	anti-CD20 multiple combos	heme tumours
RG7386	FAP-DR5 biMAb	solid tumours
RG7421	Cotellic + Tecentriq + Avastin	2/3L CRC
RG7446	Tecentriq	solid tumours
	Tecentriq	NMIBC
	T + Zelboraf ± Cotellic	melanoma
	T ± Avastin ± chemo	HCC, GC, PaC
	T ± Avastin ± chemo	solid tumours
	T + Cotellic	solid tumours
	T + ipi/IFN	solid tumours
	T + Tarceva or Alecensa	NSCLC
	T + anti-CD20 multiple combos	lymphoma
	T ± lenalidomide ± daratumumab	MM
	T + K/HP	HER2+ BC
	T ± azacitidine	MDS
	T + radium 223	mCRPC
	T + guadecitabine	AML
RG7461	FAP IL2v FP	solid tumours
RG7601	Venclexta multiple combos	NHL
	Venclexta + Gazyva	CLL
	Venclexta + Cotellic/idasanutlin	AML
RG7741	ChK1 inh	solid tumours
RG7802	CEA CD3 TCB ± Tecentriq	solid tumours
RG7813	CEA* IL2v FP + Tecentriq	solid tumours
RG7828	CD20/CD3 TDB	heme tumours
RG7876	CD40 iMAb + Tecentriq	solid tumours
	CD40 iMAb + vanucizumab	solid tumours
RG7882	ADC	ovarian cancer
RG7888	OX40 MAb	solid tumours
	OX40 MAb + Tecentriq	solid tumours
RG7986	ADC	r/r NHL
CHU	Raf/MEK dual inh	solid tumours
CHU	glypican-3/CD3 biMAb	solid tumours
RG3616	Erivedge + Esbriet	IPF
	Erivedge + ruxolitinib	myelofibrosis
RG6069	anti-fibrotic agent	Fibrosis
RG6107	C5 inh MAb	PNH
RG7159	obinutuzumab	renal transplant
RG7880	IL-22Fc	inflammatory diseases
RG7990	-	asthma
RG6080	DBO β-lactamase inh	bacterial infections
RG7834	-	HBV
RG7854	TLR7 agonist (3)	HBV
RG7861	anti-*S. aureus* TAC	infectious diseases
RG7907	HBV Capsid (2)	HBV
RG7992	FGFR1/KLB MAb	metabolic diseases
RG6000	-	ALS
RG6029	Nav1.7 inh (2)	pain
RG6100	Tau MAb	Alzheimer's
RG7203	PDE10A inh	schizophrenia
RG7800	SMN2 splicer	SMA
RG7906	-	psychiatric disorders
RG7935	α-synuclein MAb	Parkinson's
IONIS	ASO	Huntington's
CHU	PTH1 receptor agonist	hypoparathyroidism
CHU	-	hyperphosphatemia

New Molecular Entity (NME)
Additional Indication (AI)
Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
Other

RG-No Roche/Genentech
CHU Chugai managed
IONIS IONIS managed
PRO Proximagen managed
NOV Novimmune managed

*INN: cergutuzumab amunaleukin
**Ph3 in preparation
***out-licensed to Galderma and Maruho
T=Tecentriq

Phase II (22 NMEs + 12 AIs)

RG3502	Kadcyla + Tecentriq	2L HER2+ mBC
RG6046	SERD	ER+ (HER2-neg) mBC
RG7221	vanucizumab	mCRC
RG7421	Cotellic + Tecentriq ± taxane	TNBC
RG7440	ipatasertib**	CRPC
	ipatasertib	1L TNBC
	ipatasertib	TNBC neoadj
RG7596	polatuzumab vedotin	heme tumours
RG7601	Venclexta + Rituxan	DLBCL
	Venclexta + Rituxan	r/r FL
RG7604	taselisib + letrozole	(HER2-neg) BC neoadj
RG7686	codrituzumab	liver cancer
RG3637	lebrikizumab	atopic dermatitis
	lebrikizumab	COPD
	lebrikizumab ± Esbriet	IPF
RG6125	Cadherin-11 MAb	RA
RG6149	ST2 MAb	asthma
RG7159	obinutuzumab	lupus
RG7625	Cat-S antag	autoimmune diseases
RG7845	BTK inh	autoimmune diseases
CHU	nemolizumab***	atopic dermatitis
CHU	nemolizumab	pruritus in dialysis pts
PRO	VAP-1 inh	inflammatory disease
NOV	TLR4 MAb	autoimmune diseases
RG6152	CAP endonuclease inh	influenza
RG7227	danoprevir	HCV
RG7745	Flu A MAb	influenza A
CHU	URAT1 inh	gout
RG1662	basmisanil	CIAS
RG6083	olesoxime	SMA
RG7314	V1 receptor antag	autism
RG7916	SMN2 splicer(2)	SMA
RG3645	ranibizumab PDS	wAMD
RG7716	VEGF-ANG2 biMAb	wAMD, DME

Status as of 1 February 2017

Roche Group development pipeline

Phase III (8 NMEs + 33 AIs)

RG435	Avastin[1]	1L GBM
	Avastin	mesothelioma
RG1273	Perjeta + Herceptin	HER2+ BC adj
	Perjeta + Herceptin	HER2+1L gastric ca
RG3502	Kadcyla	HER2+ BC adj
	Kadcyla + Perjeta	HER2+ BC adj
RG6013	emicizumab	hemophilia A, FVIII inh
	emicizumab	pediatric hemophilia A, FVIII inh
	emicizumab	hemophilia A, w/o FVIII inh
	emicizumab	Q4W hemophilia A
RG7204	Zelboraf	BRAFmut melanoma adj
RG7388	idasanutlin	AML
RG7421	Cotellic + Tecentriq	3L CRC
	Cotellic + T + Zelboraf	BRAFmut melanoma
RG7446	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	T + Abraxane	1L non-sq NSCLC
	T + chemo + Avastin	1L non-sq NSCLC
	T + chemo + pemetrexed	1L non-sq NSCLC
	T + Abraxane	1L sq NSCLC
	T + Abraxane	TNBC
	T + Avastin	RCC
	T ± chemo	1L mUC
	T + chemo	1L extensive stage SCLC
	T + enzalutamide	CRPC
	Tecentriq Dx+	1L sq + non-sq SCLC
	Tecentriq	RCC adj
RG7601	Venclexta + Rituxan	r/r CLL
	Venclexta + Gazyva	1L CLL
	Venclexta + bortezomib	MM
RG7604	taselisib + fulvestrant	ER+(HER2-neg) mBC
RG7853	Alecensa	1L ALK+ NSCLC
RG105	MabThera	pemphigus vulgaris
RG1569	Actemra	systemic sclerosis
RG7413	etrolizumab	ulcerative colitis
	etrolizumab	Crohn's disease
RG1450	gantenerumab	Alzheimer's disease
RG6168	IL-6R MAb	neuromyelitis optica
RG7412	crenezumab	Alzheimer's disease
RG7417	lampalizumab	geographic atrophy
RG3645	Lucentis 0,3mg PFS[1]	DME

Registration (3 NMEs + 7 AIs)

RG105	MabThera SC[2]	CLL, NHL
RG435	Avastin[3]	rel. ovarian ca. Pt-sensitive
RG7159	Gazyva[4]	1L FL
RG7446	Tecentriq[5]	1L cis-ineligible + 2L mUC
	Tecentriq[6]	2L+ NSCLC
RG7853	Alecensa[7]	2L ALK+ NSCLC
RG1569	Actemra	giant cell arteritis
CHU	Actemra	large-vessel vasculitis
RG1594	OCREVUS®	PPMS, RMS
RG3645	Lucentis[1]	diabetic retinopathy w/o DME

1. US only
2. Approved in EU – Filed in US
3. Approved in US, filed in EU for chemo backbone extension
4. Filed in EU
5. Filing based on IMvigor210 approved in US for 2L, filed in US for 1L, phase 3 ongoing
6. Approved in US
7. Approved in US and Japan

New Molecular Entity (NME)
Additional Indication (AI)
Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
Other

RG-No Roche/Genentech
CHU Chugai managed
RG105 Branded as Rituxan (US, Japan)
RG1569 Branded as RoActemra (EU)
RG7159 Branded as Gazyvaro (EU)
RG-No Roche/Genentech
CHU Chugai managed
T=Tecentriq

Status as of 1 February 2017

NME submissions and their additional indications

Projects currently in phase 2 and 3

2016	2017	2018	2019 and beyond
RG1594 **OCREVUS®** PPMS & RMS ✓		RG6013 **emicizumab** Hemophilia A, w/o FVIII inh	RG7388 **idasanutlin** AML
RG7446 **Tecentriq*** 2L mUC ✓	RG6013 **emicizumab** Hemophilia A, FVIII inh	RG6013 **emicizumab** Q4W hemophilia A	RG7604 **taselisib + letrozole** ER+ (HER2-neg) BC neoadj
		RG7604 **taselisib+fulvestrant** PIK3CAmut ER+ (HER2-neg) mBC	RG7440 **ipatasertib** TNBC neoadj
		RG6168 **IL-6R MAb SA237** Neuromyelitis optica	RG7440 **ipatasertib** 1L TNBC
		RG7417 **lampalizumab** Geographic atrophy	RG7440 **ipatasertib** CRPC
			RG1450 **gantenerumab** Alzheimer's disease
			RG1662 **basmisanil** CIAS
			RG6083 **olesoxime** SMA
			RG7314 **V1 receptor antag** Autism
			RG7412 **crenezumab** Alzheimer's disease
			RG7916 **SMN2 splicer(2)** SMA
			RG6152 **CAP endo-nuclease inh** Influenza
			RG7227 **danoprevir** HCV
			RG7745 **Flu A MAb** Influenza
			RG7716 **VEGF/ANG2 biMAb** wAMD, DME
			RG3637 **lebrikizumab** Atopic dermatitis
			RG3637 **lebrikizumab ± Esbriet** IPF
			RG3637 **lebrikizumab** COPD
			RG6125 **Cadherin-11 MAb** RA
			RG6149 **ST2 MAb** Asthma
			RG7413 **etrolizumab** Ulcerative colitis
			RG7413 **etrolizumab** Crohn's disease
			RG7625 **Cat S antag** Autoimmune diseases
			RG7845 **BTK inh** Autoimmune diseases

Unless stated otherwise, submissions are planned to occur in US and EU

✓indicates a submission which has occurred with regulatory action pending ; *approved in US

New Molecular Entity (NME)
Additional Indication (AI)
Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
Other

Status as of 1 February 2017

AI submissions for existing products

Projects currently in phase 2 and 3

2016

RG3645	**Lucentis** Diabetic retinopathy w/o DME ✓
RG3645	**Lucentis 0.5mg PFS (US)[1]** AMD, RVO ✓
RG3645	**Lucentis (US)[1]** Myopic CNV ✓
RG1569	**Actemra** Giant cell arteritis ✓
RG435	**Avastin[2]** Rel. Pt-sens. ovarian cancer ✓
RG7159	**Gazyva (EU)** 1L FL ✓
RG7446	**Tecentriq[1]** 2L+ NSCLC ✓
RG7446	**Tecentriq (US)** 1L cis-ineligible bladder cancer ✓

2017

RG3645	**Lucentis 0.3mg PFS (US)[1]** DME
RG435	**Avastin (US)** GBM
RG435	**Avastin** Mesothelioma
RG1273	**Perjeta + Herceptin** 1L HER2+ gastric cancer
RG1273	**Perjeta + Herceptin** HER2+ BC adj.
RG7159	**Gazyva (US)** 1L FL
RG7204	**Zelboraf** Melanoma adj.
RG7601	**Venclexta + Rituxan** r/r CLL
RG7853	**Alecensa** 1L Alk+ NSCLC

2018

RG105	**MabThera** Pemphigus vulgaris
RG1569	**Actemra** Systemic sclerosis
RG7446	**Tecentriq + chemo** 1L extensive stage SCLC
RG7446	**Tecentriq + chemo + Avastin** 1L non-sq NSCLC
RG7446	**Tecentriq + Abraxane** 1L sq NSCLC
RG7446	**Tecentriq + Abraxane** 1L non-sq NSCLC
RG7446	**Tecentriq + Avastin** RCC
RG7446	**Tecentriq + Abraxane** TNBC

2019 and beyond

RG3502	**Kadcyla + Tecentriq** 2L Her2+ mBC
RG3502	**Kadcyla + Perjeta** HER2+ BC adj.
RG3502	**Kadcyla** HER2+ BC adj.
RG7446	**Tecentriq** 1L non-sq + sq NSCLC (Dx+)
RG7446	**Tecentriq + enzalutamide** CRPC
RG7601	**Venclexta + Rituxan** r/r FL
RG7601	**Venclexta + Gazyva** 1L CLL
RG7601	**Venclexta + bortezomib** MM
RG7601	**Venclexta + Rituxan** DLBCL
RG3502	**Kadcyla + Tecentriq** 2L Her2+ mBC
RG3645	**ranibizumab PDS** wAMD
RG7159	**obinutuzumab** Lupus nephritis
RG7421	**Cotellic + Tecentriq** 3L CRC
RG7421	**Cotellic + Tecentriq + Zelboraf** BRAFmut melanoma
RG7421	**Cotellic + Tecentriq ± taxane** TNBC
RG7446	**Tecentriq + chemo + pemetrexed** 1L non-sq NSCLC
RG7446	**Tecentriq ± chemo** 1L mUC
RG7446	**Tecentriq** NSCLC adj
RG7446	**Tecentriq** MIBC adj
RG7446	**Tecentriq** RCC adj

✓ indicates submission to health authorities has occurred
1 Approved in US
2 Approved in EU
Unless stated otherwise, submissions are planned to occur in US and EU.

New Molecular Entity (NME)
Additional Indication (AI)
Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
Other

Status as of 1 February 2017

Major granted and pending approvals 2016

Approved

US		EU		Japan-Chugai	
RG7604	**Venclexta 17p del** r/r CLL April 2016	RG105	**MabThera SC** CLL June 2016	CHU	**Bonviva** Osteoporosis (oral) January 2016
RG7446	**Tecentriq** 2L mUC May 2016	RG435	**Avastin + Tarceva** EGFRmut NSCLC June 2016	CHU	**Avastin** Cervical cancer May 2016
RG7446	**Tecentriq** 2L+ NSCLC October 2016	RG7159	**Gazyva** Rituximab-ref. iNHL June 2016		
RG7159	**Gazyva** Rituximab-ref. iNHL February 2016				
RG435	**Avastin** Rel. Pt-sens. ovarian ca. December 2016				
RG3645	**Lucentis 0.5mg PFS** AMD, RVO October 2016				
RG3645	**Lucentis** mCNV January 2017				

Pending approval

RG7446	**Tecentriq** 1L cis-ineligible bladder ca. Filed October 2016	RG7853	**Alecensa** 2L ALK+ NSCLC Filed September 2015	CHU	**Actemra** Large-vessel vasculitis Filed November 2016
RG1569	**Actemra** Giant cell arteritis Filed November 2016	RG7446	**Tecentriq** 2L mUC Filed April 2016		
RG1594	**OCREVUS®** PPMS & RMS Filed April 2016	RG7446	**Tecentriq** 2L+ NSCLC Filed April 2016		
RG3645	**Lucentis** Diabetic retinopathy w/o DME Filed October 2016	RG7159	**Gazyva** 1L follicular lymphoma Filed October 2016		
		RG1569	**Actemra** Giant cell arteritis Filed November 2016		
		RG1594	**OCREVUS®** PPMS & RMS Filed April 2016		

New Molecular Entity (NME)
Additional Indication (AI)
Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
Other

Status as of 1 February 2017

Roche Group Development pipeline
Combinations

Phase I (5 NMEs + 22 AIs)

RG6058	TIGIT ± Tecentriq	solid tumours
RG6078	IDO inh +Tecentriq	solid tumours
RG7155	Emactuzumab + Tecentriq	solid tumours
	Emactuzumab + CD40 iMAb	solid tumours
RG7159	anti-CD20 multiple combos	heme tumours
RG7421	Cotellic + Tecentriq + Avastin	2/3L CRC
RG7446	T + Zelboraf ± Cotellic	melanoma
	T ± Avastin ± chemo	HCC, GC, PaC
	T ± Avastin ± chemo	solid tumours
	T + Cotellic	solid tumours
	T + ipi/IFN	solid tumours
	T + Tarceva or Alecensa	NSCLC
	T + anti-CD20 multiple combos	lymphoma
	T ± lenalidomide ± daratumumab	MM
	T + K/HP	HER2+ BC
	T + azacitidine	MDS
	T + radium 223	mCRPC
RG7601	Venclexta multiple combos	NHL
	Venclexta + Gazyva	CLL
	Venclexta + Cotellic/idasanutlin	AML
RG7802	CEA CD3 TCB ± Tecentriq	solid tumours
RG7813	CEA* IL2v FP + Tecentriq	solid tumours
RG7876	CD40 iMAb + Tecentriq	solid tumours
	CD40 iMAb + vanucizumab	solid tumours
RG7888	OX40 Mab + Tecentriq	solid tumours
RG3616	Erivedge + Esbriet	IPF
	Erivedge + ruxolitinib	myelofibrosis

Phase II (6 AIs)

RG3502	Kadcyla + Tecentriq	2L HER2+ mBC
RG7421	Cotellic + Tecentriq ± taxane	TNBC
RG7601	Venclexta + Rituxan	DLBCL
	Venclexta + Rituxan	r/r FL
RG7604	taselisib + letrozole	(HER2-) BC neoadj
RG3637	Lebrikizumab ± Esbriet	IPF

Phase III (1 NMEs + 17 AIs)

RG1273	Perjeta + Herceptin	HER2+ BC adj
	Perjeta + Herceptin	1L HER2+ gastric ca
RG3502	Kadcyla + Perjeta	HER2+ BC adj
RG7421	Cotellic + Tecentriq	3 L CRC
	Cotellic + T + Zelboraf	BRAFm melanoma
RG7446	T + Abraxane	1L non-sq NSCLC
	T + chemo + Avastin	1L non-sq NSCLC
	T + chemo + pemetrexed	1L non-sq NSCLC
	T + Abraxane	1L sq NSCLC
	T + Abraxane	TNBC
	T + Avastin	RCC
	T ± chemo	1L mUC
	T + chemo	1L extensive stage SCLC
	T + enzalutamide	CRPC
RG7601	Venclexta + Rituxan	r/r CLL
	Venclexta + Gazyva	1L CLL
	Venclexta + bortezomib	MM
RG7604	taselisib + fulvestrant	ER+ (HER2-neg) mBC

New Molecular Entity (NME)
Additional Indication (AI)
Oncology
Immunology

RG-No Roche/Genentech
CHU Chugai managed

*INN: cergutuzumab amunaleukin
T=Tecentriq

Status as of 1 February 2017

Cancer immunotherapy pipeline overview

Phase I (10 NMEs + 28 AIs)

RG6058	TIGIT ± Tecentriq	solid tumours
RG6078	IDO inh	solid tumours
	IDO inh + Tecentriq	solid tumours
RG6180	personalised cancer vaccine	oncology
RG7155	emactuzumab + Tecentriq	solid tumours
	emactuzumab + CD40 iMAb	solid tumours
RG7421	Cotellic + Tecentriq + Avastin	2/3L CRC
RG7446	Tecentriq	solid tumours
	Tecentriq	NMIBC
	T + Zelboraf ± Cotellic	melanoma
	T ± Avastin ± chemo	HCC, GC, PaC
	T ± Avastin ± chemo	solid tumours
	T + Cotellic	solid tumours
	T + Ipi/IFN	solid tumours
	T + Tarceva/Alecensa	NSCLC
	T + anti-CD20 multiple combos	lymphoma
	T ± lenalidomide ± daratumumab	MM
	T + K/HP	HER2+ BC
	T + azacitidine	MDS
	T + radium 223	mCRPC
	T + guadecitabine	AML
RG7461	FAP IL2v FP	solid tumours
RG7802	CEA CD3 TCB ± Tecentriq	solid tumours
RG7813	CEA* IL2v FP + Tecentriq	solid tumours
RG7828	CD20/CD3 TDB	heme tumours
RG7876	CD40 iMAb + Tecentriq	solid tumours
	CD40 iMAb + vanucizumab	solid tumours
RG7888	OX40 iMAb	solid tumours
	OX40 iMAb + Tecentriq	solid tumours
INCY**	Tecentriq + IDO inh	solid tumours
CLDX**	Tecentriq + varlilumab	solid tumours
CRVS**	Tecentriq + CPI-4444	solid tumours
KITE**	Tecentriq + KTE-019	r/r DLBCL
AMGN**	Tecentriq + T-vec	TNBC, CRC
JNJ**	Tecentriq ± daratumumab	solid tumours
CLVS**	Tecentriq + rucaparib	ovarian ca
Epizyme**	Tecentriq + tazemetostat	r/r DLBCL
BioLine Rx**	Tecentriq + BL-8040	AML, solid tumours

Phase II (4 AIs)

RG3502	Kadcyla + Tecentriq	2L HER2+ mBC
RG7421	Cotellic + Tecentriq ± taxane	TNBC
IMDZ**	Tecentriq + NY-ESO-1	soft tissue sarcoma
SNDX**	Tecentriq + entinostat	TNBC

Phase III (15 AIs)

RG7421	Cotellic + Tecentriq	3L CRC
	Cotellic + T + Zelboraf	BRAFm melanoma
RG7446	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	T + Abraxane	1L non-sq NSCLC
	T + chemo + Avastin	1L non-sq NSCLC
	T + chemo + pemetrexed	1L non-sq NSCLC
	T + Abraxane	1L sq NSCLC
	T + Abraxane	TNBC
	T + Avastin	RCC
	T ± chemo	1L mUC
	T + chemo	1L extensive stage SCLC
	T + enzalutamide	CRPC
	Tecentriq Dx+	1L sq + non-sq SCLC
	Tecentriq	RCC adj

Registration (1 NMEs + 1 AIs)

RG7446	Tecentriq[5]	1L cis-ineligible + 2L mUC
	Tecentriq[6]	2L+ NSCLC

1 Filing based on IMvigor210 approved in US for 2L, filed in US for 1L, phase 3 ongoing

2 Approved in US

New Molecular Entity (NME)
Additional Indication (AI)
Oncology

RG-No Roche/Genentech
*INN: cergutuzumab amunaleukin
T=Tecentriq

** External collaborations: INCY- Incyte INCB024360, CLDX - Celldex CD27 MAb; CLVS – Clovis PARPi, CRVS – Corvus CPI-444, KITE – Kite KTE-C19, AMGN – Amgen oncolytic virus (talimogene laherparapvec), JNJ – Janssen CD38 MAb., IMDZ – Immune Design CMB305, SNDX – Syndax HDACi

Status as of 1 February 2017

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Diagnostics

Alecensa (alectinib, RG7853, AF802)

New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	Treatment-naïve ALK-positive advanced non-small cell lung cancer (NSCLC)	ALK-positive advanced NSCLC in ALK inhibitor-naïve patients who are chemotherapy-naïve or have received one previous line of chemotherapy	ALK-positive crizotinib-naïve advanced NSCLC
Phase/study	**Phase III** **ALEX**	**Phase III** **J-ALEX/Japic CTI-132316** **Japanese study**	**Phase I/II** **AF-001JP** Japanese study
# of patients	N=286	N=207	N=70
Design	▪ **ARM A**: Alecensa 600mg BID ▪ **ARM A**: crizotinib 250mg BID	▪ **ARM A**: Alecensa 300mg BID ▪ **ARM A**: crizotinib 250mg BID	▪ **Part 1**: Dose escalation monotherapy ▪ **Part 2**: Monotherapy, dose selected based on the results of Part 1
Primary endpoint	▪ Progression free survival	▪ Progression free survival	▪ Phase I: Determination of recommended dose ▪ Phase II: Safety and efficacy
Status	▪ Recruitment completed Q3 2015 ▪ Data expected in 2017	▪ Primary analysis positive ▪ Data presented at ASCO 2016 ▪ Breakthrough therapy designation granted by US FDA Q3 2016	▪ Results published in *Lancet Oncology* 2013 Jun;14(7):590-8 ▪ Approved in Japan July 2014

In collaboration with Chugai
ASCO=American Society of Clinical Oncology

Alecensa (alectinib, RG7853, AF802)

New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	ALK-positive advanced NSCLC after progression on crizotinib treatment	ALK-positive advanced NSCLC after progression on crizotinib treatment
Phase/study	**Phase I/II** **AF-002JG/NP28761** US study	**Phase I/II** **ACCALIA/NP28673** Global study
# of patients	Phase I: N=36 Phase II: N=85	N=130
Design	▪ **Part 1**: Dose escalation monotherapy ▪ **Part 2**: Monotherapy, dose selected based on the results of Part 1	▪ **Part 1**: Dose escalation monotherapy ▪ **Part 2**: Monotherapy, dose selected based on the results of Part 1
Primary endpoint	▪ Phase I: Determination of recommended dose ▪ Phase II: Safety and efficacy	▪ Phase I: Determination of recommended dose ▪ Phase II: Safety and efficacy
Status	▪ Phase I data presented at ECC 2013 ▪ Phase I full cohort, including CNS data, published in *Lancet Oncology* 2014, Sept.15(10):1119-28 ▪ Phase II FPI Q3 2013 ▪ Primary analysis positive Q1 2015 ▪ Data presented at ASCO 2015 ▪ Updated data presented at WCLC 2015	▪ Phase II FPI Q3 2013 ▪ Primary analysis positive Q4 2014 ▪ Updated analysis in Q1 2015 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ECC 2015 ▪ Updated data presented at ESMO 2016
	▪ Filed Q2 (US) and Q3 (EU) 2015 ▪ Priority review granted by FDA Q3 2015 ▪ Breakthrough therapy designation granted by US FDA June 2013 ▪ Approved in US Q4 2015 ▪ EU CHMP positive opinion received Dec 2016	

In collaboration with Chugai
ECC=European Cancer Congress; ASCO=American Society of Clinical Oncology;
WCLC=World Conference on Lung Cancer; ESMO=European Society for Medical Oncology

Avastin

Clinical development program

Indication	Relapsed platinum-sensitive ovarian cancer	Newly diagnosed glioblastoma
Phase/study	**Phase III GOG-0213**	**Phase III AVAglio**
# of patients	N=674	N=920
Design	▪ **ARM A**: carboplatin and paclitaxel ▪ **ARM B**: carboplatin, paclitaxel and Avastin (from cycle 2 onwards until disease progression).	▪ **ARM A:** Concurrent radiation and temozolomide plus placebo; followed by maintenance TMZ plus placebo for 6 cycles; then placebo until disease progression ▪ **ARM B:** Concurrent radiation and TMZ plus Avastin; followed by maintenance TMZ plus Avastin for 6 cycles; then Avastin (15mg/kg q3 weeks) monotherapy until disease progression
Avastin dose	▪ 15 mg/kg q3 weeks	▪ 10 mg/kg q2 weeks or 15 mg/kg q3 weeks
Primary endpoint	▪ Overall survival	▪ Progression free survival (PFS), Overall survival
Status	▪ Study showed a 4.9 mo overall survival benefit ▪ Presented SGO Q1 2015 ▪ Approved in US in Q4 2016; filed in EU for chemo backbone extension	▪ Co-primary endpoint of PFS met Q3 2012 ▪ Overall survival data presented at ASCO 2013 ▪ Filed in EU Q1 2013 ▪ Negative CHMP opinion Q3 2014 ▪ US filing pending

SGO=Society of Gynecologic Oncology; ASCO=American Society of Clinical Oncology; TMZ=Temozolomide

Cotellic (cobimetinib)

Selective small molecule inhibitor of mitogen-activated protein kinase kinase

Indication	Third-line advanced or metastatic colorectal cancer	2L/3L metastatic colorectal cancer	Locally advanced or metastatic tumours
Phase/study	**Phase III IMblaze370**	**Phase I**	**Phase I**
# of patients	N=360	N=33	N=151
Design	▪ **ARM A:** Tecentriq ▪ **ARM B:** Cotellic + Tecentriq ▪ **ARM C:** regorafenib	Open-label, single-arm, two-stage study with Cotellic plus Tecentriq plus Avastin ▪ **Stage 1:** Safety run-in ▪ **Stage 2:** Dose-expansion with two cohorts – (1) expansion, (2) biopsy	▪ **ARM A:** Dose-finding - Cotellic + Tecentriq ▪ **ARM B:** Dose-expansion - Cotellic + Tecentriq
Primary endpoint	▪ Overall survival	▪ Safety	▪ Safety
Status	▪ FPI Q2 2016	▪ FPI Q3 2016	▪ FPI Q4 2013 ▪ CRC data presented at ASCO and ESMO 2016

In collaboration with Exelixis

ESMO=European Society for Medical Oncology; ASCO=American Society of Clinical Oncology

Cotellic (cobimetinib)

Selective small molecule inhibitor of mitogen-activated protein kinase kinase

Indication	First-line metastatic triple negative breast cancer	Relapsed or refractory AML not eligible for cytotoxic therapy
Phase/study	**Phase II COLET**	**Phase I/II**
# of patients	N=160	N=140
Design	▪ **ARM A:** Cotellic + paclitaxel ▪ **ARM B:** placebo + paclitaxel ▪ **ARM C:** Cotellic + Tecentriq + nab-paclitaxel ▪ **ARM D:** Cotellic + Tecentriq + paclitaxel	Phase I (dose escalation) ▪ **ARM A:** Cotellic + Venclexta ▪ **ARM B:** idasanutlin + Venclexta Phase II (expansion) ▪ **ARM A:** Cotellic + Venclexta ▪ **ARM B:** idasanutlin + Venclexta
Primary endpoint	▪ Progression free survival, safety	▪ Safety and efficacy
Status	▪ FPI Q1 2015 ▪ FPI Arms C and D: Q4 2016	▪ FPI Q1 2016

In collaboration with Exelixis

Cotellic (cobimetinib)

Selective small molecule inhibitor of mitogen-activated protein kinase kinase

Indication	First-line BRAFv600 mutation-positive metastatic or unresectable locally advanced melanoma	First-line BRAF-WT metastatic or unresectable locally advanced melanoma	Previously untreated metastatic melanoma BRAF mutation-positive
Phase/study	**Phase III IMspire150 TRILOGY**	**Phase III IMspire170**	**Phase I**
# of patients	N=500	N=500	N=70
Design	Double-blind, randomised, placebo-controlled study ▪ **ARM A:** Tecentriq + Cotellic + Zelboraf[1] ▪ **ARM B:** placebo + Cotellic + Zelboraf[1]	▪ **ARM A:** Cotellic + Tecentriq ▪ **ARM B:** pembrolizumab	▪ Dose-finding study of Cotellic + Tecentriq (PD-L1 MAb) + Zelboraf[1] and Tecentriq (PD-L1 MAb) + Zelboraf[1] combinations
Primary endpoint	▪ Progression free survival	▪ Progression free survival, Overall survival	▪ Safety, PK
Status	▪ FPI Jan 2017	▪ FPI expected Q2 2017	▪ FPI Q4 2012 ▪ Data presented at ESMO 2016

In collaboration with Exelixis

[1]Zelboraf In collaboration with Plexxikon, a member of Daiichi Sankyo Group; ESMO=European Society for Medical Oncology

Erivedge

A novel small molecule inhibitor of the hedgehog signalling pathway

Indication	Locally advanced or metastatic basal cell carcinoma	Idiopathic pulmonary fibrosis	Intermediate- or high-risk myelofibrosis (MF)
Phase/study	**Phase II STEVIE**	**Phase Ib ISLAND 2**	**Phase Ib MYLIE**
# of patients	N=1,200	N=20	N=20
Design	▪ Erivedge orally once daily	▪ Erivedge plus Esbriet	▪ Erivedge plus ruxolitinib
Primary endpoint	▪ Safety	▪ Safety and tolerability	▪ Safety and efficacy
Status	▪ FPI Q2 2011 ▪ Recruitment completed Q3 2014 ▪ Interim data presented at SMR 2014 ▪ EU conversion to full approval Q4 2016	▪ FPI Q1 2016	▪ FPI Q1 2016

In collaboration with Curis
SMR=Society for Melanoma Research

Gazyva/Gazyvaro (obinutuzumab)

Oncology development program

Indication	Diffuse large B-cell lymphoma (DLBCL)	Indolent non-Hodgkin's lymphoma MabThera/Rituxan refractory	Front-line indolent non-Hodgkin's lymphoma
Phase/study	**Phase III** **GOYA**	**Phase III** **GADOLIN** Induction and maintenance study	**Phase III** **GALLIUM** Induction and maintenance study
# of patients	N=1,418	N=411	N=1,401
Design	▪ **ARM A:** Gazyva 1000mg IV plus CHOP ▪ **ARM B:** MabThera/Rituxan plus CHOP	▪ **ARM A:** Gazyva 1000mg IV plus bendamustine followed by Gazyva maintenance ▪ **ARM B:** bendamustine	▪ **ARM A:** Gazyva 1000mg IV + chemo followed by Gazyva maintenance ▪ **ARM B:** MabThera/Rituxan + chemo followed by MabThera/Rituxan maintenance Chemotherapy: ▪ For follicular lymphoma (FL): CHOP, CVP or bendamustine ▪ For non-FL: physician's choice
Primary endpoint	▪ Progression free survival	▪ Progression free survival	▪ Progression free survival in FL patients (N=1,202)
Status	▪ Final analysis: Primary endpoint not met July 2016 ▪ Data presented at ASH 2016	▪ Trial stopped at interim for efficacy Q1 2015 ▪ Approved by the FDA Q1 2016 after priority review and by EMA Q2 2016 ▪ Data presented at ASH 2016	▪ Trial stopped at interim for efficacy (May 2016) ▪ Data presented at ASH 2016 ▪ Filed in EU Q4 2016

In collaboration with Biogen

CHOP=Cyclophosphamide, doxorubicin, vincristine and prednisone; CVP=Cyclophosphamide, vincristine and prednisolone

Kadcyla

Evaluating new treatment options in HER2-positive breast and lung cancer

Indication	HER2-positive early breast cancer high-risk patients	Operable HER2-positive early breast cancer	HER2-positive 2L metastatic breast cancer	HER2-positive advanced (2L+) NSCLC
Phase/study	**Phase III KATHERINE**	**Phase III KAITLIN**	**Phase II KATE2**	**Phase II**
# of patients	N=1,484	N=1,850	N=200	N=40
Design	▪ **ARM A:** Kadcyla 3.6mg/kg Q3W ▪ **ARM B:** Herceptin	Following surgery and antracycline-based therapy: ▪ **ARM A:** Herceptin 6mg/kg Q3W plus Perjeta 420 mg/kg Q3W plus chemo ▪ **ARM B:** Kadcyla 3.6mg/kg Q3W plus Perjeta 420mg/kg Q3W plus chemo	▪ **ARM A:** Kadcyla plus Tecentriq ▪ **ARM B:** Kadcyla plus placebo	▪ Single-agent Kadcyla 3.6 mg/kg Q3W
Primary endpoint	▪ Invasive disease-free survival (IDFS)	▪ Invasive disease-free survival (IDFS)	▪ Progression free survival	▪ Overall response rate and safety
Status	▪ Enrolment completed Q4 2015 ▪ Data expected in 2018	▪ Enrolment completed Q2 2015 ▪ Data expected in 2019	▪ FPI Q3 2016	▪ FPI Q4 2014 ▪ Enrolment completed Q2 2016 ▪ Study did not meet efficacy criteria Q4 2016

In collaboration with ImmunoGen, Inc.
ASCO=American Society of Clinical Oncology

MabThera/Rituxan

Oncology and immunology development programs

Indication	Previously untreated chronic lymphocytic leukemia	Front-line follicular non-Hodgkin's lymphoma	Moderate to severely active pemphigus vulgaris
Phase/study	**Phase Ib** **SAWYER** Subcutaneous study (ex-US)	**Phase III** **SABRINA** Subcutaneous study (ex-US)	**Phase III** **PEMPHIX**
# of patients	N=225	N=405	N=124
Design	▪ Two-stage design: - Stage 1 (dose-finding, N=55) - Stage 2 (N=170): CLL dose confirmation: ▪ **ARM A**: MabThera IV plus chemotherapy (fludarabine and cyclophosphamide) ▪ **ARM B**: MabThera 1600mg SC plus chemotherapy (fludarabine and cyclophosphamide)	▪ ARM A: MabThera iv plus chemotherapy (CHOP or CVP) ▪ ARM B: MabThera 1400mg SC plus chemotherapy (CHOP or CVP) *Two-stage design:* ▪ Stage 1 (dose confirmation, N=127): PK primary endpoint ▪ Stage 2 (N=280): Efficacy primary endpoint (ORR) *Responders will continue on maintenance every 8 weeks over 24 months*	▪ **ARM A:** Rituxan ▪ **ARM B:** mycophenolate mofetil
Primary endpoint	▪ Part 1: PK (dose selection) ▪ Part 2: PK of MabThera IV versus MabThera SC (arm A vs. arm B)	▪ Pharmacokinetics, safety and efficacy	▪ Proportion of patients who achieve sustained complete remission
Status	▪ Stage 2 data confirmed non-inferior PK and comparable safety/efficacy of MabThera 1600mg SC vs. MabThera IV ▪ Presented at ASH 2014 ▪ EMA approval granted May 2016 ▪ Filed US Q3 2016	▪ Stage 1 primary endpoint (PK noninferiority) met ▪ Presented at ASH 2012 ▪ Received EMA approval in Q2 2016 ▪ Filed US Q3 2016	▪ FPI Q2 2015

Subcutaneous MabThera=applies Enhanze technology, partnered with Halozyme
SC=subcutaneous; ASH=American Society of Hematology

Perjeta

First-in-class HER2 dimerisation inhibitor

Indication	Adjuvant HER2-positive breast cancer	Neoadjuvant/adjuvant HER2-positive breast cancer	Advanced HER2-positive gastric cancer
Phase/ study	**Phase III APHINITY**	**Phase II BERENICE**	**Phase III JACOB**
# of patients	N=4,803	N=401	N=780
Design	▪ **ARM A:** Perjeta (840mg loading, 420 q3w) plus Herceptin for 52 weeks plus chemotherapy (6-8 cycles) ▪ **ARM B**: placebo plus Herceptin (52 weeks) plus chemotherapy (6-8 cycles)	Neoadjuvant treatment: ▪ **ARM A:** ddAC q2w x4 cycles followed by weekly paclitaxel for 12 weeks, with P+H x4 cycles ▪ **ARM B:** FEC+P+H x4 cycles followed by docetaxel+P+H x4 cycles Adjuvant treatment: ▪ P+H q3w to complete 1 year of HER2 therapy ▪ Hormonal and radiation therapy as indicated	▪ **ARM A:** Perjeta (840mg loading, 420mg q3w) plus Herceptin and chemotherapy ▪ **ARM B:** placebo plus Herceptin and chemotherapy
Primary endpoint	▪ Invasive disease-free survival (IDFS)	▪ Safety	▪ Overall survival
Status	▪ Recruitment completed Q3 2013 ▪ Data expected in Q1 2017	▪ Enrolment completed Q3 2015 ▪ Data in-house ▪ Data presented at SABCS 2016	▪ Recruitment completed Q1 2016 ▪ Data expected in 2017

ddAC=Dose-dense doxorubicin plus cyclophosphamide; FEC=Fluorouracil, epirubicin, and cyclophosphamide; SABCS=San Antonio Breast Cancer Symposium

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – lung cancer

Indication	1L non-squamous and squamous NSCLC PD-L1-selected patients	1L non-squamous NSCLC	1L non-squamous NSCLC	1L non-squamous NSCLC
Phase/study	**Phase III IMpower110**	**Phase III IMpower150**	**Phase III IMpower130**	**Phase III IMpower132**
# of patients	N=570	N=1,200	N=650	N=568
Design	▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B**: (NSq) carboplatin or cisplatin + pemetrexed (Sq) carboplatin or cisplatin +gemcitabine	▪ **ARM A:** Tecentriq + paclitaxel + carboplatin ▪ **ARM B**: Tecentriq + Avastin + paclitaxel + carboplatin ▪ **ARM C**: Avastin + paclitaxel + carboplatin	▪ **ARM A:** Tecentriq + nab-paclitaxel + carboplatin ▪ **ARM B**: nab-paclitaxel + carboplatin	▪ **ARM A:** Tecentriq + carboplatin or cisplatin + pemetrexed ▪ **ARM B**: carboplatin or cisplatin + pemetrexed
Primary endpoint	▪ Progression free survival and overall survival	▪ Progression free survival and overall survival	▪ Progression free survival and overall survival	▪ Progression free survival and overall survival
Status	▪ FPI Q3 2015 ▪ IMpower111 consolidated into IMpower110 Q3 2016	▪ FPI Q2 2015 ▪ Recrutiment completed Q4 2016	▪ FPI Q1 2015	▪ FPI Q2 2016

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – lung cancer

Indication	Adjuvant NSCLC	1L squamous NSCLC	1L extensive-stage SCLC
Phase/study	**Phase III IMpower010**	**Phase III IMpower131**	**Phase III IMpower133**
# of patients	N=1,127	N=1,025	N=400
Design	Following adjuvant cisplatin-based chemotherapy ▪ **ARM A:** Tecentriq ▪ **ARM B**: best supportive care	▪ **ARM A:** Tecentriq + paclitaxel + carboplatin ▪ **ARM B**: Tecentriq + nab-paclitaxel + carboplatin ▪ **ARM C**: nab-paclitaxel + carboplatin	▪ **ARM A:** Tecentriq + carboplatin + etoposide ▪ **ARM B**: Placebo + carboplatin + etoposide
Primary endpoint	▪ Disease-free survival	▪ Progression free survival and overall survival	▪ Progression free survival and overall survival
Status	▪ FPI Q3 2015 ▪ Trial amended from PD-L1-selected patients to all-comers ▪ FPI for all-comer population Q4 2016	▪ FPI Q2 2015	▪ FPI Q2 2016 ▪ Orphan drug designation granted by FDA October 2016

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – lung cancer

Indication	Metastatic NSCLC 2L	Locally advanced or metastatic NSCLC PD-L1 positive	Locally advanced or metastatic NSCLC PD-L1 positive	Locally advanced or metastatic NSCLC (2L/3L)	Non-small cell lung cancer
Phase/study	**Phase III OAK**	**Phase II FIR**	**Phase II BIRCH**	**Phase II POPLAR**	**Phase I**
# of patients	N=1,225	N=130	N=667	N=287	N=53
Design	▪ **ARM A:** Tecentriq 1200mg q3w ▪ **ARM B:** docetaxel	Single arm study: ▪Tecentriq 1200mg q3w	Single arm study: ▪Tecentriq 1200mg q3w	▪ **ARM A**: Tecentriq 1200mg q3w ▪ **ARM B**: docetaxel	▪ Tecentriq plus Tarceva[1] or Alecensa
Primary endpoint	▪ Overall survival	▪ Overall response rate	▪ Objective response rate	▪ Overall survival	▪ Safety
Status	▪ Recruitment completed Q2 2015 ▪ Initial read-out in Q3 2016 ▪ Data presented at ESMO 2016 ▪ Data filed with US FDA Q3 2016	▪ Recruitment completed Q2 2014 ▪ Data presented at ASCO 2015	▪ Recruitment completed Q4 2014 ▪ Primary analysis presented at ECC 2015	▪ Recruitment completed Q2 2014 ▪ Interim data presented at ASCO 2015 ▪ Primary analysis presented at ECC 2015 ▪ Results published in *Lancet*, 9 March 2016 ▪ Updated data presented at ASCO 2016	▪ FPI Q1 2014 ▪ FPI in Alecensa arm Q3 2015 ▪ Recruitment completed in Tarceva arm Q3 2015 ▪ Data from Tarceva presented at WCLC and ESMO Asia 2016
		▪ Filed with the FDA Q1 2016 ▪ Priority review granted Q1 2016			
	▪ Approved in US October 2016				

[1] Tarceva is a registered trademark of OSI Pharmaceuticals, LLC, a subsidiary of Astellas US, LLC

ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology; ECC=European Cancer Congress

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – UC

Indication	Adjuvant high risk muscle invasive bladder cancer PD-L1-positive patients	Locally advanced or metastatic urothelial bladder cancer	
Phase/study	**Phase III IMvigor010**	**Phase III IMvigor211**	**Phase II IMvigor210**
# of patients	N=440	N=932	N=439
Design	After cystectomy: ▪**ARM A:** Tecentriq monotherapy ▪**ARM B**: observation	Patients who progressed on at least one platinum-containing regimen will receive: ▪**ARM A:** Tecentriq 1200mg q3w ▪**ARM B:** chemotherapy (vinflunine, paclitaxel or docetaxel)	▪ **Cohort 1**: Treatment-naive and cisplatin-ineligible patients ▪ **Cohort 2**: Patients with disease progression following or during platinum-containing treatment
Primary endpoint	▪ Disease-free survival	▪ Overall survival	▪ Objective response rate
Status	▪ FPI October 2015	▪ Enrolment completed Q1 2016	▪ US accelerated approval Q2 2016 ▪ Filed in EU Q2 2016 ▪ Cohort 2 results published in *Lancet*, 4 Mar 2016 ▪ Updated data (Cohorts 1 and 2) presented at ESMO 2016 ▪ Cohort 1 data filed in US Q4 2016, priority review granted; PDUFA April 30, 2017

UC=Urothelial carcinoma; ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – UC

Indication	1L metastatic urothelial carcinoma	High-risk non-muscle-invasive bladder cancer
Phase/study	**Phase III** **IMvigor130**	**Phase Ib/II**
# of patients	N=1,200	N=70
Design	▪**ARM A:** Tecentriq plus gemcitabine and carboplatin or cisplatin ▪**ARM B**: placebo plus gemcitabine and carboplatin or cisplatin ▪**ARM C**: Tecentriq monotherapy	▪**Cohort 1a:** Tecentriq (BCG-unresponsive NMIBC) ▪**Cohort 1b:** Tecentriq + BCG (BCG-unresponsive NMIBC) ▪**Cohort 2:** Tecentriq + BCG (BCG-relapsing NMIBC) ▪**Cohort 3:** Tecentriq + BCG (BCG-naive NMIBC)
Primary endpoint	▪ Progression free survival, overall survival, safety	▪ Safety, objective response rate
Status	▪ FPI Q3 2016 ▪ Trial currently being modified to include patients who are eligible for a cisplatin-containing regimen (patients ineligible for cisplatin continue to be enrolled), and to add a third arm evaluating atezolizumab monotherapy	▪ FPI Q2 2016

UC=Urothelial carcinoma; BCG=Bacille Calmette-Guérin; NMIBC=Non-muscle invasive bladder cancer

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – renal cell cancer

Indication	Untreated advanced renal cell carcinoma		Adjuvant renal cell carcinoma
Phase/study	**Phase III IMmotion151**	**Phase II IMmotion150**	**Phase III Immotion010**
# of patients	N=900	N=305	N=664
Design	▪ **ARM A**: Tecentriq plus Avastin ▪ **ARM B**: sunitinib	▪ **ARM A**: Tecentriq plus Avastin ▪ **ARM B**: Tecentriq; following PD: Tecentriq plus Avastin ▪ **ARM C**: sunitinib; following PD: Tecentriq plus Avastin	▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B:** Observation
Primary endpoint	▪ Progression free survival and overall survival co-primary	▪ Progression free survival	▪ Disease-free survival
Status	▪ FPI Q2 2015	▪ Recruitment completed Q1 2015 ▪ Data in-house Q4 2016; accepted for presentation at ASCO GU Feb 2017	▪ FPI Jan 2017

ASCO=American Society of Clinical Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – prostate cancer

Indication	Metastatic castration-resistant prostate cancer	Metastatic castration-resistant prostate cancer
Phase/study	**Phase Ib**	**Phase III IMbassador250**
# of patients	N=45	N=558
Design	▪ Tecentriq plus radium-223 dichloride	▪ **ARM A:** Tecentriq plus enzalutamide ▪ **ARM B:** enzalutamide
Primary endpoint	▪ Safety and tolerability	▪ Overall survival
Status	▪ FPI Q3 2016	▪ FPI Jan 2017

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – CRC

Indication	Third-line advanced or metastatic colorectal cancer	2/3L metastatic colorectal cancer
Phase/study	**Phase III IMblaze370**	**Phase I**
# of patients	N=360	N=33
Design	▪ **ARM A**: Tecentriq ▪ **ARM B**: Cotellic[1] + Tecentriq ▪ **ARM C**: regorafenib	Open-label, single-arm, two-stage study with Cotellic[1] + Tecentriq + Avastin ▪ **Stage 1:** Safety run-in ▪ **Stage 2:** Dose-expansion with two cohorts – (1) expansion, (2) biopsy
Primary endpoint	▪ Overall survival	▪ Safety
Status	▪ FPI Q2 2016	▪ FPI Q3 2016

[1] Cotellic in collaboration with Exelixis

CRC=Colorectal cancer; SMR=Society for Melanoma Research

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – breast cancer

Indication	Front Line Ovarian Cancer	Previously untreated metastatic triple negative breast cancer	Metastatic breast cancer and locally advanced early breast cancer HER2-positive
Phase/study	**Phase III IMaGYN050**	**Phase III IMpassion130**	**Phase I**
# of patients	N=1300	N=900	N=66
Design	▪ **ARM A:** Tecentriq plus carboplatin + paclitaxel + Avastin ▪ **ARM B:** carboplatin + paclitaxel + Avastin	▪ **ARM A**: Tecentriq plus nab-paclitaxel ▪ **ARM B**: placebo plus nab-paclitaxel	▪ **Cohort 1A** (metastatic): Tecentriq + Perjeta +Herceptin ▪ **Cohort 1B** (metastatic): Tecentriq + Kadcyla ▪ **Cohort 2A** (neoadjuvant): Tecentriq + Perjeta + Herceptin followed by docetaxel + carboplatin + Perjeta + Herceptin ▪ **Cohort 2B** (neoadjuvant): Tecentriq + Kadcyla followed by docetaxel + carboplatin + Perjeta +Herceptin ▪ **Cohort 2C** (expansion on cohort 1B): Tecentriq + Kadcyla
Primary endpoint	▪ Progression free survival and overall survival co-primary	▪ Progression free survival and overall survival co-primary	▪ Safety
Status	▪ FPI expected Q1 2017	▪ FPI Q3 2015	▪ FPI Q4 2015

SMR=Society for Melanoma Research

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – solid tumours

Indication	Solid tumours	Solid tumours	Solid tumours	Solid tumours
Phase/study	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=86	N=225	N=160	N=162
Design	▪ **ARM A**: HCC: Tecentriq + Avastin ▪ **ARM B**: HER2-neg. GC: Tecentriq + Avastin + oxaliplatin+leucovorin+5-FU ▪ **ARM C:** PaC: Tecentriq + nab-paclitaxel+gemcitabine ▪ **ARM D:** HCC: Tecentriq + vanucizumab or Tecentriq + Avastin ▪ **ARM E:** squamous cell mEC: Tecentriq + 5FU-Cis and Tecentriq + FOLFOX; adenocarcinoma mEC: Tecentriq + FOLFOX	▪ **ARM A**: Tecentriq + Avastin ▪ **ARM B**: Tecentriq + Avastin + FOLFOX ▪ **ARM C**: Tecentriq + carboplatin + paclitaxel ▪ **ARM D**: Tecentriq + carboplatin+ pemetrexed ▪ **ARM E**: Tecentriq + carboplatin+ nab-paclitaxel ▪ **ARM F**: Tecentriq + nab-paclitaxel	▪ **Part I:** sequential and single concomitant administration of Tecentriq and RG7876 (CD40 MAb, i.v. and s.c., dose escalation) ▪ **Part II:** multiple doses of concomitant Tecentriq and RG7876 (CD40 MAb), recommended dose and route per Part I ▪ **Part III:** study drugs schedule in specific indication per Part II	Tecentriq in combination with emactuzumab (CSF-1R MAb) ▪ **Part 1**: dose escalation ▪ **Part 2**: expansion
Primary endpoint	▪ Safety	▪ Safety/PK	▪ Safety	▪ Safety
Status	▪ FPI April 2016 ▪ ARM D on hold ▪ FPI Arm E Jan 2017	▪ FPI Q2 2012 ▪ Updated CRC data presented at AACR 2016 ▪ Updated TNBC data (ARM F) presented at ASCO 2016	▪ FPI Q4 2014	▪ FPI Q1 2015

AACR=American Association for Cancer Research; ASCO=American Society of Clinical Oncology; HCC=hepatocellular carcinoma; PaC=pancreatic cancer; mEC=metastatic esophageal cancer

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – solid tumours

Indication	Solid tumours	Solid tumours	Solid tumours	Solid tumours
Phase/study	**Phase Ib**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=305	N=762	N=151	N=300
Design	▪ Tecentriq in combination with RG6078 (IDO inhibitor), dose escalation and expansion cohorts	Dose escalation and expansion of RG7888 (OX40 MAb) + Tecentriq with or without Avastin ▪ **Part 1:** dose escalation ▪ **Part 2:** expansion	▪ **ARM A:** Dose-finding Tecentriq plus Cotellic ▪ **ARM B:** Dose-exspansion Tecentriq plus Cotellic	▪ **Phase 1a:** Dose escalation and expansion MTIG7192A, RG6058 (TIGIT) ▪ **Phase 1b**: Dose escalation and expansion Tecentriq plus MTIG7192A, RG6058 (TIGIT)
Primary endpoint	▪ Safety and tolerability	▪ Safety	▪ Safety	▪ Safety, tolerability, PK variability, preliminary efficacy
Status	▪ FPI Q3 2015	▪ FPI Q2 2015 ▪ Dose escalation data presented at ASCO 2016	▪ FPI Q4 2013 ▪ CRC cohort data presented at ASCO 2016, ESMO 2016	▪ FPI Q2 2016

ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – solid tumours

Indication	Locally advanced or metastatic solid tumours	CEA-positive solid tumours	Previously untreated metastatic melanoma BRAF mutation positive	Locally advanced or metastatic solid tumours
Phase/study	**Phase I**	**Phase Ib**	**Phase I**	**Phase I**
# of patients	N=200	N=100	N=67	N=660
Design	▪ **ARM A:** Tecentriq plus ipilimumab ▪ **ARM B:** Tecentriq plus interferon alpha-2b	▪ Tecentriq plus RG7802 (CEA CD3 TCB)	▪ Dose-finding study of Tecentriq + Zelboraf[1] and Tecentriq + Zelboraf[1] + Cotellic (MEK inhibitor)[2] combinations	▪ Dose escalation study
Primary endpoint	▪ Safety	▪ Safety, PK/PD, imaging, biomarkers	▪ Safety/PK	▪ Safety/PK
Status	▪ FPI Q3 2014	▪ FPI Q1 2016	▪ FPI Q4 2012 ▪ Zelboraf[1] combination data presented at SMR 2015	▪ FPI Q2 2011 ▪ Initial efficacy data presented at ASCO 2013 ▪ Data from bladder cohort presented at ASCO and ESMO 2014 ▪ Data from TNBC cohort presented at AACR 2015 ▪ Updated lung and bladder data presented at ASCO 2015 ▪ GBM data presented at SNO 2015

[1] Zelboraf in collaboration with Plexxikon, a member of Daiichi Sankyo Group; [2] Cotellic in collaboration with Exelixis
ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology; AACR=American Association for Cancer Research; SNO=Society for Neuro-Oncology; GBM=glioblastoma multiforme

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – hematology

Indication	Multiple myeloma	Myelodysplastic syndromes	Acute myelogenous leukemia (AML)
Phase/study	**Phase I**	**Phase I**	**Phase Ib**
# of patients	N=214	N=46	N=40
Design	▪ Tecentriq monotherapy ▪ Tecentriq +lenalidomide ▪ Tecentriq + daratumumab[1] ▪ Tecentriq + lenalidomide + daratumumab[2]	▪ Tecentriq monotherapy and azacitidine combination cohorts	▪ Tecentriq + guadecitabine (SGI-110)[2]
Primary endpoint	▪ Safety	▪ Safety	• Safety and efficacy
Status	▪ FPI Q3 2015 ▪ FPI daratumumab[2] cohorts Q3 2016	▪ FPI Q3 2015	• FPI Q4 2016

[1] Daratumumab cohorts in collaboration with Janssen; [2] SGI-110 in collaboration with Astex

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – hematology

Indication	1L FL and 1L DLBCL	Relapsed or refractory FL	Relapsed or refractory FL and DLBCL	Relapsed or refractory FL or DLBCL
Phase/study	**Phase I**	**Phase I**	**Phase I**	**Phase I/II**
# of patients	N=92	N=46	N=46	N=86
Design	▪ Tecentriq + Gazyva + bendamustine ▪ Tecentriq + Gazyva + CHOP	▪ Tecentriq + Gazyva + lenalidomide	▪ **Stage 1:** Safety evaluation Tecentriq plus Gazyva ▪ **Stage 2:** expansion Tecentriq plus Gazyva ▪ **Stage 3:** new cohort Tecentriq plus tazemetostat[1]	▪ **Dose escalation:** Tecentriq + Gazyva + polatuzumab vedotin ▪ **Expansion:** Tecentriq + Gazyva + polatuzumab vedotin
Primary endpoint	▪ Safety and efficacy	▪ Safety and efficacy	▪ Safety	▪ Safety and efficacy
Status	▪ FPI Q4 2015	▪ FPI Q4 2015	▪ FPI Q4 2014 ▪ FPI Stage 3 Jan 2017	▪ FPI FL Q4 2016 ▪ Study to be amended to change from Gazyva to Rituxan for DLBCL with FPI expected Q1 2017

[1] Tazemetostat tested for r/r DLBCL in collaboration with Epizyme
DLBCL=Diffuse large B cell lymphoma; FL=Follicular lymphoma

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – CLL

Indication	Untreated CLL patients with coexisting medical conditions	Relapsed or refractory CLL	Relapsed or refractory CLL with 17p deletion
Phase/study	**Phase III CLL14**	**Phase III MURANO**	**Phase II**
# of patients	N=432	N=391	N=100
Design	▪ **ARM A**: Venclexta plus Gazyva ▪ **ARM B**: chlorambucil plus Gazyva	▪ **ARM A**: Venclexta plus Rituxan ▪ **ARM B**: Rituxan plus bendamustine	▪ Single-agent Venclexta
Primary endpoint	▪ Progression free survival	▪ Progression free survival	▪ Safety, maximum tolerated dose (MTD)
Status	▪ FPI Q4 2014 ▪ Recruitment completed Q3 2016	▪ Recruitment completed Q3 2015 ▪ Data expected in 2017	▪ Breakthrough therapy designation granted by US FDA in Q2 2015 ▪ Approved by FDA in US April 2016 after priority review ▪ Approved by EMA in EU December 2016

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
CLL=Chronic lymphocytic leukemia

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – CLL

Indication	Relapsed or refractory CLL	Relapsed CLL and SLL	Relapsed or refractory or previously untreated CLL	Relapsed or refractory or previously untreated CLL
Phase/study	**Phase II**	**Phase Ib**	**Phase Ib**	**Phase Ib**
# of patients	N=120	N=50	N=100	N=90
Design	▪ Venclexta after ibrutinib therapy ▪ Venclexta after idelalisib therapy	▪ Dose-escalation study in combination with MabThera/Rituxan	▪ Venclexta in combination with MabThera/Rituxan and bendamustine	▪ Venclexta in combination with Gazyva
Primary endpoint	▪ Overall response rate	▪ Safety, maximum tolerated dose	▪ Safety, maximum tolerated dose	▪ Safety, maximum tolerated dose
Status	▪ FPI Q3 2014 ▪ Data presented at ASH 2015 ▪ Updated data presented at ASCO 2016	▪ Recruitment completed Q1 2015 ▪ Data presented at ASCO 2014 and EHA 2015 ▪ Updated data presented at ASH 2015 and ASCO 2016	▪ FPI Q2 2013 ▪ Data presented at ASH 2015	▪ FPI Q1 2014 ▪ Data presented at ASH 2015

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
CLL=Chronic lymphocytic leukemia; SLL=Small lymphocytic lymphoma
ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology; EHA=European hematology association

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – NHL

Indication	Relapsed or refractory FL	B cell NHL and front-line DLBCL
Phase/study	**Phase II** **CONTRALTO**	**Phase I/II** **CAVALLI**
# of patients	N=165	N=248
Design	▪ **ARM A:** Venclexta plus Rituxan ▪ **ARM B:** Venclexta plus Rituxan plus bendamustine ▪ **ARM C:** Rituxan plus bendamustine	Phase I (dose finding, patients with B cell NHL): ▪ **ARM A:** Venclexta + R-CHOP ▪ **ARM B:** Venclexta + G-CHOP Phase II (expansion, patients with 1L DLBCL): ▪ Venclexta + R-CHOP
Primary endpoint	▪ Overall response rate	▪ Safety and efficacy
Status	▪ FPI Q4 2014 ▪ Data presented at ASH 2016	▪ FPI Q2 2014 ▪ Data presented at ASCO 2016 and ASH 2016

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
FL=Follicular lymphoma; DLBCL=Diffuse large B cell lymphoma; NHL=Non-Hodgkin's lymphoma
ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – NHL

Indication	Relapsed or refractory FL or DLBCL	Relapsed or Refractory NHL	Relapsed or refractory CLL and NHL
Phase/study	**Phase I/II**	**Phase I**	**Phase I**
# of patients	N=116	N=60	N=211
Design	▪ **Dose escalation cohort:** polatuzumab vedotin + Gazyva + Venclexta ▪ **Expansion cohort: DLBCL** polatuzumab vedotin + Gazyva + Venclexta ▪ **Expansion cohort: FL** polatuzumab vedotin + Gazyva + Venclexta	▪ Dose escalation of Venclexta in combination with Rituxan and bendamustine	Dose-escalation study ▪ **ARM A:** CLL and SLL patients ▪ **ARM B:** NHL patients
Primary endpoint	▪ Percentage of participants with CR	▪ Overall response rate	▪ Safety, PK, Response rate
Status	▪ FPI Q1 2016	▪ FPI Q2 2012 ▪ Study resumed Q3 2013 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ASH 2015	▪ Updated CLL, SLL and NHL (DLBCL and FL) data presented at ASCO 2014 ▪ Updated data presented at ASH 2015 ▪ Arm A filed for r/r CLL indications Q4 2015 ▪ Updated data presented at ASCO 2016

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute

FL=Follicular lymphoma; DLBCL=Diffuse large B cell lymphoma; NHL=Non-Hodgkin's lymphoma; CLL=Chronic lymphocytic leukemia; SLL=Small lymphocytic lymphoma; ASCO=American Society of Clinical Oncology; ASH=American Society of Hematology

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – MM

Indication	Relapsed or refractory multiple myeloma		
Phase/study	**Phase III BELLINI**	**Phase I**	**Phase I**
# of patients	N=240	N=30	N=84
Design	▪ **ARM A**: Venclexta + bortezomib + dexamethasone ▪ **ARM B**: Placebo + bortezomib + dexamethasone	Patients receiving bortezomib and dexamethasone as standard therapy: ▪ **Dose escalation cohort:** Venclexta + bortezomib + dexamethasone ▪ **Safety expansion cohort:** Venclexta + bortezomib + dexamethasone	▪ **Dose escalation cohort:** Venclexta dose escalation ▪ **Safety expansion cohort:** Venclexta expansion ▪ **Combination:** Venclexta + dexamethasone
Primary endpoint	▪ Progression free survival	▪ Safety, maximum tolerated dose	▪ Safety, maximum tolerated dose
Status	▪ FPI July 2016	▪ FPI Q4 2012 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ASCO 2016 and ASH 2016	▪ FPI Q4 2012 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ASCO 2016 and ASH 2016

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute

MM=Multiple myeloma; ASCO=American Society of Clinical Oncology; ASH=American Society of Hematology

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – AML

Indication	Acute myelogenous leukemia (AML)	Treatment-naïve AML not eligible for standard induction therapy		Relapsed or refractory AML not eligible for cytotoxic therapy
Phase/study	**Phase II**	**Phase Ib**	**Phase I/II**	**Phase Ib/II**
# of patients	N=54	N=160	N=65	N=140
Design	▪ Dose escalation of Venclexta	▪ Venclexta (dose escalation) + decitabine ▪ Venclexta (dose escalation) + azacitidine ▪ Venclexta (dose escalation) + decitabine + posaconazole	▪ Venclexta (dose escalation) + low-dose cytarabine	Phase I (dose escalation) ▪ **ARM A:** Cotellic + Venclexta ▪ **ARM B:** idasanutlin+ Venclexta Phase II (expansion) ▪ **ARM A:** Cotellic + Venclexta ▪ **ARM B:** idasanutlin + Venclexta
Primary endpoint	▪ Overall response rate	▪ Safety	▪ Safety, PK/PD, efficacy	▪ Safety and efficacy
Status	▪ FPI Q4 2013 ▪ Data presented at ASH 2014 ▪ Updated data presented at ASCO 2016	▪ FPI Q4 2014 ▪ Data presented at ASH 2015 ▪ Updated data presented at ASCO 2016	▪ FPI Q1 2015 ▪ Initial data presented at ASCO 2016 ▪ Updated data to be presented at ASH 2016	▪ FPI Q1 2016

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology

Zelboraf

A selective novel small molecule that inhibits mutant BRAF

Indication	Adjuvant therapy in patients with resected cutaneous BRAF mutation positive melanoma
Phase/study	**Phase III** **BRIM8**
# of patients	N=475
Design	52-week treatment ▪ **ARM A:** Zelboraf 960mg bid ▪ **ARM B:** Placebo
Primary endpoint	▪ Disease-free survival
Status	▪ Enrolment completed Q2 2015 ▪ Data expected in 2017

In collaboration with Plexxikon, a member of Daiichi Sankyo Group
See also combinations with Cotellic (MEK inhibitor) and Tecentriq (PD-L1 MAb)

Actemra/RoActemra

Interleukin-6 receptor inhibitor

Indication	Systemic sclerosis		Giant cell arteritis
Phase/study	**Phase II** **faSScinate** Proof-of-concept study	**Phase III** **focuSSced**	**Phase III** **GiACTA**
# of patients	N=86	N=210	N=250
Design	Blinded 48-week treatment with weekly dosing: ▪ **ARM A:** Actemra SC 162mg ▪ **ARM B:** Placebo SC Open-label weekly dosing at weeks 49 to 96: ▪ Actemra SC 162mg	Blinded 48-week treatment with weekly dosing: ▪ **ARM A:** Actemra SC 162mg ▪ **ARM B:** Placebo SC Open-label weekly dosing at weeks 49 to 96: ▪ Actemra SC 162mg	Part 1: 52-week blinded period ▪ **ARM A:** Actemra SC 162mg qw + 26 weeks prednisone taper ▪ **ARM B:** Actemra SC 162mg q2w + 26 weeks prednisone taper ▪ **ARM C:** Placebo+ 26 weeks prednisone taper ▪ **ARM D:** Placebo+ 52 weeks prednisone taper Part II: ▪ 104-week open label extension – patients in remission followed off of the study drug; Patients with active disease receive open label Actemra SC 162mg qw
Primary endpoint	▪ Change in modified Rodnan skin score (mRSS) at week 24 ▪ Safety	▪ Change in modified Rodnan skin score (mRSS) at week 48	▪ Proportion of patients in sustained remission at week 52
Status	▪ 48 week data presented at EULAR 2015 ▪ Primary and all key secondary endpoints showed trend for improved efficacy ▪ Breakthrough designation granted Q1 2015 ▪ 96-week data presented at ACR 2016	▪ FPI Q4 2015	▪ Recruitment completed Q2 2015 ▪ Primary and key secondary endpoints met Q2 2016 ▪ Breakthrough designation granted Q3 2016 ▪ Data presented at ACR 2016 ▪ Filed globally Q4 2016; FDA priority review granted Jan 2017

In collaboration with Chugai

EULAR=European League Against Rheumatism; ACR=American College of Rheumatology

Lucentis

Anti-VEGF antibody fragment for ocular diseases

Indication	AMD port delivery device (Ranibizumab Port Delivery System)
Phase/study	**Phase II LADDER**
# of patients	N=220
Design	▪ Four arm study: Lucentis monthly intravitreal control vs. 3 ranibizumab formulations delivered via implant
Primary endpoint	▪ Time to first refill
Status	▪ FPI Q3 2015

In collaboration with Forsight and Novartis
AMD=Age-related macular degeneration

Obinutuzumab (GA101, RG7159)

Immunology development program

Indication	Lupus nephritis	Hypersensitised adult participants with end-stage renal disease awaiting transplantation
Phase/study	**Phase II NOBILITY**	**Phase I**
# of patients	N=120	N=25
Design	▪ **ARM A:** obinutuzumab 1000mg IV plus mycophenolate mofetil ▪ **ARM B:** placebo IV plus mycophenolate mofetil	▪ **Cohort 1:** single dose of obinutuzumab ▪ **Cohort 2:** repeated doses of obinutuzumab
Primary endpoint	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Safety
Status	▪ FPI Q4 2015	▪ FPI Q4 2015 ▪ Enrolment completed Q3 2016

In collaboration with Biogen

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Diagnostics

Emicizumab (RG6013, ACE910)

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A		
Phase/study	**Phase I** Study in Japan	**Phase I/II** Study in Japan	**Non-Interventional study**
# of patients	N=82	N=18	N>90
Design	▪ Enrolled 64 healthy volunteers and 18 patients	▪ Extension study in patients from phase 1	▪ A single arm, multicenter, non-interventional study evaluating bleeding incidence, health-related quality of life and safety in patients with Hemophilia A and inhibitors to factor VIII under standard-of-care treatment
Primary endpoint	▪ Exploratory safety and efficacy	▪ Exploratory safety and efficacy	▪ Number of bleeds over time, sites of bleed, type of bleed
Status	▪ Recruitment completed Q2 2014 ▪ Data presented at ASH 2014	▪ Recruitment completed Q4 2014 ▪ Data presented at ISTH 2015 ▪ Extension data presented at WFH 2016	▪ Inhibitor cohort closed Q4 2015 except China ▪ FPI in non-inhibitor and paediatric subjects in Q1 2016 ▪ Initial data presented at ASH 2016

In collaboration with Chugai

ASH=American Society of Hematology, ISTH=International Society on Thrombosis and Haemostasis; WFH=World Federation of Hemophilia

Emicizumab (RG6013, ACE910)

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients with inhibitors to factor VIII	Hemophilia A paediatric patients with inhibitors to factor VIII
Phase/study	**Phase III HAVEN 1**	**Phase III HAVEN 2**
# of patients	N=118	N=40
Design	Patients on episodic treatment prior to study entry: ▪ **ARM A:** episodic treatment + emicizumab prophylaxis ▪ **ARM B:** episodic treatment (no prophylaxis); switch to emicizumab prophylaxis possible after 24 weeks Patients on prophylactic treatment with bypassing agents prior to study entry: ▪ **ARM C:** emicizumab prophylaxis + episodic treatment Patients on episodic treatment previously on non-interventional study: ▪ **ARM D:** emicizumab prophylaxis + episodic treatment	Patients on prophylactic or episodic treatment prior to study entry: ▪ Emicizumab prohylaxis+episodic treatment
Primary endpoint	▪ Number of bleeds over 24 week period	▪ Number of bleeds over 52 weeks
Status	▪ FPI Q4 2015 ▪ Enrolment completed in Arms A and B Q2 2016 ▪ Primary and all secondary endpoints met Q4 2016	▪ FPI Q3 2016

In collaboration with Chugai

Emicizumab (RG6013, ACE910)

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients without inhibitors to factor VIII	Hemophilia A patients with and without inhibitors to Factor VIII, dosing every 4 weeks
Phase/study	**Phase III** **HAVEN 3**	**Phase III** **HAVEN 4**
# of patients	N=135	N=46
Design	Patients on FVIII episodic treatment prior to study entry: ▪ **Arm A**: emicizumab prophylaxis qw ▪ **Arm B**: emicizumab prophylaxis q2w ▪ **Arm C**: episodic FVIII treatment; switch to emicizumab prophylaxis possible after 24 weeks Patients on FVIII prophylaxis prior to study entry: ▪ **Arm D**: emicizumab prophylaxis qw	Multicenter, open-label, non- randomised study to assess the efficacy, safety, pharmacokinetics, and pharmacodynamics of emicizumab administered every 4 weeks. ▪ **Part 1:** pharmacokinetic (PK) run-in part (N=6) ▪ **Part 2:** expansion part (N=40)
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Number of bleeds over 24 weeks
Status	▪ FPI Q3 2016	▪ FPI Jan 2017

In collaboration with Chugai

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	1L castration-resistant prostate cancer	2L castration-resistant prostate cancer	1L metastatic gastric or gastroesophageal junction adenocarcinoma	1L triple-negative breast cancer	Neoadjuvant TNBC
Phase	**Phase III**	**Phase II A.MARTIN**	**Phase II JAGUAR**	**Phase II LOTUS**	**Phase II FAIRLANE**
# of patients	N=840	N=262	N=153	N=120	N=150
Design	▪ **ARM A:** ipatasertib + abiraterone ▪ **ARM B:** Placebo + abiraterone	▪ **ARM A:** ipatasertib (400 mg) + abiraterone ▪ **ARM B:** ipatasertib (200 mg) + abiraterone ▪ **ARM C:** Placebo + abiraterone	▪ **ARM A:** ipatasertib +mFOLFOX6 ▪ **ARM B:** Placebo +mFOLFOX6	▪ **ARM A:** Ipatasertib +paclitaxel ▪ **ARM B:** Placebo + paclitaxel	▪ **ARM A:** ipatasertib + paclitaxel ▪ **ARM B:** placebo + paclitaxel
Primary endpoint	▪ Progression free survival	▪ Progression free survival	▪ Progression free survival	▪ Progression free survival	▪ Progression free survival
Status	▪ FPI expected Q2 2017	▪ enrolment completed Q4 2014 ▪ Data in-house ▪ ITT data presented at ASCO 2016 ▪ Dx+ data presented at ESMO 2016	▪ enrolment completed Q4 2014 ▪ Data showed no benefit of the treated group vs. control Q2 2016	▪ Recruitment completed Q1 2016	▪ FPI Q1 2015

In collaboration with Array BioPharma
ASCO=American Society of Clinical Oncology; mFOLFOX6=Modified FOLFOX (folinic acid, fluorouracil, oxaliplatin);
TNBC=Triple-negative breast cancer

Polatuzumab vedotin (RG7596)

Antibody–drug conjugate targeting CD79b for the treatment of B cell malignancies

Indication	Non-Hodgkin's lymphoma	Non-Hodgkin's lymphoma 1L DLBCL	Relapsed or refractory FL and DLBCL
Phase	**Phase II ROMULUS**	**Phase Ib/II**	**Phase Ib/II**
# of patients	N=246	N=110	N=224
Design	▪ **ARM A:** pinatuzumab vedotin plus Rituxan ▪ **ARM B:** polatuzumab vedotin plus Rituxan ▪ **ARM C:** polatuzumab vedotin plus Rituxan ▪ **ARMS E, G, H:** polatuzumab vedotin plus Gazyva	▪ **PhIb:** dose escalation ▪ **PhII:** polatuzumab vedotin in combination with Rituxan or Gazyva and CHP non-randomised	▪ **PIb:** dose escalation ▪ **PhII:** polatuzumab vedotin + BR vs. BR ▪ **PhII expansion:** polatuzumab vedotin +Gazyva non-randomised
Primary endpoint	▪ Safety and anti-tumour activity	▪ Safety and response by PET/CT	▪ Safety and response by PET/CT
Status	▪ FPI in Gazyva arms Q1 2015 ▪ Enrolment completed Q3 2016 ▪ Updated data presented at ASCO, ICML and EHA 2015 ▪ Updated data presented at ASH 2016	▪ FPI Q4 2013 ▪ Enrolment completed Q3 2016 ▪ Initial data presented at ASH 2015 ▪ Updated data presented at ASH 2016	▪ FPI Q4 2014 ▪ Enrolment completed Q3 2016 ▪ Updated data presented at ASH 2016

In collaboration with Seattle Genetics

ASCO=American Society of Clinical Oncology; ICML=international conference on malignant lymphoma; EHA=European Hematology Association; ASH=American Society of Hematology; BR=Bendamustine and Rituxan; CHP=Cyclophosphamide, Hydroxydoxorubicin, Prednisone; DLBCL=Diffuse large B cell lymphoma; FL=Follicular lymphoma

Polatuzumab vedotin (RG7596)

Antibody–drug conjugate targeting CD79b for the treatment of B cell malignancies

Indication	Relapsed or refractory FL or DLBCL		
Phase	**Phase I/II**	**Phase I/II**	**Phase I/II**
# of patients	N=116	N=116	N=86
Design	▪ **Dose escalation cohort:** polatuzumab vedotin + Gazyva + Venclexta ▪ **Expansion cohort: DLBCL** polatuzumab vedotin + Rituxan + Venclexta ▪ **Expansion cohort: FL** polatuzumab vedotin + Gazyva + Venclexta	▪ **Dose escalation cohort:** polatuzumab vedotin + Gazyva + lenalidomide ▪ **Expansion cohort: DLBCL** polatuzumab vedotin + Rituxan+ lenalidomide ▪ **Expansion cohort: FL** polatuzumab vedotin + Gazyva + lenalidomide	▪ **Dose escalation cohort:** polatuzumab vedotin + Gazyva + Tecentriq ▪ **Expansion cohort: DLBCL** polatuzumab vedotin + Rituxan+ Tecentriq ▪ **Expansion cohort: FL** polatuzumab vedotin + Gazyva + Tecentriq
Primary endpoint	▪ Percentage of participants with CR	▪ Percentage of participants with CR	▪ Percentage of participants with CR
Status	▪ FPI Q1 2016	▪ FPI Q1 2016	▪ FPI Q4 2016

In collaboration with Seattle Genetics;
FL=Follicular lymphoma; DLBCL=Diffuse large B cell lymphoma

Taselisib (RG7604, GDC-0032)

Mutant-selective PI3 kinase inhibitor

Indication	HER2-negative ER-positive metastatic breast caner patients who progressed after aromatase inhibitor therapy	Neoadjuvant HER2-negative ER-positive breast cancer
Phase	**Phase III SANDPIPER**	**Phase II LORELEI**
# of patients	N=600	N=330
Design	▪ **ARM A**: taselisib plus fulvestrant ▪ **ARM B:** placebo plus fulvestrant	▪ **ARM A**: taselisib plus letrozole ▪ **ARM B:** placebo plus letozole
Primary endpoint	▪ Progression free survival	▪ Response rate and pCR
Status	▪ FPI Q2 2015	▪ Enrolment completed Q3 2016

ER=Estrogen receptor

Taselisib (RG7604, GDC-0032)

Mutant-selective PI3 kinase inhibitor

Indication	Solid tumours and HER2-negative HR-positive breast cancer	HER2-negative HR-positive locally recurrent or metastatic breast cancer	PI3KCAmut-pos. 2L squamous NSCLC Lung Master Protocol
Phase	**Phase I/II**	**Phase I**	**Phase II Lung-MAP**
# of patients	N=724	N=65	N=120
Design	**Phase I:** ▪ taselisib ▪ taselisib plus letrozole or fulvestrant **Phase II:** ▪ taselisib (multiple doses) plus letrozole or fulvestrant	▪ taselisib plus docetaxel ▪ taselisib plus paclitaxel	▪ taselisib vs. chemo
Primary endpoint	▪ Safety, PK, efficacy	▪ Safety	▪ Progression free survival
Status	▪ Recruitment completed Q2 2014 ▪ Updated data presented at SABCS 2014	▪ FPI Q2 2013	▪ FPI Q2 2014 ▪ Phase 2 portion of study did not meet pre-specified criteria for further development

SABCS=San Antonio Breast Cancer Symposium; HR=hormone receptor

Crenezumab (RG7412)

A humanised monoclonal antibody designed to target all forms of amyloid-beta

Indication	Prodromal to mild Alzheimer's disease	Alzheimer's disease	
Phase/study	**Phase III CREAD**	**Phase II ABBY** Cognition study	**Phase II BLAZE** Biomarker study
# of patients	N=750	N=446	N=91
Design	▪ **ARM A:** crenezumab IV 60mg/kg q4w ▪ **ARM B:** placebo IV q4w	▪ **ARM A**: crenezumab SC ▪ **ARM B**: crenezumab IV ▪ **ARM C:** placebo	▪ **ARM A**: crenezumab SC ▪ **ARM B**: crenezumab IV ▪ **ARM C:** placebo
Primary endpoint	▪ CDR-SB at 105 weeks	▪ Change in cognition (ADAS-cog) and Clinical Dementia Rating, Sum of Boxes (CDR-SOB) score from baseline to week 73	▪ Change in brain amyloid load from baseline to week 69
Status	▪ FPI Q1 2016	▪ Enrolment completed Q3 2012 ▪ Positive trend in cognition was observed in higher dose for people with milder disease consistently across both studies (ABBY/BLAZE) and across endpoint ▪ Data presented at AAIC 2014	▪ Enrolment completed Q3 2012 ▪ Cognition data presented at AAIC 2014 ▪ Exploratory amyloid PET analysis suggests reduced amyloid accumulation in ARM B ▪ Biomarker data presented at CTAD 2014

In collaboration with AC Immune

AAIC=Alzheimer's Association International Conference; CTAD=Clinical Trials on Alzheimer's Disease

Crenezumab (RG7412)

A humanised monoclonal antibody designed to target all forms of amyloid-beta

Indication	Mild to moderate Alzheimer's disease	Alzheimer's Prevention Initiative (API) Colombia
Phase/study	**Phase I**	**Phase II** Cognition study
# of patients	N=72	N=300
Design	▪ **ARM A/B**: crenezumab dose level I & placebo ▪ **ARM C/D**: crenezumab dose level II & placebo ▪ **ARM E/F**: crenezumab dose level III & placebo	▪ **ARM A**: 100 carriers receive crenezumab SC ▪ **ARM B**: 100 carriers receive placebo ▪ **ARM C:** 100 non-carriers receive placebo
Primary endpoint	▪ Safety (incidence and nature of MRI safety findings) and PK	▪ Change on Alzheimer's Prevention Initiative (API) Composite Cognitive Test total score
Status	▪ FPI Q1 2015 ▪ Enrolment completed Q3 2016 ▪ Interim data presented at CTAD 2016	▪ FPI Q4 2013

In collaboration with AC Immune

Gantenerumab (RG1450)

Fully human monoclonal antibody designed to bind to aggregated forms of amyloid-beta

Indication	Prodromal Alzheimer's disease	Mild Alzheimer's disease
Phase/study	**Phase II/III** **SCarlet RoAD**	**Phase III** **Marguerite RoAD**
# of patients	N=799	N=1,000
Design	104-week subcutaneous treatment period ▪ **ARM A:** gantenerumab (225 mg) ▪ **ARM B:** gantenerumab (105 mg) ▪ **ARM C:** placebo	104-week subcutaneous treatment period ▪ **ARM A:** gantenerumab ▪ **ARM B:** placebo
Primary endpoint	▪ Change in CDR-SOB at 2 years ▪ Sub-study: change in brain amyloid by PET at 2 years	▪ Change in ADAS-Cog and CDR-SB at 2 years (co-primary)
Status	▪ Phase I PET data: Archives of Neurology 2012 Feb;69(2):198-207 ▪ Enrolment completed Q4 2013 ▪ Dosing stopped due to futility Q4 2014 ▪ Data presented at AAIC 2015 ▪ FPI in open label extension study Q4 2015	▪ FPI Q1 2014 ▪ Enrolment stopped Q4 2015 ▪ FPI Q1 2016 for open label extension

In collaboration with Morphosys

CDR-SOB=Clinical Dementia Rating scale Sum of Boxes; AAIC=Alzheimer's Association International Conference

OCREVUS (ocrelizumab, RG1594)

Humanised monoclonal antibody designed to selectively target CD20-positive B cells

Indication	Relapsing multiple sclerosis (RMS)		Primary-progressive multiple sclerosis (PPMS)
Phase/study	**Phase III OPERA I**	**Phase III OPERA II**	**Phase III ORATORIO**
# of patients	N=821	N=835	N=732
Design	▪ 96-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	▪ 96-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	▪ 120-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 mg iv every 24 weeks ▪ **ARM B:** Placebo
Primary endpoint	▪ Annualised relapse rate at 96 weeks versus Rebif	▪ Annualised relapse rate at 96 weeks versus Rebif	▪ Sustained disability progression versus placebo by Expanded Disability Status Scale (EDSS)
Status	▪ Primary endpoint met Q2 2015 ▪ Data presented at ECTRIMS 2015 ▪ Filed globally in 2016	▪ Primary endpoint met Q2 2015 ▪ Data presented at ECTRIMS 2015 ▪ Filed globally in 2016	▪ Primary endpoint met Q3 2015 ▪ Data presented at ECTRIMS 2015 ▪ Filed globally in 2016

Olesoxime (RG6083)

Novel small molecule neuroprotectant that preserves mitochondrial function

Indication	Spinal muscular atrophy Type 2 and 3	
Phase/study	**Phase II** Registrational study	**Open-label study**
# of patients	N=165	N=165
Design	▪ **ARM A:** olesoxime ▪ **ARM B:** placebo	▪ Olesoxime
Primary endpoint	▪ Motor function measure	▪ Motor function measure
Status	▪ Study completed Q4 2013 ▪ Presented at AAN 2014	▪ FPI Q4 2015
Collaborator	Trophos acquisition	

AAN=Annual Meeting of the American Academy of Neurology

Etrolizumab (RG7413)

Humanised monoclonal antibody against beta 7 integrin

Indication	Ulcerative colitis patients who are TNF naïve		
Phase/study	**Phase III** **HIBISCUS I** Induction study	**Phase III** **HIBISCUS II** Induction study	**Phase III** **GARDENIA** Sustained remission study
# of patients	N=350	N=350	N=720
Design	▪ **ARM A**: etrolizumab 105mg SC q4w + adalimumab placebo SC ▪ **ARM B**: etrolizumab placebo SC + adalimumab SC ▪ **ARM C**: etrolizumab placebo SC + adalimumab placebo SC	▪ **ARM A**: etrolizumab 105mg SC q4w + adalimumab placebo SC ▪ **ARM B**: etrolizumab placebo SC + adalimumab SC ▪ **ARM C**: etrolizumab placebo SC + adalimumab placebo SC	Time on treatment 54 weeks ▪**ARM A**: etrolizumab 105mg SC q4w + placebo IV ▪**ARM B**: placebo SC q4w + inflixumab IV
Primary endpoint	▪ Induction of remission compared with placebo as determined by the Mayo Clinic Score (MCS) at week 10	▪ Induction of remission compared with placebo as determined by the Mayo Clinic Score (MCS) at week 10	▪ Proportion of patients in sustained clinical remission as determined by Mayo Clinic Score (MCS) at weeks 10, 30 and 54
Status	▪ FPI Q4 2014	▪ FPI Q4 2014	▪ FPI Q4 2014

Etrolizumab (RG7413)

Humanised monoclonal antibody against beta 7 integrin

Indication	UC patients who are TNF naïve and refractory or intolerant to immunosuppressant and/or corticosteroid treatment	UC patients who are refractory or intolerant of TNF inhibitors
Phase/study	**Phase III** **LAUREL** Maintenance study	**Phase III** **HICKORY** Induction and maintenance study
# of patients	N=350	N=800
Design	Induction phase: ▪**ARM A:** open label etrolizumab 105mg SC q4w Maintenance study: ▪**ARM B:** etrolizumab 105mg SC q4w ▪**ARM C:** placebo	Cohort 1 (open-label): ▪**ARM A:** etrolizumab induction + placebo maintenance ▪**ARM B:** etrolizumab induction + maintenance Cohort 2 (blinded): ▪**ARM A:** etrolizumab induction + maintenance ▪**ARM B:** placebo induction + maintenance
Primary endpoint	▪ Maintenance of remission (at week 62) among randomised patients in remission at Week 10 as determined by the Mayo Clinic Score (MCS)	▪ Clinical Remission (Mayo Clinic Score, MCS) at Week 14 ▪ Remission maintenance (by MCS, at Week 66) among patients with remission at Week 14
Status	▪ FPI Q3 2014	▪ FPI Q2 2014

UC=ulcerative colitis

Etrolizumab (RG7413)

Humanised monoclonal antibody against beta 7 integrin

Indication	Moderate to severe ulcerative colitis	Moderate to severe ulcerative colitis
Phase/study	**Phase II** **SPRUCE** Open label extension study	**Phase III** **COTTONWOOD** Open label extension study
# of patients	N=116	N=2,600
Design	▪ Patients who were enrolled in EUCALYPTUS study and meet enrolment criteria will receive etrolizumab 105 SC q4w	▪ Patients who were previously enrolled in etrolizumab phase III studies and meet enrolment criteria will receive etrolizumab 105 SC q4w
Primary endpoint	▪ Safety	▪ Long-term efficacy as determined by partial Mayo Clinic Score (pMCS) ▪ Incidence of adverse events
Status	▪ Recruitment completed	▪ FPI Q3 2014

Etrolizumab (RG7413)

Humanised monoclonal antibody against beta 7 integrin

Indication	Moderately to severely active Crohn's disease	Moderately to severely active Crohn's disease
Phase/study	**Phase III** **BERGAMOT**	**Phase III** **JUNIPER** Open label extension study for BERGAMOT
# of patients	N=1,250	N=900
Design	▪ **ARM A**: etrolizumab SC 210 mg (induction only) ▪ **ARM B**: etrolizumab SC 105 mg and maintainance ▪ **ARM C**: placebo	▪ Etrolizumab SC 105mg q4w
Primary endpoint	▪ Induction and maintenance of clinical remission	▪ Safety
Status	▪ FPI Q1 2015	▪ FPI Q2 2015

Lampalizumab (RG7417)

Antibody fragment to selectively block activation of alternative complement pathway

Indication	Geographic atrophy (GA) secondary to age-related macular degeneration		
Phase/study	**Phase III CHROMA**	**Phase III SPECTRI**	**Phase II**
# of patients	N=936	N=936	N=90
Design	▪ **ARM A:** lampalizumab 10mg q4w ▪ **ARM B:** lampalizumab 10mg q6w ▪ **ARM C:** placebo	▪ **ARM A:** lampalizumab 10mg q4w ▪ **ARM B:** lampalizumab 10mg q6w ▪ **ARM C:** placebo	▪ **ARM A:** lampalizumab 10mg q2w ▪ **ARM B:** lampalizumab 10mg q4w ▪ **ARM C:** placebo
Primary endpoint	▪ Primary: change in GA area ▪ Secondary: change in BCVA and in additional measures of visual function	▪ Primary: change in GA area ▪ Secondary: change in BCVA and in additional measures of visual function	▪ Change in GA area
Status	▪ FPI Q3 2014 ▪ Fast track designation received Q4 2014 ▪ Enrolment completed	▪ FPI Q3 2014 ▪ Fast track designation received Q4 2014 ▪ Enrolment completed	▪ FPI Q4 2014 ▪ Enrolment completed

Lebrikizumab (RG3637)

Humanised monoclonal antibody designed to bind specifically to IL-13

Indication	Idiopathic pulmonary fibrosis	Moderate to severe atopic dermatitis		Moderate to very severe COPD
Phase/study	**Phase II RIFF**	**Phase II TREBLE**	**Phase II ARBAN** Safety Study	**Phase II VALETA**
# of patients	N=480	N=200	N=50	N=300
Design	▪ **ARM A:** lebrikizumab SC q4w ▪ **ARM B:** placebo ▪ **ARM C:** lebrikizumab SC q4w + Esbriet ▪ **ARM D:** Esbriet	Patients on topical corticosteroids ▪**ARM A:** lebrikizumab dose 1 ▪**ARM B:** lebrikizumab dose 2 ▪**ARM C:** lebrikizumab dose 3 ▪**ARM D:** placebo	▪ **ARM A:** lebrikizumab ▪ **ARM B:** topical corticosteroids	Patients on background SOC during study ▪**ARM A:** lebrikizumab SC q4w ▪**ARM B:** placebo
Primary endpoint	▪ Change in FVC at week 52	▪ Percentage of patients achieving a 50% reduction in Eczema Area and Severity Index (EASI) score (EASI-50) from baseline to week 12	▪ Safety comparison of lebrikizumab vs. TCS	▪ Week 12 change from baseline in pre-bronchodilator forced expiratory volume (FEV-1)
Status	▪ FPI Q4 2013 (arms A&B) ▪ Data in-house for Arms A&B ▪ FPI in arms C and D in Q3 2015 ▪ Enrolment completed in arms C and D in Q3 2016	▪ Enrolment completed Q4 2015 ▪ Results Q1 2016	▪ Enrolment completed Q4 2015 ▪ Results Q1 2016	▪ Enrolment completed Q2 2016 ▪ Readout Q1 2017

COPD=Chronic obstructive pulmonary disease; SOC=Standard of care

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

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pRED (Roche Pharma Research & Early Development)

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gRED (Genentech Research & Early Development)

Diagnostics

Oncology development programs
Small molecules

Roche pRED

Molecule	Idasanutlin (MDM2 antagonist, RG7388)		
Indication	**Relapsed or refractory acute myeloid leukemia**	**Relapsed or refractory FL and DLBCL**	**Relapsed or refractory AML not eligible for cytotoxic therapy**
Phase	**Phase III**	**Phase Ib/II**	**Phase I**
# of patients	N=440	N=120	N=140
Design	▪ **ARM A:** Idasanutlin plus cytarabine ▪ **ARM B:** placebo plus cytarabine	▪ Dose escalation of idasanutlin plus Gazyva ▪ **ARM A:** Dose expansion of idasanutlin plus Gazyva in FL ▪ **ARM B:** Dose expansion of idasanutlin plus Gazyva in DLBCL	Phase I (dose escalation) ▪ **ARM A:** Cotellic plus Venclexta ▪ **ARM B:** idasanutlin plus Venclexta Phase II (expansion) ▪ **ARM A:** Cotellic plus Venclexta ▪ **ARM B:** idasanutlin plus Venclexta
Primary endpoint	▪ Overall survival	▪ Safety and efficacy	▪ Safety and efficacy
Status	▪ FPI Q4 2015	▪ FPI Q4 2015	▪ FPI Q1 2016

Oncology development programs
Small molecules

Molecule	LSD1 inhibitor (RG6016)	
Indication	**Relapsed or refractory acute myeloid leukemia**	**Extensive-stage small cell lung cancer**
Phase	**Phase I**	**Phase I**
# of patients	N=41	N=70
Design	▪ Multiple ascending dose-escalation cohort ▪ Extension cohort at recommended dose	▪ Multiple ascending dose-escalation study, monotherapy and in combination with extension cohorts
Primary endpoint	▪ Safety, efficacy and PK	▪ Safety, efficacy and PK
Status	▪ FPI Q1 2014 ▪ Extension in MLL-AML initiated Q3 2015 ▪ Data presented at AACR and ASH 2016 ▪ Study completed	▪ FPI Q4 2016
Collaborator	Oryzon Genomics, S.A.	

Oncology development programs

Small molecules

Molecule	BET inhibitor (RG6146, TEN-010)		Raf/MEK inhibitor (RG7304, CKI27)	HIF1 alpha LNA (RG6061)
Indication	**Solid tumours**	**Acute myeloid leukemia**	**Solid tumours**	**Hepatocellular carcinoma**
Phase	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=100	N=36	N=52	N=12
Design	▪ Dose escalation and expansion study	▪ Dose escalation and cohort expansion study	▪ Dose-escalation to maximum tolerated dose (MTD)	▪ RG6061, starting dose of 13 mg/kg/week, 2-hour IV infusion every week in a 6-week cycle, after two loading doses in week 1 of cycle 1 on day 1 and day 4
Primary endpoint	▪ Safety and efficacy	▪ Safety and efficacy	▪ MTD and tumour assessment	▪ Change from baseline to week 6 in HIF1A mRNA level in tumour tissue
Status	▪ FPI Q4 2013	▪ FPI Q4 2014	▪ Initiated Q4 2008 ▪ enrolment stopped in Q4 2010 ▪ Asset returned to Chugai Jan 2017	▪ FPI Q1 2016
Collaborator	Tensha acquisition		Chugai	Santaris acquisition

Oncology development programs
Monoclonal antibodies

Molecule	Codrituzumab (Glypican-3 MAb, GC33, RG7686)		
Indication	**Metastatic liver cancer (hepatocellular carcinoma)**	**2L metastatic liver cancer (hepatocellular carcinoma)**	**Metastatic liver cancer (hepatocellular carcinoma)**
Phase	**Phase Ib**	**Phase II**	**Phase Ib**
# of patients	N=40-50	N=185	N=18-27
Design	▪ Study US monotherapy ▪ Study Japan monotherapy ▪ Dose escalation study in combo with SOC	▪ Adaptive design study Double blind randomised 2:1 RG7686: placebo ▪ Patients are stratified according to the level of GPC-3 expression in tumour	▪ Dose escalation and expansion study in combo with atezolizumab
Primary endpoint	▪ Safety and tolerability	▪ Progression free survival	▪ Safety and tolerability
Status	▪ Recruitment completed Q4 2013 ▪ Data presented at ASCO 2014 ▪ Further steps under evaluation	▪ Recruitment completed Q1 2013 ▪ Data presented at ASCO 2014 ▪ Further steps under evaluation	▪ Recruitment ongoing (in Japan and Taiwan)
	▪ Monotherapy development on hold		
Collaborator	Chugai		

SOC=Standard of care; ASCO=American Society of Clinical Oncology

Oncology development programs
Monoclonal antibodies

Molecule	Vanucizumab (ANG2-VEGF biMAb, RG7221)		
Indication	**Solid tumours**	**Metastatic colorectal cancer**	**Solid tumours**
Phase	**Phase I**	**Phase II McCAVE**	**Phase I**
# of patients	N≈160	N=192	N=170
Design	▪ Multiple ascending dose study with extension cohorts in solid tumours to assess the PD effects and platinum-resistant ovarian cancer ▪ Dose escalation of vanucizumab plus Tecentriq	▪ **ARM A**: Induction: Avastin+mFOLFOX-6; followed by maintenance: Avastin+5-FU/LV ▪ **ARM B**: Induction: RG7221+mFOLFOX-6; followed by maintenance: RG7221+5-FU/LV	▪ Vanucizumab in combination with RG7876 (CD40 MAb)
Primary endpoint	▪ Safety, PK	▪ Progression free survival	▪ Safety, PD, efficacy
Status	▪ FPI Q4 2012 ▪ Dose escalation data presented at ASCO 2014 ▪ Ovarian cancer cohort data presented at ASCO 2015 ▪ Biomarker/imaging data presented at ECC 2015 ▪ FPI in combination arm Q2 2016	▪ Recruitment completed Q2 2016 ▪ Data in house Q3 2016	▪ FPI Q1 2016

ASCO=American Society of Clinical Oncology; ECC=European Cancer Congress

Oncology development programs
Monoclonal antibodies

Molecule	Emactuzumab (CSF-1R MAb, RG7155)			Cergutuzumab amunaleukin (CEA-IL2v, RG7813)	
Indication	**Solid tumours**			**Solid tumours**	
Phase	**Phase I/II**	**Phase I**	**Phase I**	**Phase I**	**Phase Ib**
# of patients	N=216	N=162	N=146	N=113	N=75
Design	▪ Multiple ascending dose study +/- paclitaxel with extension cohorts	RG7155 in combination with Tecentriq (PD-L1 MAb) ▪ **Part 1:** dose escalation ▪ **Part 2:** expansion	Emactuzumab in combination with RG7876 (CD40 Mab) ▪ **Part 1:** dose escalation ▪ **Part 2:** expansion	▪ Single and multiple dose escalation study with extension cohorts	▪ **Part 1:** dose escalation of RG7813 in combination with Tecentriq (PD-L1 MAb) ▪ **Part 2:** dose expansion RG7813 in combination with Tecentriq (PD-L1 MAb)
Primary endpoint	▪ Safety, PK, PD, preliminary clinical activity	▪ Safety	▪ Safety, PK, PD	▪ Safety, PK, PD	▪ Safety, Efficacy, PK, PD
Status	▪ FPI Q4 2011 ▪ Biomarker data presented at AACR 2013 and 2014 ▪ Data presented at ASCO 2014 ▪ Updated data presented at ASCO 2015 ▪ Recruitment completed Q1 2016	▪ FPI Q1 2015	▪ FPI Q2 2016	▪ Recruitment completed Q1 2016 ▪ Imaging data presented at ASCO 2015 ▪ Biomarker/imaging data presented at ECC 2015 ▪ Final imaging data presented at ESMO 2016	▪ FPI in Q2 2015

AACR=American Association for Cancer Research; ASCO=American Society of Clinical Oncology; ECC=European Cancer Congress; ESMO=European Society for Medical Oncology

Oncology development programs
Monoclonal antibodies

Molecule	CEA CD3 T-cell bispecific (TCB) (RG7802)		CD20/CD3 TCB (RG6026)
Indication	**CEA-positive solid tumours**		**r/r NHL**
Phase	**Phase Ia**	**Phase I**	**Phase I**
# of patients	N~300-350 (DE & DF)	N~200-250	N~30 (+40+20)
Design	▪ **Part I:** Dose escalation of RG7802 ▪ **Part II:** Dosing strategy ▪ **Part III**: Assessment of schedule ▪ **Part IV:** Dose and schedule expansion	▪ **Part I:** RG7802 dose escalation plus Tecentriq ▪ **Part II**: Expansion at defined dose and schedule	First-in-man single-agent dose escalation study ▪ Initial dose escalation (N~30) ▪ Expansion cohort in r/r DLBCL (N=40) ▪ Expansion cohort in r/r FL (N=20) All patients will receive pre-treatment with a single dose of Gazyva (1000mg)
Primary endpoint	▪ Safety, Efficacy, PK, PD	▪ Safety, Efficacy, PK, PD	▪ Safety
Status	▪ FPI Q4 2014	▪ FPI Q1 2016	▪ FPI expected Q1 2017

Oncology development programs
Monoclonal antibodies

Molecule	FAP-DR5 biMAB (RG7386)	FAP-IL2v FP (RG7461)	CD40 MAb (RG7876)	
Indication	**Solid tumours**	**Solid tumours**	**Solid tumours**	**Solid tumours**
Phase	**Phase I**	**Phase I**	**Phase Ib**	**Phase I**
# of patients	N=120	N=60	N=160	N=170
Design	▪ **Part I:** Dose escalation ▪ **Part II:** tumour biopsy and imaging evaluation for assessment of treatment-induced pharmacodynamic (PD) effects ▪ **Part III:** Evaluation of antitumour activity of single-agent RO6874813 (RG7386) in patients with histologically confirmed recurrent or metastatic, non-resectable FAP+ sarcomas with two or fewer prior regimens for advanced disease	▪ Dose escalation study	▪ **Part I:** RG7876 single dose escalation in combination with Tecentriq ▪ **Part II:** RG7876 multiple doses, in combination with Tecentriq ▪ **Part III:** Indication specific extension	▪ RG7876 dose escalation in combination with vanucizumab (ANG2-VEGF biMAb)
Primary endpoint	▪ Parts I & II – safety and tolerability ▪ Part III – antitumour activity	▪ Safety, PK/PD	▪ Safety, PD, efficacy	▪ Safety, PD, efficacy
Status	▪ FPI Q3 2015	▪ FPI Q4 2015	▪ FPI Q4 2014	▪ FPI Q1 2016

Neuroscience development programs

Roche pRED

Molecule	Basmisanil (GABRA5 NAM, RG1662)	
Indication	**Cognitive impairment associated with schizophrenia**	**Stroke recovery**
Phase	**Phase II**	**Phase II**
# of patients	N=180	N=80 (95 enrolled)
Design	For 24 weeks patients will receive: ▪ **ARM A**: RG1662 80mg twice daily ▪ **ARM B**: RG1662 240mg twice daily ▪ **ARM C**: Placebo	Starting on day 5-7 post stroke patients will receive treatment for 90-days. ▪ **ARM A**: RG1662 240mg twice daily ▪ **ARM B**: Placebo
Primary endpoint	▪ Efficacy (cognitive function), PK, safety and tolerability	▪ PK, PD, safety and tolerability
Status	▪ FPI Q4 2016	▪ Expect FPI Q1 2017

Neuroscience development programs

Roche pRED

Molecule	NME (RG7906)	PDE10A inhibitor (RG7203)
Indication	Psychiatric disorders	Schizophrenia
Phase	Phase I	Phase I
# of patients	N=164	N=48
Design	▪ **Part 1:** Adaptive single ascending dose in healthy volunteers. Single-center, randomised, placebo-controlled, parallel study ▪ **Part 2:** Adaptive multiple ascending dose in healthy volunteers. Single-center, randomised, double-blind, placebo-controlled, parallel study	▪ Multicenter, randomised, double-blind, placebo-controlled, crossover study to evaluate the effects of RG7203 in participants with mild to moderate negative symptoms of schizophrenia treated with antipsychotics.
Primary endpoint	▪ Safety, tolerability, PK, PD	▪ Safety, tolerability, PK, PD
Status	▪ FPI Q1 2016 ▪ Part 1 completed, Part 2 on going	▪ FPI Q2 2016

Neuroscience development programs

Spinal muscular atrophy

Molecule	SMN2 splicing modifier (RG7800)	SMN2 splicing modifier (2) (RG7916)
Indication	Spinal muscular atrophy	Spinal muscular atrophy
Phase	**Phase Ib MOONFISH**	**Phase I**
# of patients	N=48	N=33
Design	▪ randomised, double-blind, 12-week, placebo-controlled multiple dose study in adult and pediatric patients	▪ randomised, double-blind, adaptive single ascending dose (SAD), placebo-controlled study in healthy volunteers
Primary endpoint	▪ Safety and tolerability	▪ Safety and tolerability
Status	▪ First cohort completed ▪ Healthy volunteer data presented at AAN and CureSMA 2015 ▪ SMA patient data from first cohort presented at WMS 2015 ▪ Study terminated	▪ FPI Q1 2016 ▪ Study completed Q3 2016 ▪ Data presented at Child Neurology Society conference 2016 ▪ Orphan drug designation granted by FDA in Q1 2017
Collaborator	PTC Therapeutics, SMA Foundation	

AAN=American Academy of Neurology; SMA=Spinal muscular atrophy; WMS=World Muscle Society

Neuroscience development programs

Spinal muscular atrophy

Molecule	**SMN2 splicing modifier (2)** (RG7916)		
Indication	**Spinal muscular atrophy**		
Phase	**Phase II SUNFISH**	**Phase II FIREFISH**	**Phase II JEWELFISH**
# of patients	N=186	N=48	N=24
Design	Randomised, double-blind, placebo-controlled study in adult and pediatric patients with type 2 or type 3 SMA ▪ **Part 1** (dose-finding): at least 12 weeks ▪ **Part 2** (confirmatory): 24 months	Open-label study in infants with type 1 SMA ▪ **Part 1** (dose-finding): at least 4 weeks ▪ **Part 2** (confirmatory): 24 months	▪ Open-label single arm study in adolescents and adults (12-60 y.o.) with SMA type 2/3 previously treated with SMN2 targeting therapy.
Primary endpoint	▪ Safety and tolerability, pharmacokinetics, pharmacodynamics, efficacy	▪ Safety and tolerability, pharmacokinetics, pharmacodynamics, efficacy	▪ Safety and tolerability, pharmacokinetics
Status	▪ FPI Q4 2016	▪ FPI Q4 2016	▪ FPI expected Q1 2017
	▪ Orphan drug designation granted by FDA in Q1 2017		
Collaborator	PTC Therapeutics, SMA Foundation		

SMA=Spinal muscular atrophy

Neuroscience development programs

Roche pRED

Molecule	V1 receptor antagonist (RG7314)		Anti-αSynuclein (RG7935, PRX002)	
Indication	**Autism**		**Parkinson's disease**	
Phase	**Phase II VANILLA**	**Phase II AVIATION**	**Phase Ia**	**Phase Ib**
# of patients	N=225	N=300	N=40	N=80
Design	▪ Multi-center, randomised, double-blind, placebo-controlled proof-of-concept study in individuals with Autism Spectrum Disorder (ASD)	▪ Multi-center, randomised, double-blind, placebo-controlled proof-of-concept study in pediatrics (5-17 yrs) with Autism Spectrum Disorder (ASD)	▪ Double-blind, placebo-controlled, single, ascending dose study of RG7935/PRX002 in healthy subjects	▪ Double-blind, placebo-controlled, multiple ascending dose study of RG7935/PRX002 in patients with Parkinson's disease
Primary endpoint	▪ Safety and efficacy	▪ Safety and efficacy	▪ Safety, tolerability and PK	▪ Safety, tolerability and PK
Status	▪ FPI Q3 2013	▪ FPI Q4 2016	▪ Study completed Q1 2015 ▪ Data presented at MDS 2015	▪ Study completed Q4 2016 ▪ Data to be presented at AD/PD 2017
Collaborator			Prothena	

MDS=Movement Disorder Society; AD/PD=Alzheimer's & Parkinson's Diseases Congress

Infectious diseases development programs

Roche pRED

Molecule	DBO beta lactamase inhibitor (RG6080, OP0595)	NME (RG7834)	TLR7 agonist (3) (RG7854)	Capsid inhibitor CAPi (2) (RG7907)
Indication	**Infectious diseases**	**Chronic hepatitis B**	**Chronic hepatitis B**	**Chronic hepatitis B**
Phase	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=40	N=165	N=110	N=128
Design	▪ randomised, double-blind, placebo-controlled, single-ascending dose study in healthy volunteers	▪ Healthy volunteer and chronic hepatitis B patient study	▪ Healthy volunteer and chronic hepatitis B patient study	▪ Healthy volunteer and chronic hepatitis B patient study
Primary endpoint	▪ Safety, PK	▪ Safety, PK, PD	▪ Safety, PK, PD	▪ Safety, PK, PD
Status	▪ Study completed	▪ FPI Q4 2015	▪ FPI Q4 2016	▪ FPI Q4 2016
Collaborator	Meiji and Fedora			

Ophthalmology development programs

Roche pRED

Molecule	VEGF-Ang2 biMAb (RG7716)	
Indication	**Wet age-related macular degeneration**	**Center-involving diabetic macular edema (CI-DME)**
Phase/study	**Phase II AVENUE**	**Phase II BOULEVARD**
# of patients	N=271	N=210
Design	▪ **ARM A:** SoC (Lucentis, q4w ▪ **ARM B:** 1.5 mg VA2, q4w ▪ **ARM C:** 6mg VA2, q4w / q8w ▪ **ARM E:** Soc q4w x 3 doses, switch group to 6 mg VA2 q4w	▪ **ARM A:** SOC (Lucentis) 0.3 mg q4w ▪ **ARM B:** 1.5mg VA2, q4w ▪ **ARM C:** 6 mg VA2, q4w
Primary endpoint	▪ Visual acuity (change in BCVA) after 32 weeks	▪ Mean change from baseline in BCVA at week 24
Status	▪ FPI Q3 2015 ▪ enrolment completed Q1 2017	▪ FPI Q2 2016

Immunology development programs

Molecule	Cathepsin S inhibitor (RG7625)		Cadherin 11 MAb (RG6125)	C5 inh MAb (RG6107/SKY59)
Indication	**Primary Sjögren's syndrome**	**Celiac disease**	**Rheumatoid Arthritis**	**Paroxysmal nocturnal hemoglobinuria (PNH)**
Phase/study	**Phase II**	**Phase I**	**Phase IIa/b**	**Phase I/II**
# of patients	N=70	N=19	N~250	N=49
Design	▪ **ARM A**: RG7625 ▪ **ARM B**: placebo	▪ **ARM A**: RG7625 ▪ **ARM B**: placebo	Ph IIa (PoC) • **ARM A:** RG6125 • **ARM B:** placebo Ph IIb (DRF) • **ARM A, B, C:** RG6125 • **ARM D:** placebo	▪ An adaptive, single ascending dose (SAD) study in healthy volunteers followed by an intra-patient SAD in treatment naïve and an multiple dose study in pretreated patients with PNH
Primary endpoint	▪ Percentage of participants with a Clinically Relevant Decrease in European League Against Rheumatism (EULAR) Sjoören's Syndrome Disease Activity Index (ESSDAI) Score	▪ Overall numbers of participants who are Responders to the gluten challenge	▪ Overall numbers of participants who are Responders to the gluten challenge	▪ Safety, PK, PD
Status	▪ FPI Q3 2016	▪ FPI Q1 2016 ▪ LPI Q3 2016	▪ FPI Q4 2016	▪ FPI Q4 2016
Collaborator				Chugai

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Diagnostics

Oncology development programs
Monoclonal antibodies

gRED Genentech Research & Early Development

Molecule	OX40 MAb (RG7888, MOXR0916)		CD20/CD3 TDB (RG7828)	Anti-TIGIT (RG6058, MTIG7192A)
Indication	**Solid tumours**	**Solid tumours**	**Hematologic tumours**	**Solid tumours**
Phase	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=400	N=762	N=170	N=300
Design	▪ RG7888 dose escalation and expansion study	▪ Dose escalation and expansion of RG7888 + Tecentriq with or without Avastin	▪ Dose escalation and expansion	▪ Dose escalation and expansion as single agent and in combination with Tecentriq
Primary endpoint	▪ Safety	▪ Safety	▪ Safety, PK/PD	▪ Safety,PK/PD
Status	▪ FPI Q3 2014 ▪ Dose escalation data presented at AACR 2016	▪ FPI Q2 2015 ▪ Dose escalation data presented at ASCO 2016 ▪ FPI Avastin cohort Q3 2016	▪ FPI Q3 2015	▪ FPI Q2 2016

AACR=American Association for Cancer Research; ASCO=American Society of Clinical Oncology; TDB=T cell–dependent bispecific

Oncology development programs

Antibody–drug conjugates

gRED Genentech Research & Early Development

Molecule	NME ADC (RG7882)	NME ADC (RG7986)
Indication	**Pt-resistant ovarian cancer or unresectable pancreatic cancer**	**Relapsed or refractory B cell non-Hodgkin's lymphoma**
Phase	**Phase I**	**Phase I**
# of patients	N=95	N=80
Design	▪ Dose escalation and expansion study	▪ Dose escalation and expansion
Primary endpoint	▪ Safety/PK	▪ Safety, PK
Status	▪ FPI Q2 2014	▪ FPI Q3 2015
Collaborator	Seattle Genetics	

Oncology development programs

Small molecules

gRED Genentech Research & Early Development

Molecule	**Selective estrogen receptor degrader (SERD)** (RG6046, GDC-0810/ARN-810)		**Selective estrogen receptor degrader (SERD(2))** (RG6047, GDC-0927/SRN-927)
Indication	**Metastatic ER+ HER2-neg. breast cancer**		**Metastatic ER+ HER2-neg. breast cancer**
Phase	**Phase I/IIa**	**Phase II HydranGea**	**Phase I**
# of patients	N=195	N=152	N=90
Design	▪ **Phase I:** dose escalation ▪ **Phase IIa:** dose expansion ▪ **Ph1b:** RG6046 in combination with palbociclib and/or an LHRH agonist	▪ **ARM A:** RG6046 ▪ **ARM B:** furvestrant	▪ Dose escalation study
Primary endpoint	▪ Safety, PK, maximum tolerated dose	▪ Progression free survival for all participants and for sub-set of participants with Estrogen Receptor (ESR)1 mutations	▪ Safety
Status	▪ FPI Q4 2014 ▪ Initial data presented at SABCS 2014 and AACR 2015 ▪ FPI in palbociclib arm Q1 2016	▪ FPI Q4 2015	▪ FPI Q1 2015
	▪ Decision on discontinuation Q4 2016		
Collaborator	Seragon acquisition		

Oncology development programs
Small molecules

gRED Genentech Research & Early Development

Molecule	Indoleamine 2, 3-dioxygenase (IDO) Inhibitor (RG6078, GDC-0919, NLG919)		Checkpoint kinase 1 (ChK1) inhibitor (RG7741,GDC-0575)	Phosphatidylinositol 3-kinase (PI3K) inhibitor (RG6114, GDC-0077)
Indication	**Solid tumours**	**Solid tumours**	**Solid tumours**	**PIK3CA mutant solid tumours and metastatic ER+ HER2- breast cancer**
Phase	**Phase I**	**Phase Ib**	**Phase I**	**Phase Ib**
# of patients	N=35	N=305	N=112	N=156
Design	▪ Dose escalation study	▪ Dose escalation and expansion study of RG6078 and Tecentriq combination	▪ Stage 1: Dose escalation ▪ Stage 2: Cohort expansion	▪ Monotherapy and in combination with SOC (letrozole; letrozole +palbociclib; fulvestrant) ▪ **Stage 1:** dose escalation ▪ **Stage 2:** expansion
Primary endpoint	▪ Safety	▪ Safety and tolerability	▪ Safety/PK	▪ Safety, tolerability and PK
Status	▪ FPI Q1 2014 ▪ Safety and PK/PD data presented at ECC 2015	▪ FPI Q3 2015	▪ FPI Q2 2012	▪ FPI Q4 2016
Collaborator	NewLink Genetics		Array BioPharma	

ECC=European Cancer Congress

Immunology development programs

gRED Genentech Research & Early Development

Molecule	IL22-Fc (RG7880)	NME (RG7990, BITS7201A)	NME (RG6069, GDC-3280)
Indication	**Inflammatory diseases**	**Mild atopic asthma**	**Interstitial lung disease**
Phase	**Phase Ib**	**Phase I**	**Phase I**
# of patients	N=48	N=80	N=80
Design	▪ Multiple ascending dose study with healthy volunteer and patient cohorts	▪ Single and multiple ascending dose study with healthy volunteer and patient cohorts	▪ randomised, double-blind, placebo-controlled, ascending, single and multiple oral dose study
Primary endpoint	▪ Safety, tolerability	▪ Safety and tolerability	▪ Safety, tolerability, and PK
Status	▪ FPI Q2 2016	▪ FPI Q2 2016	▪ Study completed Q1 2016
Collaborator		Novimmune SA	

Immunology development programs

gRED Genentech Research & Early Development

Molecule	BTKi (RG7845, GDC-0853)		ST2 MAb (RG6149, AMG 282, MSTT1041A)
Indication	**Rheumatoid arthritis**	**Lupus**	**Asthma**
Phase	**Phase II**	**Phase II**	**Phase IIb ZENYATTA**
# of patients	N=580	N=240	N=500
Design	▪ Randomised, double-blind, parallel group study in rheumatoid arthritis patients ▪ **Cohort 1:** RG7845 vs adalimumab ▪ in patients with IR to previous MTX ▪ **Cohort 2:** RG7845 vs placebo in patients with IR to previous TNF	▪ randomised, double-blind, placebo-controlled study in rheumatoid arthritis patients ▪ **ARM A:** GDC-0853 (high dose) ▪ **ARM B:** GDC-0853 (low dose) ▪ **ARM C:** Drug: Placebo	▪ Add-on therapy for the treatment of high-need, uncontrolled asthma in adults (50-week subcutaneous treatment period): ▪ **ARM A:** RG6149 (70 mg) ▪ **ARM B:** RG6149 (210mg) ▪ **ARM C:** RG6149 (490mg) ▪ **ARM D:** placebo
Primary endpoint	▪ ACR 50, safety	▪ Systemic Lupus Erythematosus Responder Index (SRI)-4 Response at Week 48	▪ Percentage of participants with asthma exacerbations
Status	▪ FPI Q3 2016	▪ FPI expected Q1 2017	▪ FPI Q3 2016 ▪ Phase 2 trial enrolling
Collaborator			Amgen

Neuroscience development programs

gRED Genentech Research & Early Development

Molecule	Nav1.7 (2) (RG6029, GDC-0310)	NME (RG6000, GDC-0134)	Anti-Tau (RG6100)
Indication	**Pain**	**Amyotrophic lateral sclerosis**	**Prodromal to mild Alzheimer's disease**
Phase	**Phase I**	**Phase I**	**Phase I**
# of patients	N=95	N=39	N=71
Design	▪ randomised, placebo-controlled, double-blind study in healthy volunteers	▪ randomised, double-blind, placebo-controlled, multicenter, single and multiple ascending dose study	▪ randomised, double-blind, placebo-controlled, single-center single ascending dose (HVs) and multiple dose study (HVs and AD patients)
Primary endpoint	▪ Safety, tolerability, pharma-cokinetics; single and multiple doses	▪ Safety, tolerability, PK of single and multiple doses	▪ Safety, tolerability, PK of single doses and multiple doses
Status	▪ FPI Q3 2015	▪ FPI Q2 2016	▪ FPI Q2 2016
Collaborator	Xenon Pharmaceuticals Inc.		AC Immune

Infectious diseases development programs

gRED Genentech Research & Early Development

Molecule	Flu A MAb (RG7745)		Anti-S. aureus TAC (RG7861)
Indication	**Influenza A**	**Acute uncomplicated seasonal influenza A**	**Serious infections caused by *Staphylococcus aureus***
Phase	**Phase IIb**	**Phase II**	**Phase Ia**
# of patients	N~330	N=141	N=30
Design	Hospitalised patients requiring oxygen with severe influenza A ▪ **ARM A:** RG7745 (high dose) + Tamiflu ▪ **ARM B**: RG7745 (low dose) + Tamiflu ▪ **ARM C**: placebo + Tamiflu	▪ **ARM A:** RG7745 dose level 1 ▪ **ARM B**: RG7745 dose level 2 ▪ **ARM C:** placebo	▪ Healthy volunteer study
Primary endpoint	▪ Safety and efficacy (time to normalisation of respiratory function)	▪ Safety	▪ Safety
Status	▪ FPI Q1 2015 ▪ FPI high dose cohort Q3 2016	▪ FPI Q1 2016	▪ FPI Q4 2015 ▪ Study completed
Collaborator			Seattle Genetics and Symphogen

TAC=THIOMAB™ antibiotic conjugate

Metabolic diseases development programs

gRED Genentech Research & Early Development

Molecule	FGFR1/KLB MAb (RG7992)
Indication	Metabolic diseases
Phase	Phase I
# of patients	N=56
Design	▪ Healthy volunteer study ▪ **ARM A:** Single ascending dose of RG7992 ▪ **ARM B:** placebo
Primary endpoint	▪ Safety and tolerability
Status	▪ FPI Q4 2015

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Diagnostics

2016: Diagnostics Division CER growth
By Region and Business Area (vs. 2015)

	Global		North America		EMEA[1]		RoW	
	CHFm	% CER growth	CHFm	% CER growth	CHFm	% CER growth	CHFm	% CER growth
Centralised and Point of Care Solutions	6,698	9	1,444	7	2,488	4	2,766	16
Diabetes Care	2,016	-4	285	-27	1,258	-2	473	10
Molecular Diagnostics	1,845	7	725	6	668	4	452	14
Tissue Diagnostics	914	14	553	14	223	12	138	15
Diagnostics Division	**11,473**	**7**	**3,007**	**3**	**4,637**	**2**	**3,829**	**15**

CER=Constant Exchange Rates
[1] Europe, Middle East and Africa

Diagnostics Division quarterly sales and CER growth[1]

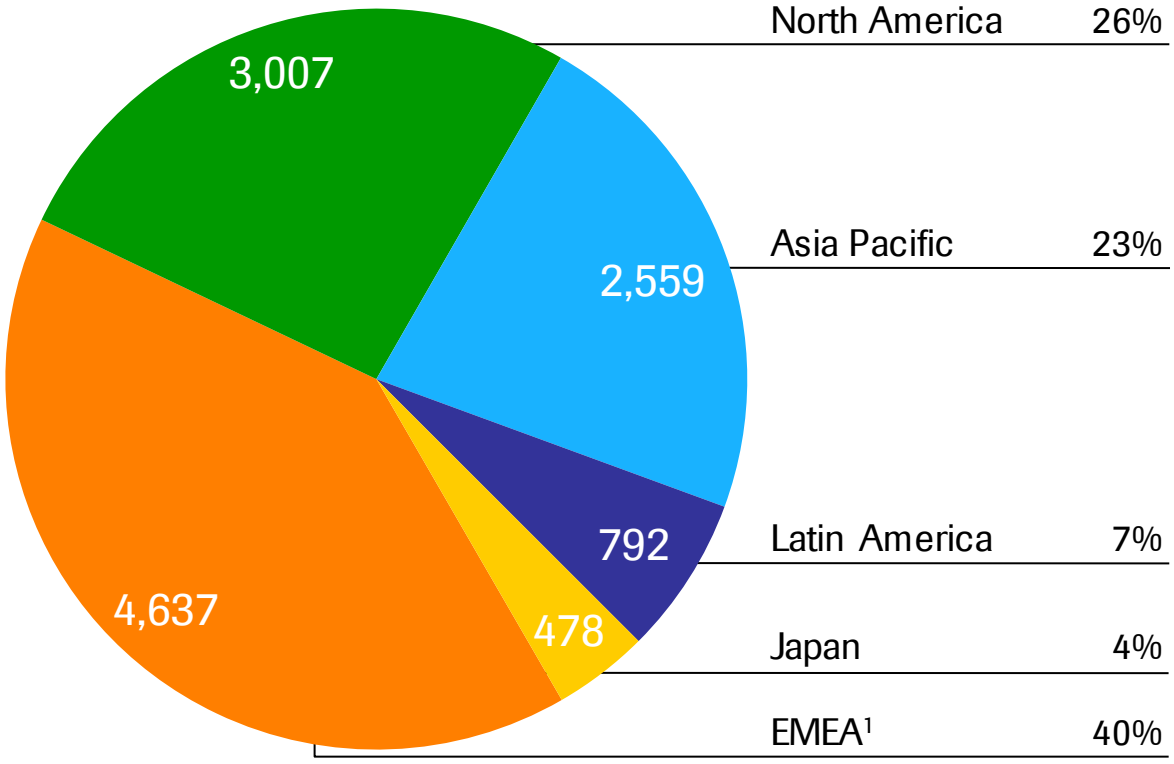
	Q3 15		Q4 15		Q1 16		Q2 16		Q3 16		Q4 16	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Centralised and Point of Care Solutions	1,515	7	1,688	9	1,519	7	1,714	11	1,651	9	1,814	9
Diabetes Care	476	-9	595	-3	443	-11	555	1	486	3	532	-9
Molecular Diagnostics	416	8	471	9	446	11	457	5	442	6	500	6
Tissue Diagnostics	193	11	225	10	206	13	222	11	224	15	262	16
Dia Division	**2,600**	**4**	**2,979**	**7**	**2,614**	**5**	**2,948**	**8**	**2,803**	**8**	**3,108**	**5**

CER=Constant Exchange Rates

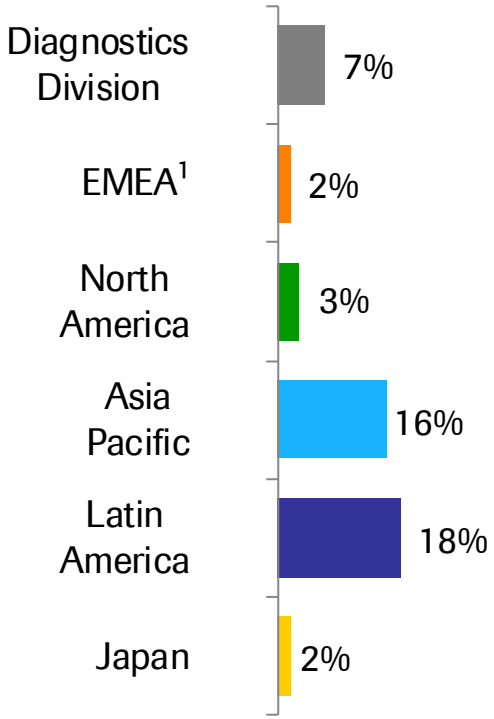
[1] versus same period of prior year

2016: Diagnostics Division sales
Growth driven by Asia Pacific

CHF 11,473 m



CER sales growth

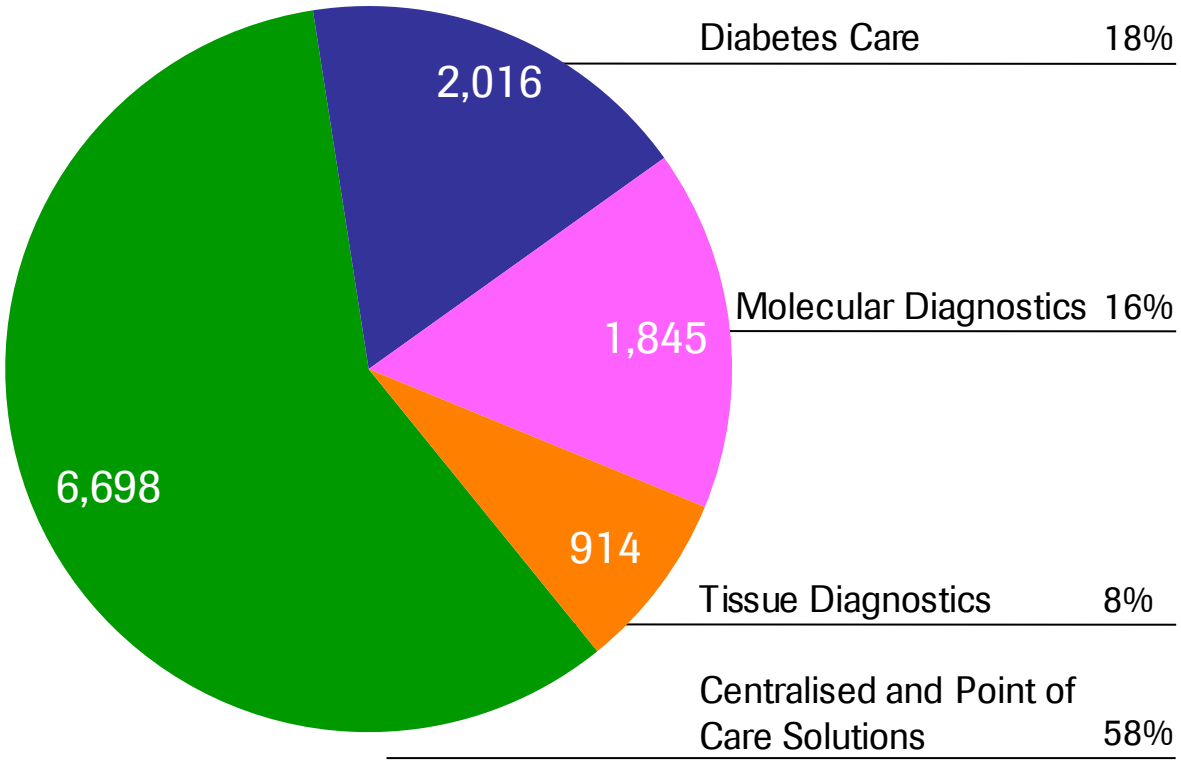


CER=Constant Exchange Rates
[1] Europe, Middle East and Africa

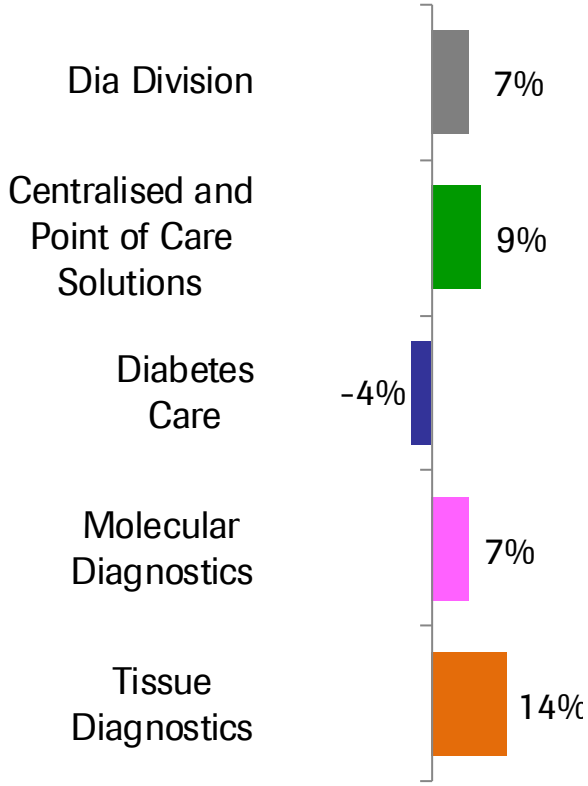
2016: Diagnostics Division sales

Growth driven by Centralised and Point of Care solutions

CHF 11,473 m

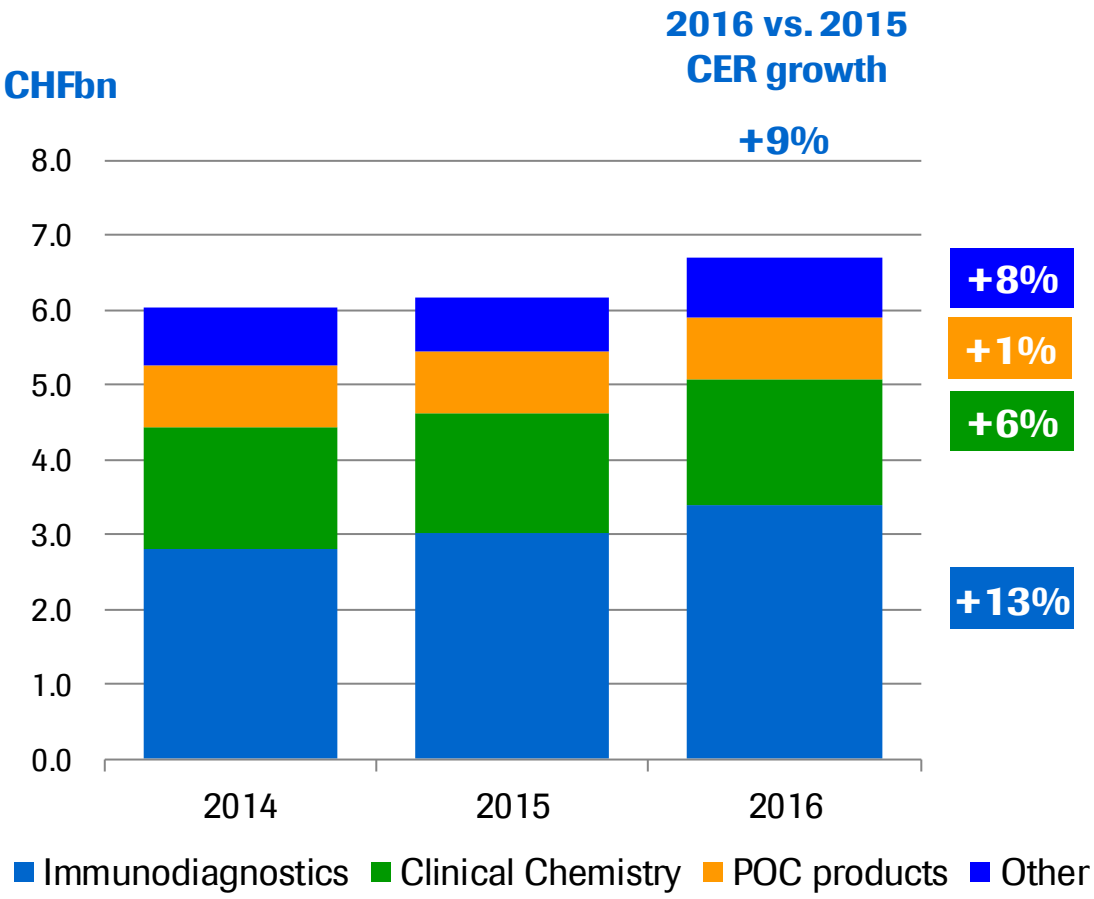


CER sales growth



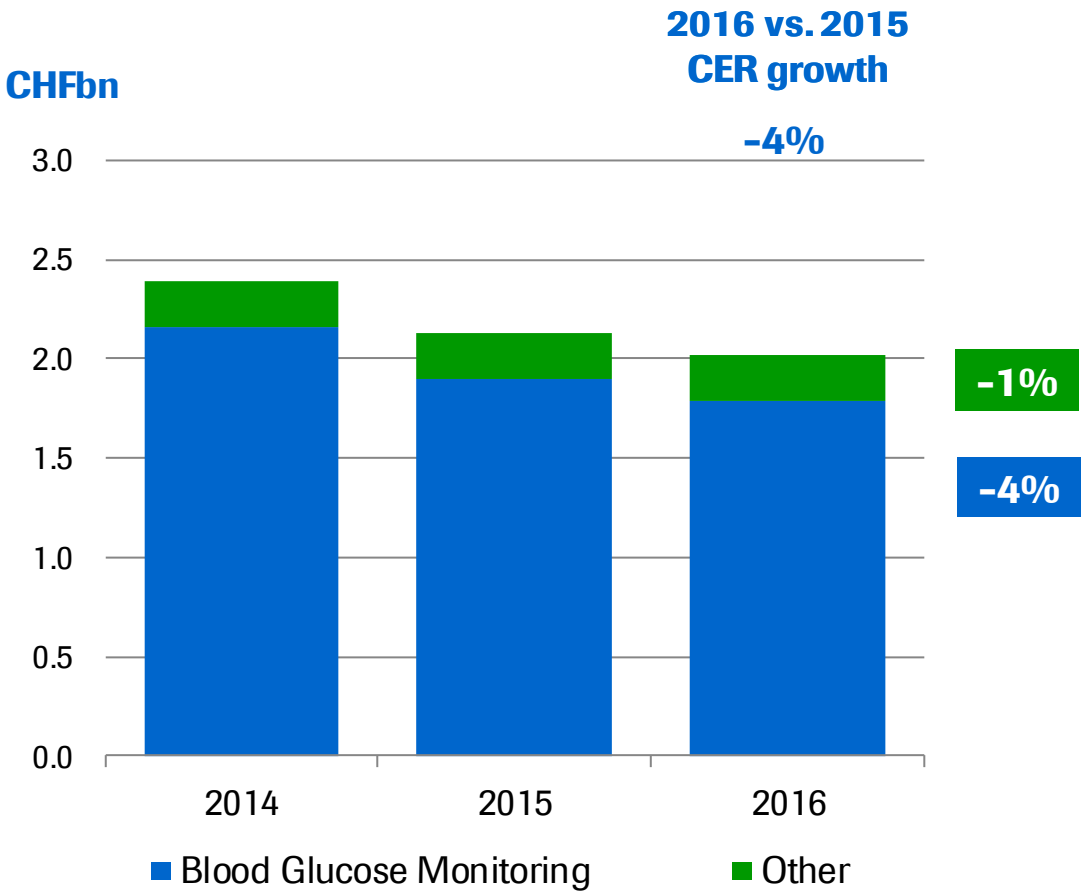
CER=Constant Exchange Rates

Centralised and Point of Care Solutions



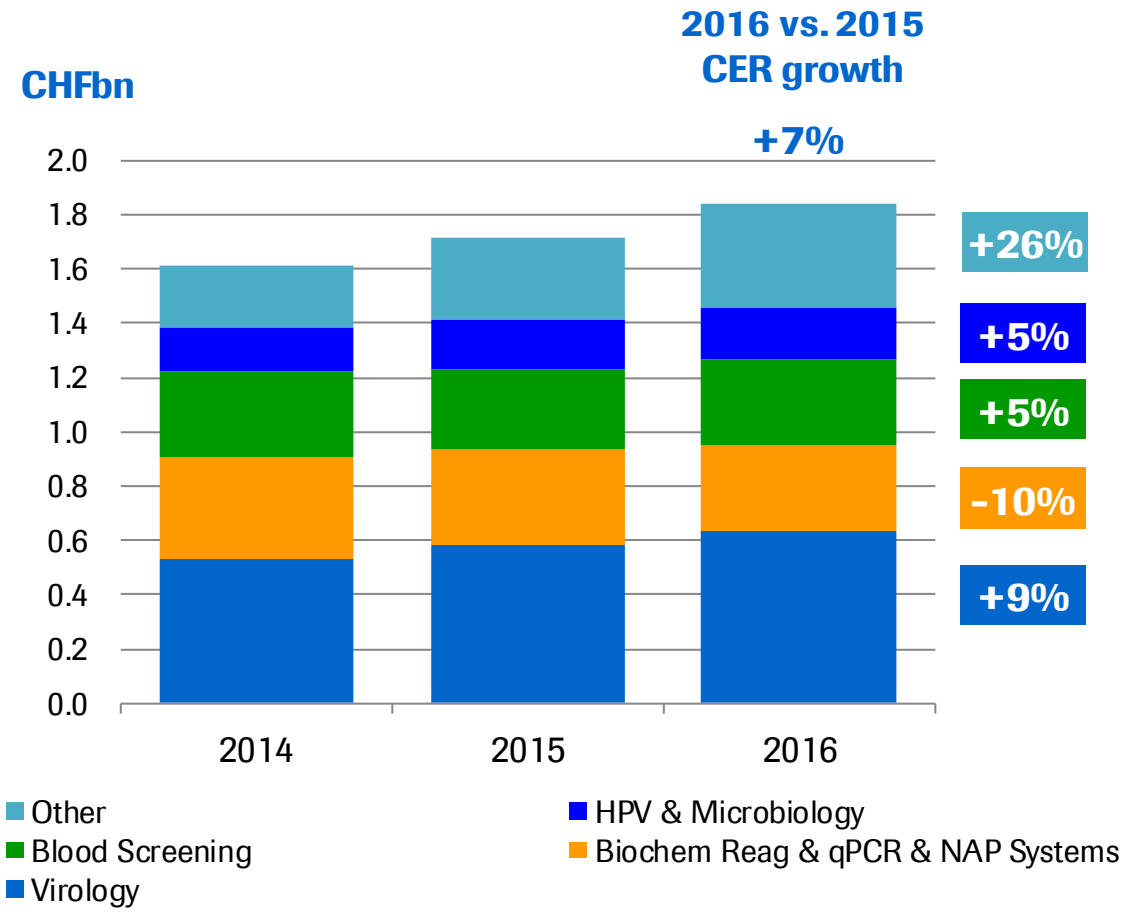
CER=Constant Exchange Rates

Diabetes Care



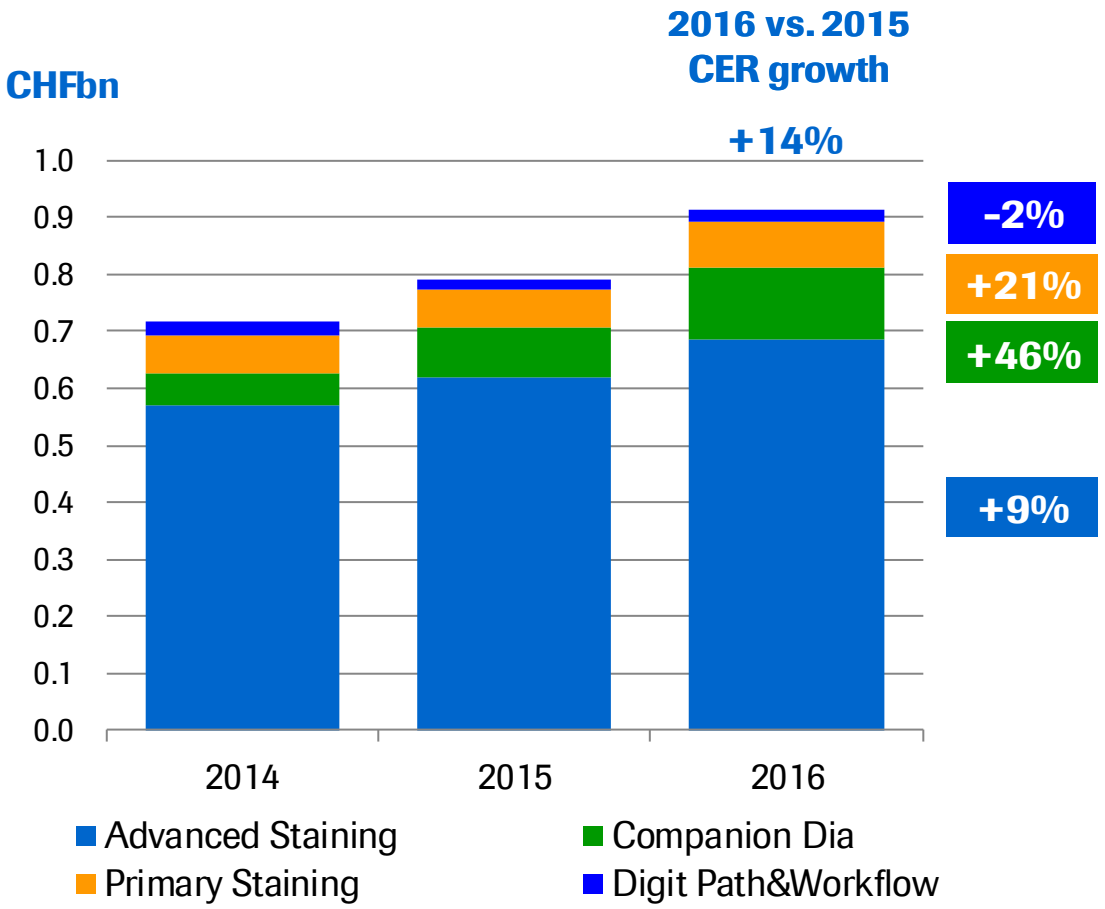
CER=Constant Exchange Rates

Molecular Diagnostics



CER=Constant Exchange Rates

Tissue Diagnostics



CER=Constant Exchange Rates

2017: Key planned product launches
Centralised and point of care solutions

Product	Description	Region
cobas e 801	High throughput immunochemistry analyser	US
cobas t 511 / t 711	Medium and high volume coagulation systems	EU
CoaguChek Vantus	Hand-held coagulation monitoring system for Patient Self-Testing	US
AMH	Immunoassay for the in vitro quantitative determination of anti-Mullerian hormone (AMH) in human serum and plasma for the assessment of the ovarian reserve in women presenting to fertility clinics	US
CCM High Speed	Sample transportation laboratory workflow solution; up to 6000 samples/hour	WW

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2017: Key planned product launches
Molecular Diagnostics

Product	Description	Region
cobas HIV 1&2 Qual	For use on the cobas 6800/8800 Systems; for diagnosis of acute HIV 1 or 2 infection and for confirmation of HIV 1 or 2 infection	EU
cobas HPV	Next generation HPV DNA test leveraging 68/8800 Automation to detect 14 hrHPV with simultaneous detection of genotypes 16 and 18	EU
cobas Liat C.diff	Qualitative IVD test, that utilises real-time PCR, for the direct detection of the tcdB gene of toxigenic *C. difficile* in unformed stool specimens	EU
cobas Liat MRSA/SA	Qualitative IVD test, that utilises real-time PCR, for the direct detection of MRSA and *Staphylococcus aureus* DNA from nasal swabs	EU

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2017: Key planned product launches
Tissue Diagnostics

Product	Description	Region
PD-L1 Assays	PD-L1 (SP142) for Bladder Cancer – complementary diagnostic for Tecentriq PD-L1 (SP142) for NSCLC – complementary diagnostic for Tecentriq	EU
CINtec Histology	Diagnostic component of the Roche Cervical Cancer portfolio	US

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2017: Key planned product launches
Sequencing

Product	Description	Region
AVENIO ctDNA panels	Liquid biopsy for circulating tumor DNA, 3 panels: targeted panel (17 genes for cancer therapy selection), expanded panel (77 genes for cancer therapy selection), surveillance panel (197 genes)	EU/US

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2017: Key planned product launches
Diabetes Care

Product	Description	Region
Accu-Chek Instant bG System		EU

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

Doing now what patients need next