Media & Investor Release

Ad hoc announcement pursuant to Art. 53 LR

Roche enters into a definitive agreement to acquire Telavant including rights to novel TL1A directed antibody (RVT-3101) for the treatment of inflammatory bowel disease from Roivant

- **Roche will gain the rights to develop, manufacture and commercialise RVT-3101 in the US and Japan for the treatment of inflammatory bowel disease and potentially multiple other diseases**
- **RVT-3101 is a Phase 3-ready antibody with first-in-class and best-in-disease potential, a novel mode of action and strong Phase 2b data in ulcerative colitis**
- **Roche will also obtain an option to enter into a global collaboration with Pfizer on a next-generation p40/TL1A directed bispecific antibody, currently in Phase 1**
- **Under the terms of the agreement, Roche will pay a purchase price of US$ 7.1 billion upfront and a near-term milestone payment of US$ 150 million**

Basel, 23 October 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the entry into a definitive agreement to acquire Telavant Holdings, Inc. (Telavant), a Roivant company, owned by Roivant Sciences Ltd. and Pfizer Inc.. The agreement includes the development, manufacturing and commercialisation rights in the US and Japan for Telavant's RVT-3101, a novel TL1A directed antibody. RVT-3101 is a promising new therapy in development for people suffering from inflammatory bowel disease, including ulcerative colitis and Crohn's disease. Inflammatory bowel disease is a group of chronic gastrointestinal disorders with almost 8 million people diagnosed worldwide and 80% of all individuals not experiencing lasting remission.[1] Given the antibody's novel mode of action targeting both inflammation and fibrosis, it has potential to be applied in multiple other diseases.

RVT-3101 has been investigated in the TUSCANY-2 phase 2b study in patients with moderate to severe ulcerative colitis. The global, randomised, double-blinded, placebo controlled trial delivered the first long-term, dose finding data in a large number of patients (n=245). The maintenance treatment phase following induction resulted in improved clinical remission (36% at week 56) and endoscopic improvement (50% at week 56) at the proposed Phase 3 dose administered subcutaneously every month. Beyond the efficacy results, the maintenance dosing period of RVT-3101 also showed a favourable safety profile across all patients.

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“We strongly believe this novel TL1A directed antibody has the transformational potential to make a significant difference for patients living with inflammatory bowel disease and potentially other diseases,” said Thomas Schinecker, CEO Roche Group. “We are excited to add this promising new therapy in development to our portfolio and to make it available to patients as quickly as possible.”

“The recent Phase 2b for RVT-3101 delivered the first long-term, robust dataset demonstrating improved clinical remission in the maintenance treatment phase,” says Levi Garraway, Roche’s Chief Medical Officer and Head of Global Product Development. “Given this promising data, we believe that RVT-3101 has the potential to be the first therapy that offers both high efficacy and safety for people with inflammatory bowel disease and the convenience of an at-home, subcutaneous administration."

Terms of the acquisition

Under the terms of the agreement, Roche will pay a purchase price of US$ 7.1 billion upfront and a near-term milestone payment of US$ 150 million. Upon closing of the transaction, Roche will have full rights to further develop and manufacture RVT-3101 and commercialise it in the US and in Japan pending clinical and regulatory success. Roche is committed to starting a global Phase 3 trial for RVT-3101 as soon as possible to bring this promising therapy to the patients suffering from inflammatory bowel disease. Outside of the US and Japan, Pfizer holds commercialisation rights.

In addition, following the closing of the transaction, Roche will also have an option to enter into a global collaboration with Pfizer on a next-generation p40/ TL1A directed bispecific antibody, currently in Phase 1. Telavant was jointly formed by Roivant and Pfizer in 2022 to develop and commercialise RVT-3101 in the US and Japan. Roivant owns 75% of the issued and outstanding shares of common stock and preferred stock of Telavant and Pfizer owns the remaining 25%.

The transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions. The closing of the transaction is currently expected to take place in Q4 2023 or in Q1 2024.

Citi is acting as the exclusive financial advisor to Roche and Davis Polk & Wardwell LLP is acting as legal counsel to Roche. Freshfields Bruckhaus Deringer LLP is acting as legal counsel for Roivant.

About RVT-3101

RVT-3101 is a potential first-in-class agent that targets both inflammatory and fibrotic pathways by inhibiting TL1A. It has been shown to modulate the severity of inflammation and fibrosis by stimulating the TH1 and TH17 pathways, in addition to activating fibroblasts. As such, RVT-3101 has the potential to provide greater efficacy by hitting multiple inflammatory and fibrotic pathways.

RVT-3101 has been evaluated in a Phase 2 study (TUSCANY) in 50 patients, and in a large global Phase 2b study (TUSCANY-2) in 245 adult participants with moderate to severe ulcerative colitis. TUSCANY-2, a large, global, randomised, double-blinded, placebo-controlled dose-ranging Phase 2b study was set up to investigate the efficacy, safety and pharmacokinetics of RVT-3101 administered monthly subcutaneously in adult patients.

Key efficacy analyses from the induction period were measured at week 14 and the maintenance (chronic) phase at week 56. Patients who received RVT-3101 in the induction period were preassigned to receive either the same or a lower dose in the maintenance (chronic) period. Roivant reported positive data for the induction period of the study in January 2023 and the chronic phase in June 2023. A Phase 2 study in Crohn's disease is ongoing.

About inflammatory bowel diseases and ulcerative colitis

Inflammatory bowel diseases (IBD) are a group of chronic gastrointestinal disorders affecting almost 8 million people worldwide.[1] The two main types of IBD are ulcerative colitis (mainly affecting the colon and rectum) and Crohn's disease (affecting the entire gastrointestinal tract).[2,3] Patients can experience unpredictable symptoms that include abdominal pain and cramping, frequent and urgent bowel movements, diarrhoea, leakage, rectal bleeding, weight loss, energy loss and fatigue.[2,3] About 80% of all individuals with IBD do not experience lasting remission, which can have a long-term impact on quality of life and leave many feeling like they have little control over their daily lives.[4]

Ulcerative colitis is most commonly diagnosed in young people aged 15 to 30 years, affecting them over the course of their entire future lives.[5] Up to a quarter of people with ulcerative colitis will require a colectomy within 10 years of diagnosis, in which all or part of the colon is removed.[6]

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and

develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

References

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