PRESS RELEASE

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Sobi initiates rolling biologics license application to FDA for SEL-212 for the potential treatment of chronic refractory gout

Sobi® today announced the initiation of a rolling Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for SEL-212. The submission is based on the results of the DISSOLVE I and II pivotal studies. SEL-212 is an innovative biologic therapy in development for the treatment of chronic refractory gout, a debilitating condition characterised by the persistent and painful buildup of urate crystals in the joints.

This significant milestone follows the FDA's Fast Track designation of SEL-212 in March 2024, underscoring the urgent need for new treatment options for patients with chronic refractory gout. The FDA's Fast Track program is intended to facilitate the development and expedite the review of medicines that treat serious conditions and fill an unmet medical need.

"We are very pleased to initiate the rolling submission of the BLA for SEL-212, bringing Sobi one step closer to providing a potential new, effective treatment option for patients with chronic refractory gout," said Lydia Abad-Franch, MD, MBA, Head of Research, Development, and Medical Affairs, and Chief Medical Officer at Sobi. "The Fast Track designation confirms the previously released SEL-212 phase 3 clinical data, highlighting the significant need for innovative therapies in this space and reinforcing our commitment to transforming the lives of patients with rare diseases."

SEL-212 is a novel investigational combination medicine designed to reduce serum urate (SU) levels in people with chronic refractory gout, potentially reducing harmful tissue urate deposits which can lead to gout flares and joint deformity when left untreated. Sobi licensed SEL-212 from Selecta Biosciences (now Cartesian Therapeutics) in June 2020 and is responsible for development, regulatory and commercial activities in all markets outside of China.

About SEL-212

SEL-212 is a novel investigational combination medicine designed to reduce serum urate (SU) levels in people with chronic refractory gout, potentially reducing harmful tissue urate deposits which when left untreated can lead to debilitating gout flares and joint deformity. SEL-212 consists of pegadricase, Selecta's proprietary pegylated uricase, co-administered with ImmTOR™, designed to mitigate the formation of anti-drug antibodies (ADAs). ADAs develop due to unwanted immune responses to biologic medicines, reducing their efficacy and tolerability, which remains an issue across multiple therapeutic modalities and disease states including chronic refractory gout.

About Chronic refractory gout

Gout is the most common form of inflammatory arthritis with more than 8.3 million people in the United States having been diagnosed with gout, which is caused by high levels of uric acid in the body that accumulate around the joints and other tissues and can result in flares that cause intense pain. Approximately 200,000 people in the United States suffer from chronic gout refractory to conventional medicines, a painful and debilitating condition in people with SU levels above 6 mg/dL and therefore have several flares per year and can develop nodular masses of uric acid crystals known as tophi. Elevated SU levels have been associated with diseases of the heart, vascular system, metabolism, kidney and joints.

About Cartesian Therapeutics

Cartesian Therapeutics is a clinical-stage company pioneering mRNA cell therapies for the treatment of autoimmune diseases. The Company's lead asset, Descartes-08, is a potential first-in-class mRNA CAR-T in phase 2b clinical development for patients with generalised myasthenia gravis. Additional phase 2 studies are planned in systemic lupus erythematosus under an allowed IND, as well as basket trials in additional autoimmune indications. The Company's clinical-stage pipeline also includes Descartes-15, a next-generation, autologous anti-BCMA mRNA CAR-T.

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About Sobi®
Sobi® is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases. Providing reliable access to innovative medicines in the areas of haematology, immunology, and specialty care. Sobi has approximately 1,800 employees across Europe, North America, the Middle East, Asia, and Australia. In 2023, revenue amounted to SEK 22.1 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com and LinkedIn.

Contacts
For details on how to contact the Sobi Investor Relations Team, please click here. For Sobi Media contacts, click here.