Sumitomo Dainippon Pharma Announces Acquisition of Rights for Certain Sinovant Development Compounds in China and Other Asian Countries

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President, and CEO: Hiroshi Nomura; Securities Code: 4506, First Section of TSE) and Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (hereinafter, “Sumitomo Pharmaceuticals (Suzhou”), a Chinese subsidiary of Sumitomo Dainippon Pharma, today announced that they have entered into an asset purchase agreement with Roivant Sciences Ltd. (Head Office: London, U.K., Basel, Switzerland; CEO: Matthew Gline; hereinafter, “Roivant”), Roivant China Holdings Ltd. (Head Office: Bermuda), a subsidiary of Roivant, and Sinovant Sciences HK Limited (Head Office: Hong Kong; CEO: Rae Yuan; hereinafter, “Sinovant HK”), a subsidiary of Roivant China Holdings Ltd. (Roivant China Holdings Ltd. and Sinovant HK, hereinafter, “Sinovant”), that Sumitomo Pharmaceuticals (Suzhou) will acquire the exclusive development and marketing rights, etc. in China, Hong Kong, Taiwan, etc., for multiple Sinovant development compounds (hereinafter, the “Agreement”).

Under the terms of the Agreement, Sinovant will assign the license agreement for lefamulin (generic name) with Nabriva Therapeutics Ireland DAC (Head Office: Dublin, Ireland; CEO: Ted Schroeder) to Sumitomo Pharmaceuticals (Suzhou), which will, in turn, acquire the exclusive development and marketing rights in Greater China for lefamulin. Furthermore, Sumitomo Pharmaceuticals (Suzhou) will acquire the rights in China, etc. for vibegron (generic name), RVT-802 (development code), and rodaristat ethyl (generic name) from Sinovant.

Under the strategic alliance agreement concluded with Roivant in 2019, Sumitomo Dainippon Pharma obtained options (right to negotiate under certain conditions) to acquire Roivant’s ownership interests in six of its subsidiaries (Sinovant HK, Lysovant Sciences Ltd., Cytovant (Roivant Asia Cell Therapy Holdings Ltd.), Metavant Sciences Ltd., Dermavant Sciences Ltd., and Genevant Sciences Ltd. (hereinafter, “Genevant”)). Sumitomo Dainippon Pharma will terminate its five remaining options to acquire Roivant’s ownership interest in its subsidiaries as part of this transaction. In addition, under the terms of the Agreement, Sumitomo Pharmaceuticals (Suzhou) will make a payment to Sinovant HK as consideration for the Agreement. Sumitomo Dainippon Pharma has also agreed to enter into an agreement with respect to certain potential future collaborations on lipid nanoparticle (LNP) development programs, etc. with Genevant.

Each of the above transactions under the Agreement is subject to the satisfaction of the closing conditions set forth in the Agreement and is expected to complete in the first quarter of fiscal 2021.
Sumitomo Dainippon Pharma and Sumitomo Pharmaceuticals (Suzhou) will strive to further contribute to the treatment of infectious diseases in China and other parts of Asia by adding lefamulin to the infectious disease area that Sumitomo Pharmaceuticals (Suzhou) is focusing on. Sumitomo Dainippon Pharma also expects the three development assets that will be acquired under the Agreement to contribute to its sustained growth in China and other Asian markets, with contribution to a greater number of patients in China and other parts of Asia.

Reference Information

About Roivant
Roivant was founded in 2014 and is a private company. Roivant aims to improve health by rapidly delivering innovative medicines and technologies to patients. Roivant does this by building Vants – nimble, entrepreneurial biotech and healthcare companies with a unique approach to sourcing talent, aligning incentives, and deploying technology to drive greater efficiency in R&D and commercialization.

About Sinovant
Sinovant, one of Roivant’s subsidiaries, is an innovative biopharmaceutical company with bases in Beijing, Shanghai, and Hong Kong. It has multiple development pipelines in China and other Asian regions.

About lefamulin
Lefamulin is a pleuromutilin antimicrobial agent discovered and developed by Nabriva Therapeutics. It is a novel treatment for infectious diseases with a mechanism of action that differs from existing antibiotics. The drug has been approved for the indication of community-acquired bacterial pneumonia in adults by the U.S. Food and Drug Administration (FDA), Health Canada and the European Medicines Agency (EMA). The drug is currently being marketed in the United States under the brand name XENLETA™. Phase 3 study is currently being conducting in China for community-acquired bacterial pneumonia.

About vibegron
Vibegron is an oral, once-daily, small molecule β3 adrenergic receptor agonist. Urovant Sciences, a consolidated subsidiary of Sumitomo Dainippon Pharma, obtained the approval for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence (UUI), urgency, and urinary frequency in adults from the FDA in December 2020. The drug is currently being marketed by Urovant Sciences in the United States under the brand name GEMTESA®. A development plan in China is currently being evaluated.

About RVT-802
RVT-802, a one-time regenerative therapy, is cultured human thymus tissue engineered to generate a functioning immune response when implanted in pediatric patients with congenital athymia. In the United States, Enzyvant Therapeutics, a consolidated subsidiary of Sumitomo
Dainippon Pharma, has resubmitted the Biologics Licensing Application (BLA) to the FDA for RVT-802, for pediatric congenital athymia in April 2021. A development plan in China is currently being evaluated.

About rodatristat ethyl
Rodatristat ethyl is a prodrug of tryptophan hydroxylase (TPH) inhibitor designed to reduce peripheral production of serotonin without entering the brain. In the United States, Altavant Sciences, a consolidated subsidiary of Sumitomo Dainippon Pharma, is conducting Phase 2b study for pulmonary arterial hypertension. A development plan in China is currently being evaluated.

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