July 23, 2019

Submission of Vadadustat (MT-6548) New Drug Application in Japan for renal anemia

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director: Masayuki Mitsuka) today announced MTPC has submitted to the Ministry of Health, Labour and Welfare in Japan an application for the manufacturing and marketing approval of vadadustat (MT-6548). Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor for the treatment of renal anemia.

Positive top-line results were confirmed from four Phase 3 studies evaluating vadadustat in Japanese non-dialysis subjects, hemodialysis subjects and peritoneal dialysis subjects with renal anemia.

In Japan, it is estimated that around 13 million people are suffering from chronic kidney disease (CKD)* and around 10% of patients with CKD stage 3-5 have renal anemia**. Symptoms associated with anemia include fatigue, shortness of breath, insomnia, headache, and decreased energy, which may decrease a patient's quality of life (QOL). Injectable erythropoiesis stimulating agent (ESA) is currently the standard of care. Vadadustat, if approved for marketing in Japan, would provide patients with a once-daily treatment option and has the potential to set a new oral standard of care for the treatment of renal anemia.

MTPC and Akebia Therapeutics, Inc. (Akebia) , a US biopharmaceutical company entered into a collaboration agreement in 2015 providing MTPC with exclusive rights to develop and commercialize vadadustat in Japan and certain other Asian countries. As a result of the JNDA submission announced today, MTPC will make $10 million milestone payment to Akebia, anticipated to be paid in the second third quarter of FY2019. Akebia is eligible to receive up to approximately $205 million in additional milestone payments, based upon achievement of certain regulatory and sales milestones. MTPC is also obligated make tiered double-digit royalty payments to Akebia of up to 20% on sales of vadadustat in Japan and certain other Asian countries, subject to vadadustat’s regulatory approval.

Mitsubishi Tanabe Pharma will provide new and more convenient therapeutic medication for renal anemia to Japanese patients by supplying vadadustat. In addition, the Company will also advance the development of vadadustat in other

Asian countries in which it has exclusive development and sales rights.

*Japanese Society of Nephrology, Evidence-based Clinical Practice Guideline for CKD 2018

**Kohagura K, et al. Prevalence of anemia according to stage of chronic kidney disease in a large screening cohort of Japanese. Clin Exp Nephrol. 2009

Mitsubishi Tanabe Pharma Corporation
Corporate Communications Department
Media contacts: TEL:+81 6 6205 5119
Investor contacts: TEL:+81 6 6205 5110

◆Reference◆

About Vadadustat

Vadadustat, in-licensed from Akebia Therapeutics, Inc., is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor currently in global Phase 3 development for the treatment of anemia due to chronic kidney disease. Vadadustat's proposed mechanism of action is designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with increased production of HIF, which coordinates the interdependent processes of iron mobilization and erythropoietin production to increase red blood cell production and, ultimately, improve oxygen delivery. Vadadustat is an investigational therapy and is not approved by the U.S. Food and Drug Administration or any other regulatory authority.

About Akebia Therapeutics, Inc.

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company focused on the development and commercialization of therapeutics for patients with kidney disease. The company was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit www.akebia.com.