May 18th, 2020

Co-marketing agreement concerning Vadadustat (MT-6548) for renal anemia in Japan with Fuso Pharmaceutical in hemodialysis and peritoneal dialysis patients

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director: Hiroaki Ueno) today announced that MTPC and Fuso Pharmaceutical Industries Ltd. (Fuso Pharmaceutical, Head Office: Chuo-ku, Osaka; President & Representative Director: Mikio Toda) concluded a co-marketing agreement concerning vadadustat (MT-6548) which is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor for the treatment of renal anemia currently has submitted to the Ministry of Health, Labour and Welfare in Japan in hemodialysis and peritoneal dialysis patients on May 7th, 2020.

In Japan, it is estimated that around 13 million people are suffering from chronic kidney disease (CKD)*. It is reported that renal anemia develops from an early stage of CKD and its frequency increases as CKD progresses**.
Symptoms associated with anemia include fatigue, shortness of breath, insomnia, headache, and decreased energy, which may decrease a patient's quality of life (QOL). Renal anemia can present prior to dialysis and at any time during hemodialysis or peritoneal dialysis.
Injectable erythropoiesis stimulating agent (ESA) is currently the standard of care. Vadadustat 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 are confident that by partnering with Fuso Pharmaceutical, which has strength in the dialysis field, we can provide appropriate information to more healthcare professionals.
MTPC has been providing antidiabetic drugs with different mechanisms of action to patients with diabetes and having a track record in the field of diabetes. As part of strengthening this area, MTPC newly established the Diabetes and Renal Product Marketing Department in April this year.
Through this collaboration, the two companies will contribute to the pre-dialysis storage period, peritoneal dialysis, and treatment of renal anemia for hemodialysis patients.

Mitsubishi Tanabe Pharma will continue providing appropriate pharmaceutical information and strive to add new value to medical practice by bridging the diabetes area with the renal area.

*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

◆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 renal anemia. 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 induces endogenous 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.