



June 29, 2020

**Manufacturing and Marketing Approval of
VAFSEO[®] Tablets (HIF-PH inhibitor, vadadustat) for renal anemia in Japan**

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director: Hiroaki Ueno) today announced MTPC obtained manufacturing and marketing approval of VAFSEO[®] Tablets 150mg and 300mg (VAFSEO[®], vadadustat), which is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor for the treatment of renal anemia by the Ministry of Health, Labour and Welfare in Japan on June 29, 2020. MTPC filed an application for VAFSEO[®] in July 2019.

Renal anemia can present prior to dialysis and at any time during hemodialysis or peritoneal dialysis and symptoms associated with anemia include fatigue, shortness of breath, insomnia, headache, and decreased energy.

VAFSEO[®] 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 in both dialysis-dependent and non-dialysis dependent patients.

MTPC will provide a new and convenient therapeutic medication for renal anemia to patients in Japan by supplying VAFSEO[®]. In addition, MTPC will also advance the development of vadadustat in certain other Asian countries in which it has exclusive development and commercialization rights.

About renal anemia

In Japan, it is estimated that 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 used to prescribed for the treatment of renal anemia.

*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

About VAFSEO[®]

VAFSEO[®] (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 CKD. VAFSEO[®] is designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, which can lead to increased red blood cell production and improved oxygen delivery to tissues.

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