

## News Release

August 26, 2020

## Launch of VAFSEO®, for the treatment of renal anemia (HIF-PH inhibitor) in Japan

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director: Hiroaki Ueno) today announced that MTPC is launching VAFSEO® Tablets 150mg and 300mg (VAFSEO®, vadadustat) which is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor in-licensed from Akebia Therapeutics, Inc., for the treatment of renal anemia on August 26, 2020, in Japan following today's inclusion of VAFSEO® in the NHI drug price listing.

Renal anemia can present prior to dialysis and at any time during hemodialysis or peritoneal dialysis. Symptoms associated with anemia include fatigue, shortness of breath, insomnia, headache, and decreased energy, which may decrease a patient's quality of life (QOL). It is reported that renal anemia develops from an early stage of chronic kidney disease (CKD) and its frequency increases as CKD progresses\*.

VAFSEO<sup>®</sup> would provide patients with a once-daily treatment option in Japan and has the potential to set a new oral standard of care for the treatment of renal anemia in both dialysis and non-dialysis patients in Japan.

MTPC and Fuso Pharmaceutical Industries Ltd. which has strength in the dialysis field concluded a co-marketing agreement concerning VAFSEO<sup>®</sup> in Japan, in May 2020. Through this collaboration, the two companies will be able to provide appropriate information to more healthcare professionals in Japan.

MTPC will provide a new and convenient, oral therapeutic medication for renal anemia patients in Japan by promoting the appropriate usage of VAFSEO<sup>®</sup>.

\*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

Product Name VAFSEO® Tablet 150mg/ VAFSEO® Tablet 300mg

JAN Vadadustat

Indication Renal anemia

Dosage once daily, starting dose is 300 mg, and maximum dose is 600

mg.

Packaging 150mg 100tablets [10tablets (PTP) ×10]

300mg 100tablets [10tablets (PTP) ×10]

Retail Price 213.50 yen / 150mg tablet

376.20 yen / 300mg tablet

Approval(Japan) June 29,2020

HVL Listing August 26,2020

Release(Japan) August 26,2020

Manufacturer Mitsubishi Tanabe Pharma Corporation.

## About VAFSEO®

VAFSEO<sup>®</sup> (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<sup>®</sup> 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. VAFSEO<sup>®</sup> was obtained manufacturing and marketing approval by the Ministry of Health, Labour and Welfare in Japan on June 29, 2020