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For Immediate Release

Company name	Otsuka Holdings Co., Ltd.
Representative	Tatsuo Higuchi President and Representative Director, CEO
Code number	4578 First Section , Tokyo Stock Exchange
Inquiries	Yuji Kogure Director, Investors Relations Department

Otsuka and Akebia Announce U.S. FDA Acceptance for Filing of New Drug Application for Vadadustat for the Treatment of Anemia Due to Chronic Kidney Disease

Otsuka Pharmaceutical Co., Ltd. (Otsuka) and Akebia Therapeutics, Inc., announce that the U.S. Food and Drug Administration (FDA) accepted for filing the New Drug Application (NDA) for vadadustat for the treatment of anemia due to chronic kidney disease (CKD) in both adult patients on dialysis and adult patients not on dialysis.

The FDA has assigned the application standard review and a Prescription Drug User Fee Act (PDUFA) target action date of March 29, 2022.

Otsuka and Akebia are collaborating on the development and commercialization of vadadustat in the U.S., Europe, China, Russia, Canada, Australia, the Middle East, and certain other territories.

In addition, Otsuka is working with Akebia to prepare a Marketing Authorization Application for vadadustat for submission to the European Medicines Agency expected in 2021.

Akebia, founded in 2007 and headquartered in Cambridge, Massachusetts, is a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease.

About Vadadustat

Akebia's vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor 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.

Vadadustat recently completed its global phase 3 clinical development program for the treatment of anemia due to CKD.

About Anemia due to Chronic Kidney Disease

Anemia is a condition in which a person lacks enough healthy red blood cells to carry adequate oxygen to the body's tissues. It commonly occurs in people with CKD because their kidneys do not produce enough erythropoietin (EPO), a hormone that helps regulate production of red blood cells. Anemia due to CKD can have a profound impact on a person's quality of life as it can cause fatigue, dizziness, shortness of breath and cognitive dysfunction. Left untreated, anemia leads to deterioration in health and is associated with increased morbidity and mortality in people with CKD.