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Otsuka and Akebia Announce Submission of New Drug Application to the FDA for Approval of Akebia's Vadadustat

Indications for renal anemia associated with chronic kidney disease in both dialysis-dependent and non-dialysis-dependent adult patients

Otsuka Pharmaceutical Co., Ltd. (Otsuka) announces that its U.S.-based collaborator Akebia Therapeutics, Inc. (Akebia) has submitted a New Drug Application (NDA) to the Food and Drug Administration in the U.S. (FDA) seeking approval for Akebia's investigational drug vadadustat as an oral medication for the treatment of renal anemia due to chronic kidney disease (CKD) in adult patients who receive dialysis and those who do not receive dialysis.

Kabir Nath, senior managing director, Global Pharmaceutical Business, Otsuka Pharmaceutical Co., Ltd., noted, "Kidney-related diseases were long a dormant area for drug research, but this has changed in the past decade and thankfully drug candidates such as vadadustat are now emerging from the R&D process. We look forward to continuing the journey to strengthen our nephrology portfolio and honor our commitment to changing the standard of care worldwide for people living with chronic kidney diseases."

In 2016, Otsuka and Akebia signed a collaboration and license agreement for vadadustat in the U.S. The two companies subsequently signed a collaboration and license Agreement in 2017 for vadadustat in certain other areas. The two companies share development rights in Europe. Contingent on regulatory approvals, Otsuka has exclusive rights to market this drug in Europe, Canada, Australia and China and certain other areas, but excluding Japan and Latin America.

About Akebia's Vadadustat

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 development program for the treatment of anemia due to CKD. Vadadustat is not approved by the U.S. Food and Drug Administration or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare. In Japan, vadadustat is approved and marketed under the trade name Vafseo™, as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis-dependent adult patients.