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Otsuka and Akebia seek USFDA approval for renal anemia drug

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

Otsuka Pharmaceutical has announced that its 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.

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.

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."