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Akebia Therapeutics Receives Complete Response Letter from U.S. FDA for Vadadustat for the Treatment of Anemia associated with Chronic Kidney Disease in Adult Patients

Otsuka Pharmaceutical Co., Ltd. (Otsuka) and Akebia Therapeutics, Inc. (Akebia) announce that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) to Akebia's New Drug Application (NDA) for Akebia's vadadustat, an investigational oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor under review for the treatment of anemia due to chronic kidney disease (CKD). The FDA issues CRLs to indicate that the review cycle for an application is complete and that the application is not ready for approval in its present form.

Akebia and Otsuka will review the CRL closely and consider the future direction.

In October 2021, Otsuka, in collaboration with Akebia, submitted an initial marketing authorization application (MAA) to the European Medicines Agency (EMA) for vadadustat, for the treatment of anemia associated with CKD in adults. The review is ongoing.