

Akebia submits new application for anemia drug in Japan

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JNDA Submission represents first regulatory submission for marketing approval of vadadustat



Akebia Therapeutics, Inc. has announced that Mitsubishi Tanabe Pharma Corporation (MTPC), its development and commercialization collaboration partner in Japan for vadadustat, Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), has submitted a Japanese New Drug Application (JNDA) to the Ministry of Health, Labor and Welfare in Japan for manufacturing and marketing approval of vadadustat as a treatment for anemia due to chronic kidney disease (CKD).

The JNDA is the first regulatory submission for marketing approval of vadadustat and, if approved, is expected to lead to the first launch of vadadustat worldwide. This submission is supported by positive top-line data from MTPC's two Phase 3, active-controlled, pivotal studies evaluating the efficacy and safety of vadadustat in Japanese subjects with anemia due to CKD and two additional Phase 3 single-arm studies in peritoneal and hemodialysis subjects, which were announced by Akebia and MTPC in March 2019.

In Japan, an estimated 13 million people have advanced stages of CKD. Anemia is common in patients with CKD and its prevalence increases as CKD progresses. Injectable erythropoiesis-stimulating agents (ESAs) are currently the standard of care. Vadadustat, if approved for marketing in Japan, would provide patients with a once-daily oral treatment option and has the potential to set a new oral standard of care for the treatment of anemia due to CKD.

Akebia and MTPC entered into a collaboration agreement in 2015 providing MTPC with exclusive rights to develop and commercialize vadadustat in Japan and certain other Asian countries for the treatment of anemia due to CKD. As a result of the JNDA submission announced today, Akebia will receive a \$10 million milestone payment from MTPC, anticipated to be received in the third quarter of 2019.

Akebia is eligible to receive up to approximately \$205 million in additional milestone payments, based upon achievement of certain regulatory and sales milestones. MTPC is also obligated to make tiered double-digit royalty payments to Akebia of up to 20% on sales of vadadustat in Japan and certain other Asian countries, subject to vadadustat's regulatory approval.