



November 1, 2017

## **Notice of the Start of Japanese Phase 3 Clinical Studies of the HIF-PH Inhibitor MT-6548 in Renal Anemia**

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President & Representative Director: Masayuki Mitsuka) has initiated a Japanese phase 3 clinical study of the hypoxia inducible factor prolyl hydroxylase (HIF-PH) inhibitor MT-6548 (generic name: vadadustat) in patients with renal anemia secondary to chronic kidney disease (CKD) who are either not dependent on dialysis (NDD-CKD) or receiving peritoneal dialysis (PD-CKD).

The study in patients with NDD-CKD is a randomized, open-label, comparative study to demonstrate the efficacy and safety of MT-6548 using as a control drug the erythropoiesis-stimulating agent (ESA) darbepoetin alfa (genetical recombination), which is the standard therapeutic medication. The therapeutic efficacy of MT-6548 in renal anemia will be evaluated by demonstrating the noninferiority of MT-6548 to darbepoetin alfa in the hemoglobin level improvement effect/switching from ESA and maintenance efficacy.

MT-6548 is an HIF-PH inhibitor that has been in-licensed from Akebia Therapeutics, a US biopharmaceutical company located in the state of Massachusetts. In December 2015, Mitsubishi Tanabe Pharma signed an agreement with Akebia giving Mitsubishi Tanabe Pharma exclusive development and marketing rights for MT-6548 in Japan and other countries in Asia. Akebia is currently conducting global phase 3 clinical studies of vadadustat in patients with anemia associated with CKD.

In Japan, it is estimated that around 11 million people are afflicted with Stage 3 or higher CKD (CKD Treatment Guidelines), meaning that a great many persons are suffering from anemia, including all the people who are receiving dialysis (around 320 thousand people, according to the Japanese Society for Dialysis Therapy). These cases of anemia are caused by the progressive loss of kidney function in patients with kidney disease, and the associated hypoxia results in a loss of the physiologic functions that regulate erythrocyte production. It is also believed that if the anemia is left untreated, this results in progression of the CKD, and in a worsening of the patient's overall health.

Mitsubishi Tanabe Pharma is proceeding to develop MT-6548 as a therapeutic medication for renal anemia in order to be able to offer this treatment to patients in Japan by the end of FY2020.

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## ◆ Reference ◆

### **About Vadadustat**

Vadadustat is an oral hypoxia-inducible factor (HIF) stabilizer currently in Global Phase 3 development for the treatment of anemia related to chronic kidney disease. Vadadustat exploits the same mechanism of action used by the body to adapt naturally to lower oxygen availability associated with a moderate increase in altitude. At higher altitudes, the body responds to lower oxygen availability with increased production of HIF, which coordinates the interdependent processes of iron mobilization and erythropoietin production to increase red blood cell production and, ultimately, improve oxygen delivery.

### **About Akebia Therapeutics Inc.**

Akebia Therapeutics is a biopharmaceutical company headquartered in Cambridge, Massachusetts that is focused on providing innovative therapies to patients with CKD via the biology of HIF. Phase 2 clinical studies of an oral formulation of vadadustat in the US, Akebia's leading product, have been completed in both NDD-CKD and DD-CKD, and global phase 3 studies are underway.

<http://akebia.com/>