November 11, 2019

HIF-PH Inhibitor Vadadustat (MT-6548) Japan Phase 3 results for the treatment of renal anemia at American Society of Nephrology, Kidney Week 2019

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director: Masayuki Mitsuka, Ph.D.) today announced that Phase 3 results of Vadadustat (MT-6548) in Japan have been presented at American Society of Nephrology (ASN) Kidney Week 2019 from November 5 to November 10, 2019 in Washington DC. MTPC has submitted to the Ministry of Health, Labour and Welfare in Japan an application for the manufacturing and marketing approval of Vadadustat (MT-6548) on July 2019.

◆Title; Randomized, Open-Label, Active-Controlled (Darbepoetin Alfa), Phase 3 Study of Vadadustat for Treating Anemia in Non-Dialysis-Dependent CKD* Patients in Japan

*chronic kidney disease

The Phase 3 randomized, open-label, active-controlled study was conducted with 304 non-dialysis-dependent CKD (NDD-CKD) subjects with anemia with a treatment duration of 52 weeks.

- The study showed non-inferiority of MT-6548 in mean hemoglobin (Hb) level at week 20 and week 24 to that of Darbepoetin Alfa（Genetical Recombination）(Injectable erythropoiesis stimulating agent [ESA]) group. In addition, MT-6548 maintained mean Hb level within the target Hb range up to week 52, confirming the durability of the efficacy of MT-6548 in NDD-CKD subjects.
- MT-6548 showed a decrease in hepcidin, which were known as a negatively regulator of iron metabolism, suggesting improvement of iron utilization.
- The study showed no major difference from the previously reported safety profile of MT-6548, confirming its safety for the NDD-CKD subjects.

◆Title; Randomized, Double-Blinded, Active-Controlled (Darbepoetin Alfa), Phase 3 Study of Vadadustat in CKD Patients with Anemia on Hemodialysis in Japan

The Phase 3 randomized, double-blinded, active-controlled study was conducted with 323 hemodialysis-dependent CKD (HD-CKD) subjects with anemia receiving ESA therapy, with a treatment duration of 52 weeks.

- The study showed non-inferiority of the MT-6548 in mean Hb level at week 20 and week 24 to that of Darbepoetin Alfa（Genetical Recombination）. In addition, MT-6548 maintained mean Hb level up to week 52, confirming the efficacy of MT-6548 in the HD-CKD subjects after switched receiving ESA therapy.
- MT-6548 showed a decrease in hepcidin level, suggesting improvement of iron metabolism.
- The study showed no major difference from the previously reported safety profile of MT-6548, confirming its safety for the HD-CKD subjects.

In Japan, it is estimated that around 13 million people are afflicted with higher CKD meaning that a great many people are suffering from anemia due to CKD. ESA (Injectable agent) is currently the standard of care. The further development of Vadadustat, which makes possible once-a-day oral administration, is expected to make a contribution to the treatment of anemia due to CKD.

Mitsubishi Tanabe Pharma will provide new and more convenient therapeutic medication for renal anemia to Japanese patients by supplying Vadadustat. In addition, Mitsubishi Tanabe Pharma will also advance the development of Vadadustat in other Asian countries in which it has exclusive development and sales rights.

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◆Reference◆

About Vadadustat

Vadadustat, in-licensed from Akebia Therapeutics, Inc., is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor currently in global Phase 3 development for the treatment of anemia due to chronic kidney disease. MTPC filed Vadadustat to NDA as a therapeutic medication for renal anemia. Vadadustat's proposed mechanism of action is designed to mimic the physiologic effect of altitude on oxygen availability. 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. Vadadustat is an investigational therapy and is not approved by the U.S. Food and Drug Administration or any other regulatory authority.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company focused on the development and commercialization of therapeutics for people living with kidney disease. The Company was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com.