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Positive Top-Line Results from Global Phase 3 Program of Vadadustat for Treatment of Anemia Due to Chronic Kidney Disease in Adult Patients on Dialysis

Otsuka Pharmaceutical Co., Ltd. (president and representative director Makoto Inoue; headquarters in Tokyo; hereafter Otsuka) announces that its collaborator Akebia Therapeutics, Inc. announced positive top-line results from INNO$_2$VATE, its global Phase 3 clinical trial program evaluating vadadustat, Akebia Therapeutics' investigational hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) as an oral treatment for adult patients on dialysis with anemia associated with chronic kidney disease (CKD). Akebia Therapeutics is a fully integrated biopharmaceuticals company with nephrology-focused commercial and development capabilities and is headquartered in Cambridge, Massachusetts, U.S. John P. Butler is the company's president and CEO.

In two clinical trials (INNO$_2$VATE trials), the efficacy and safety of vadadustat was evaluated versus darbepoetin alfa injection in adult dialysis-dependent patients with anemia associated with CKD. Vadadustat met the primary efficacy endpoint in each of the two trials, demonstrating non-inferiority to darbepoetin alfa as measured by a mean change in hemoglobin (Hb) within the target range between baseline and the primary evaluation period (weeks 24 to 36) and secondary evaluation period (weeks 40 to 52). Vadadustat also met the primary safety endpoint, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of major adverse cardiovascular events (MACE), which is a composite of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke.

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. Otsuka has exclusive rights to market this drug in Europe, Canada, Australia and China and certain other areas,* but excluding Japan and Latin America.

Outline of INNO$_2$VATE trials

The INNO$_2$VATE trials are global, multicenter, open-label (sponsor-blind), active-comparator-drug (darbepoetin alfa), non-inferiority Phase 3 trials that enrolled 3,923 adult hemodialysis patients with anemia related to chronic kidney disease. Patients were randomized 1: 1 to receive either vadadustat or the control-group drug. See clinicaltrials.gov for more information on the trials:

NCT02892149
https://clinicaltrials.gov/ct2/show/NCT02892149?term=NCT02892149&draw=2&rank=1
NCT02865850
https://clinicaltrials.gov/ct2/show/NCT02865850?term=NCT02865850&draw=2&rank=1

About Akebia's Vadadustat

Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor currently in global Phase 3 development for the treatment of anemia due to CKD. Vadadustat is designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, which can lead to increased red blood cell production and improved oxygen delivery to tissues. Vadadustat is an investigational therapy and is not approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority.

*Countries other than Japan and specific other Asian countries licensed by Akebia to Mitsubishi Tanabe Pharma Corporation