Press Release

Astellas Announces Positive Topline Results for Global Phase 3 Trial of Roxadustat in Chronic Kidney Disease (CKD) Patients with Anemia not on Dialysis

TOKYO, September 20, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that roxadustat, an inhibitor of hypoxia inducible factor (HIF) prolyl hydroxylase activity, met its primary endpoints in the Phase 3 ALPS study by demonstrating superiority in efficacy versus placebo in terms of both hemoglobin (Hb) response rate in the first 24 weeks and Hb change from baseline at Weeks 28 to 52.[1] The preliminary safety analysis for this trial shows an overall event profile consistent with the results seen in previous roxadustat studies in CKD patients with anemia.

"The ALPS study adds to the growing body of evidence to support roxadustat as a potential treatment of anemia associated with CKD," said Salim Mujais, M.D, senior vice president and global therapeutic area head, Medical Specialties Development, Astellas. "This condition can have a debilitating impact on the patients affected, and we look forward to continuing our work to potentially make a new therapeutic option available to the physicians who care for them."

The ALPS study is the first of three Astellas Phase 3 studies conducted mainly in EMEA to report. The study forms part of a wider large-scale global Phase 3 development program for roxadustat conducted in collaboration with its partner FibroGen, Inc. (NASDAQ: FGEN), and will ultimately support filing and reimbursement in Europe. The ALPS study is a randomized, double-blind, placebo-controlled study of the efficacy and safety of roxadustat for the treatment of anemia in CKD in patients not on dialysis.[2]

Further detailed data from this study are expected to be reported in the future.

About the ALPS Study

The ALPS study is a Phase 3, multi-center, double-blind, placebo-controlled study with a treatment duration of 52-104 weeks. The study population consists of patients with anemia of CKD (average screening Hb ≤ 10 g/dL) and not receiving dialysis. Patients were randomized to either roxadustat or placebo in a 2:1 ratio. The study was designed to evaluate the efficacy and safety of roxadustat compared to placebo and has two primary endpoints. The first primary endpoint is the proportion of patients who achieved Hb response in the first 24 weeks (for US submission). The second primary endpoint is the change in Hb from baseline to the average level of week 28-52, regardless of rescue therapy (for EMA submission).

About Chronic Kidney Disease and Anemia

CKD is estimated to affect more than 200 million people worldwide.[3] Although CKD can occur at any age, it becomes more common in aging populations, and the prevalence is increasing.[4] Anemia is a common

complication of CKD and is associated with significant morbidity and mortality in dialysis and non-dialysis populations. In the EU5 (Germany, Italy, Spain, France, UK), approximately 371,000 patients have Stage 5 CKD and of which approximately 291,000 have anemia; and approximately 724,000 patients have Stage 4 CKD and of which approximately 432,000 patients have anemia.[5] In addition, CKD can be both a cause and a consequence of cardiovascular disease[6] and is now a critical worldwide healthcare issue[7] that represents a large and growing unmet medical need.

Around 10% of the European population is affected by some degree of chronic kidney disease, and approximately 70 million Europeans have lost kidney function to some extent[8] – this leaves them at risk of becoming dependent on renal replacement therapies including dialysis or organ transplantation.

About roxadustat

Roxadustat, discovered and developed by FibroGen, is a compound currently in Phase 3 development as a potential therapy for anemia associated with CKD in both patients on dialysis and not on dialysis. Roxadustat is an orally administered small molecule inhibitor of HIF prolyl hydroxylase activity. HIF is a protein transcription factor that induces the natural physiological response to conditions of low oxygen, "turning on" erythropoiesis (the process by which red blood cells are produced).

Astellas is collaborating with FibroGen on the development of roxadustat for the potential treatment of anemia in patients with CKD and myelodysplastic syndromes in territories including Europe, the Commonwealth of Independent States, the Middle East and South Africa. FibroGen and AstraZeneca are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in patients with CKD in the U.S., China and other markets. For information about roxadustat studies, please visit clinicaltrials.gov at this link**:**
https://clinicaltrials.gov/ct2/results?term=roxadustat&Search=Search.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at https://www.astellas.com/en

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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[1] Data on File. A Phase 3, Randomized, Double-Blind, Placebo Controlled Study of the Efficacy and Safety of Roxadustat for the Treatment of Anemia in Chronic Kidney Disease Patients not on Dialysis September 2018
[2] Clinicaltrials.gov. Safety and Efficacy Study of Roxadustat to Treat Anemia in Patients With Chronic Kidney Disease (CKD), Not on Dialysis. Found online at: https://clinicaltrials.gov/ct2/show/NCT02174627?term=roxadustat&draw=2&rank=14 (Last accessed: June 2018)
[3] Ojo, A. Addressing the Global Burden of Chronic Kidney Disease Through Clinical and Translational Research. *Transactions of the American Clinical and Climatological Association*. 2014; 125: 229-246.
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[5] Chronic Kidney Disease | Epidemiology | Europe Data. © 2016 DR/Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.
[6] M. Liu et al 2014, Cardiovascular disease and its relationship with chronic kidney, Available at: https://www.europeanreview.org/wp/wp-content/uploads/2918-2926.pdf Last accessed September 2018
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