Press Release

Astellas to Present New Research Further Supporting Roxadustat Safety in the Treatment of Symptomatic Anemia of Chronic Kidney Disease at 59th ERA Congress 2022

Three abstracts provide additional insights into roxadustat safety profile and effect on iron parameters

TOKYO, May 16, 2022 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") announced the presentation of new roxadustat data at the 59th European Renal Association (ERA) Congress, taking place May 19–22, 2022.

Two presentations focus on pooled analyses from the comprehensive ALPINE Phase 3 clinical trial program, reinforcing the overall safety profile of roxadustat with further details on cardiovascular safety. Both compare roxadustat with current standard of care, erythropoietin-stimulating agents (ESAs), for patients with symptomatic anemia associated with chronic kidney disease (CKD) not receiving dialysis or just starting dialysis (incident dialysis). An evaluation of iron metabolism parameters and its clinical implications in patients with anemia of CKD in a similar population will also be presented.

"At Astellas, we strive to improve outcomes for patients most in need of innovative new treatments," said Ahsan Arozullah, Senior Vice President and Head of Development Therapeutic Areas, Astellas. "The clinical research being presented at the ERA Congress further validates the safety and efficacy profile of roxadustat as a new treatment option for those living with anemia of CKD and demonstrates Astellas' continued commitment to this community of patients."

Mini-Oral Presentations
Presentations and abstracts are available online starting Thursday, May 19, 2022, at 8:00 a.m. CEST, when all prerecorded presentations are published on the congress platform.

Presentation Title	Lead Author	Presentation Details
Safety of Roxadustat Versus Erythropoiesis-Stimulating Agents for Treatment of Anemia in Patients With Chronic Kidney Disease Incident to or Not Receiving Dialysis: Pooled Analysis of Four Phase 3 Studies	J. Barratt	Type: Mini-oral presentation Abstract 631
Cardiovascular Safety of Roxadustat Versus Erythropoiesis-Stimulating Agents for Treatment of Anemia in Patients With Chronic Kidney Disease Incident to or Not Receiving Dialysis: Pooled Subgroup Analysis of Four Phase 3 Studies	J. Barratt	Type: Mini-oral presentation Abstract 2379
Iron Parameters in Patients Treated With Roxadustat for Anemia Associated With Chronic Kidney Disease: Post Hoc Analysis of	L. Nicola	Type: Mini-oral presentation Abstract 1008

the Non-Dialysis-Dependent or Incident Dialysis Population From Four Phase 3 Studies.		

About CKD and Anemia of CKD
CKD is a progressive disease characterized by gradual loss of kidney function that may eventually lead to kidney failure or end-stage renal disease, requiring dialysis or kidney transplant.[1] Many patients with CKD die of cardiovascular complications before progressing to kidney failure and as such the prevalence of early kidney disease is much greater than end-stage disease.[1,2] CKD impacts one in 10 people globally and is predicted to become the fifth most common cause of premature death globally by 2040.[3,4]

Anemia, a serious medical condition in which patients have insufficient red blood cells and low levels of hemoglobin, is a common complication that can be observed during CKD progression, affecting approximately 20% of CKD patients.[5,6] Anemia of CKD is associated with an increased risk of hospitalization, cardiovascular complications and death, and can also cause significant fatigue, cognitive dysfunction and reduced quality of life.[7,8] ESAs and blood transfusions are used for treating severe anemia, however, they may reduce a patient's opportunity for kidney transplant and can increase the risk of infection and/or complications such as heart failure and allergic reactions.[9,10]

About Roxadustat
Roxadustat, an oral medicine, is the first in a new class of medicines, HIF-PH inhibitors, that promote erythropoiesis, or red blood cell production, through increased endogenous production of erythropoietin; improved iron absorption and mobilization; and downregulation of hepcidin. Roxadustat is also in Phase 3 clinical development for anemia associated with myelodysplastic syndromes and Phase 2 for chemotherapy-induced anemia.

Roxadustat is approved in EU member states, including the European Economic Area countries, as well as in Great Britain, Japan, Kuwait, United Arab Emirates, Russia, China, Chile and South Korea for the treatment of anemia of CKD in adult patients on dialysis and not on dialysis. Several other licensing applications for roxadustat have been submitted by Astellas and AstraZeneca to regulatory authorities across the globe and are currently in review.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia of CKD in territories including Japan, Europe, Turkey, Russia and 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 of CKD in the U.S., China, other markets in the Americas, in Australia/New Zealand, and Southeast Asia.

Important Safety Information
The full European Summary of Product Characteristics (SPC/SmPC) for roxadustat will be available from the European Medicines Agency at https://www.ema.europa.eu/en/documents/product-information/evrenzo-epar-product-information_en.pdf.[11]

About Astellas
Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at https://www.astellas.com/en.

Astellas 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) that is included in this press release is not intended to constitute an advertisement or medical advice.

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