



Press Release

New Roxadustat Data in Anemia of Chronic Kidney Disease to be Released at ASN Kidney Week 2020 Reimagined

42 abstracts featuring additional insights into roxadustat and anemia of chronic kidney disease to be presented

TOKYO, OCTOBER 19, 2020 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, PhD, “Astellas”) today announced that in collaboration with FibroGen and AstraZeneca, 42 roxadustat abstracts will be presented at the American Society of Nephrology (ASN) Kidney Week 2020 Reimagined congress.

Six abstracts (one oral presentation and five ePosters) sponsored by Astellas focus on the use of roxadustat as a treatment in adult patients with anemia of chronic kidney disease (CKD). These abstracts include presentations of the Phase 3 DOLOMITES study (abstract [#TH-OR02](#)) and a Japanese Phase 3 CL-0310 study ([#PO0269](#)), with both studies evaluating roxadustat versus darbepoetin alfa as a treatment for patients with anemia of CKD not on dialysis. Other presentations include safety data from two Japanese Phase 3 studies assessing the ophthalmological effects of roxadustat treatment in patients with anemia of CKD on dialysis and not on dialysis, and a study of patients’ treatment preferences for anemia of CKD.

“We are delighted by the breadth of roxadustat data being presented at ASN Kidney Week 2020,” said Salim Mujais, M.D., Senior Vice President and Global Therapeutic Area Head, Medical Specialties Development, Astellas. “It is encouraging that we continue to see the potential of roxadustat, a first-in-class hypoxia-inducible factor-prolyl hydroxylase inhibitor, for patients with anemia of CKD, and how its profile compares with existing treatment options.”

FibroGen and AstraZeneca will present roxadustat data (nine oral presentations, including two late-breaking presentations, and 27 ePosters) predominantly focused on the efficacy and safety data from pooled analyses from several Phase 3 clinical studies of patients on dialysis and not on dialysis. Additional presentations evaluate data related to health care resource use, inflammation, iron homeostasis and safety event rates in patient populations with comorbid conditions like diabetes.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in Japan, Europe, the Commonwealth of Independent States, the Middle East and South Africa. FibroGen and AstraZeneca are

collaborating on the development and commercialization of roxadustat in the U.S., China, other markets in the Americas, Australia/New Zealand and Southeast Asia. Roxadustat is under regulatory review in Japan for the treatment of anemia in adult patients with CKD not on dialysis, and in the U.S. and EU in both patients on dialysis and not on dialysis.

Astellas oral presentations:

Title: Roxadustat for the Treatment of Anemia in Chronic Kidney Disease Patients Not on Dialysis: A Phase 3, Randomized, Open-Label, Active-Controlled Study ([#TH-OR02](#))

Presenter: Jonathan Barratt, University of Leicester, United Kingdom

- Session date/time: Thursday, October 22, 2020 from 17:00-19:00 EDT

Astellas key presentations and ePosters will be available online starting Thursday, October 22, 10:00 a.m. EDT:

Title: A Phase 3, Multicenter, Randomized, Open-label, Active Comparator Conversion Study of Roxadustat in Non–Dialysis-Dependent (NDD) Patients with Anemia in CKD ([#PO0269](#))

Title: Ophthalmological Effects of Roxadustat in the Treatment of Anemia in Dialysis-Dependent and Non–Dialysis-Dependent CKD Patients: Findings From Two Phase 3 Studies ([#PO0267](#))

Title: Impact of Renal Impairment and Dialysis on the Pharmacokinetics and Pharmacodynamics of Roxadustat ([#PO2369](#))

Title: Patient Preferences Study for Treatments of Anemia in CKD Patients Not on Dialysis (NDD) ([#PO0289](#))

Title: A Marginal Structural Model to Estimate Causal Effect of Time-Dependent Anemia Status on Renal and Cardiovascular Outcomes Among Community-Dwelling Japanese Subjects at Beginning of Impaired Renal Function ([#PO0270](#))

About CKD and Anemia

CKD is characterised by a progressive loss of kidney function caused by damage to the kidneys resulting from conditions such as hypertension, diabetes or immune-regulated inflammatory conditions.¹ Worldwide one in 10 people are living with CKD.² In Europe, one in eight people are living with CKD.² Based on UK data, one in five CKD patients are affected by anemia; this rate increases to one in two in people with the most severe CKD (CKD Stage 5).³ Globally, CKD is predicted to become the fifth most common cause of premature death by 2040.⁴ It is a critical worldwide healthcare issue that represents a large and growing unmet medical need.

Anemia is a common complication of CKD,⁵ resulting from the failing kidneys' ability to produce erythropoietin, reduced oxygen sensing, and increased hepcidin and iron deficiency resulting from chronic inflammation. It is associated with significant morbidity and mortality in dialysis and non-dialysis populations, increasing in both prevalence and severity as kidney disease worsens.⁶ CKD anemia increases the risk of adverse cardiovascular events, worsens renal outcomes and can negatively impact patients' quality of life.⁷⁻⁹

About Roxadustat

Roxadustat is approved and launched for the treatment of anemia associated with CKD in Japan in dialysis dependent (DD) patients and in China in both DD and non-dialysis dependent (NDD) patients. A supplemental New Drug Application has been submitted in Japan for NDD patients and a New Drug Application has been filed for the FDA review in the U.S. in both DD and NDD patients. In the EU, a marketing authorisation application for roxadustat has been accepted for regulatory review for both DD and NDD patients. Several other licensing applications for roxadustat have been submitted by Astellas and AstraZeneca to regulatory authorities across the globe.

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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Contacts for enquiries or additional information:

Astellas Portfolio Communications
Anna Otten
TEL: +1 (224) 205-6651 | Email: anna.otten@astellas.com

Astellas Pharma Inc.
Corporate Advocacy & Relations
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473

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