Press Release

European Medicines Agency Accepts Astellas' Marketing Authorization Application for Roxadustat

Submission for the treatment of anemia in adult patients with chronic kidney disease

TOKYO and San Francisco, May 21, 2020 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and FibroGen, Inc. (Nasdaq: FGEN, CEO: Enrique Conterno, "FibroGen") today announced the marketing authorization application (MAA) for roxadustat for the treatment of anemia in adult patients with chronic kidney disease (CKD) has been accepted by the European Medicines Agency (EMA) for regulatory review.

The MAA is supported by positive results from a pivotal Phase 3 program, which involved more than 9,000 patients worldwide.[1-7] The MAA dossier includes the DOLOMITES study, the results of which will be disclosed later this year.[8,9] Results from these studies support roxadustat as efficacious in increasing and maintaining target hemoglobin levels with reduced use of intravenous iron in adult patients with CKD anemia, both those who are dialysis dependent (DD) and those non-dialysis dependent (NDD). These data also support a favorable risk:benefit profile with cardiovascular (CV) and general safety of roxadustat reflective of the underlying conditions of the CKD population.[1-6]

"This acceptance marks a significant milestone for roxadustat, which we believe has the potential to offer an important new oral therapeutic option in the EU for the management of anemia in adults with chronic kidney disease," said Bernhardt G. Zeiher, M.D., Chief Medical Officer, Astellas. "Chronic kidney disease impacts one in eight people in Europe, of whom one in five are affected by anemia that is often untreated or not treated to target. We look forward to the review and assessment by EMA in the hope of bringing this innovative treatment to patients across the EU."

"There is significant unmet medical need for patients with anemia of CKD, a serious and often life-threatening disease," said K. Peony Yu, M.D., Chief Medical Officer, FibroGen. "This submission and FibroGen's recent submission of a New Drug Application in the U.S. are

supported by positive results from the largest global phase 3 program in patients with CKD anemia. We look forward to working with Astellas during the EMA's review of the MAA, and to the potential of roxadustat as a new therapeutic option for treating anemia in CKD patients on dialysis and not on dialysis across Europe."

EMA's acceptance of the roxadustat MAA for treatment of anemia in adult patients with CKD on dialysis and not on dialysis triggers a milestone payment of $130 million by Astellas to FibroGen.

About Clinical Trials

For more information about the clinical trials associated with the accepted MAA (1517-CL-0613 (PYRENEES),[1] 1517-CL-0608 (ALPS),[2] FGCL-4592-060 (ANDES),[3] FGCL-4592-063 (HIMALAYAS),[4] FGCL-4592-064 (SIERRAS),[5] D5740C00001 (OLYMPUS),[6] D5740C00002 (ROCKIES),[7] 1517-CL-0610 (DOLOMITES)[8,9]), please visit www.clinicaltrials.gov or clinicaltrialsregister.eu.

About CKD and Anemia

CKD is a progressive loss of kidney function caused by damage to the kidneys resulting from conditions such as hypertension, diabetes or immune-regulated inflammatory conditions.[10] Worldwide 1 in 10 people are living with CKD.[11] In Europe 1 in 8 people are living with CKD,[11] of whom 1 in 5 are affected by anemia, this rises to 1 in 2 in people with the most severe CKD (CKD stage 5).[12] CKD is predicted to become the fifth most common cause of premature death globally by 2040.[13] It is a critical worldwide healthcare issue that represents a large and growing unmet medical need.

Anemia is a common complication of CKD,[14] resulting from the failing kidneys' diminished ability to produce erythropoietin, which stimulates red blood cell production in the bone marrow. It is associated with significant morbidity and mortality in dialysis and non-dialysis populations, increasing in both prevalence and severity as kidney disease worsens.[15] Anemia associated with CKD increases the risk of adverse cardiovascular events, worsens renal outcomes and can negatively impact patients' quality of life.[16–18]

About Roxadustat

Roxadustat is a first-in-class orally administered inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase (PH), which increases hemoglobin levels with a mechanism of action that is different from that of erythropoiesis-stimulating agents. As a HIF-PH inhibitor, roxadustat activates a response that occurs naturally when the body responds to reduced oxygen levels in

the blood. This response involves the regulation of multiple, complementary processes to promote erythropoiesis and to increase the blood's oxygen-carrying capacity.

Roxadustat is approved and launched for the treatment of anemia associated with CKD in Japan in DD patients and in China in both DD and NDD patients. A supplemental New Drug Application (sNDA) has been submitted to Japan's Pharmaceuticals and Medical Devices Agency for NDD patients and a New Drug Application (NDA) has been submitted in the US in both DD and NDD patients.

Astellas and FibroGen are collaborating on the development and commercialization of roxadustat for the potential treatment of anemia in territories including 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 for the potential treatment of anemia in the US, China and other markets in the Americas and in Australia/New Zealand as well as Southeast Asia.

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 https://www.astellas.com/en.

About FibroGen
FibroGen, Inc., headquartered in San Francisco, with subsidiary offices in Beijing and Shanghai, is a leading biopharmaceutical company discovering, developing, and commercializing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in hypoxia-inducible factor, connective tissue growth factor biology and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease and cancer. For more information, please visit www.fibrogen.com.

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.

FibroGen Forward-Looking Statements

This release contains forward-looking statements regarding FibroGen's strategy, future plans and prospects, including statements regarding the development of the company's product candidates, the potential safety and efficacy profile of our product candidates, our clinical and regulatory plans and those of our partners. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may", "will", "should", "on track", "could", "expect", "plan", "anticipate", "believe", "estimate", "predict", "potential", "continue" and similar words, although some forward-looking statements are expressed differently. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of our various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in our Annual Report on Form 10-K for the fiscal year that ended December 31, 2019 and our quarterly report on 10-Q for the fiscal quarter that ended March 31, 2020 filed with the Securities and Exchange Commission, including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press release, except as required by law.

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