Press Release

Astellas Receives Approval of EVRENZO® (roxadustat) in Japan for the Treatment of Anemia of Chronic Kidney Disease in Adult Patients Not on Dialysis

Approval by MHLW provides new HIF-PH inhibitor treatment option for healthcare providers and adult patients with anemia of CKD not on dialysis

TOKYO, November 27, 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 that Japan's Ministry of Health, Labour and Welfare (MHLW) approved EVRENZO® (roxadustat) for the treatment of anemia of chronic kidney disease (CKD) in adult patients not on dialysis. This marks the second approval in Japan for roxadustat through the Astellas and FibroGen collaboration, after the therapy was approved and launched for use in adult patients with anemia of CKD on dialysis last year.

"We are delighted roxadustat is now approved in Japan for adults with anemia of CKD not on dialysis, as it allows even more patients to access this important new treatment option," said Bernhardt G. Zeiher, M.D., Chief Medical Officer, Astellas. "With its novel mechanism of action and oral administration, we hope roxadustat will alleviate some of the burden associated with anemia of CKD prior to the initiation of dialysis and deliver meaningful improvements in the lives of these patients."

This approval is based on results obtained from three clinical studies in more than 500 Japanese patients with anemia of CKD not on dialysis. The first, an open-label Phase 3 conversion study versus active comparator, darbepoetin alfa, met the primary efficacy endpoint of non-inferiority and continued to demonstrate maintenance of hemoglobin (Hb) levels over time.[1] Roxadustat was generally well tolerated, and the safety profile was comparable with that of darbepoetin alfa.[1] The other two studies (one Phase 3 and one Phase 2) support the safety and efficacy of roxadustat in erythropoiesis-stimulating agent (ESA)-untreated patients.[2,3]

"Today's approval is another milestone achievement for both FibroGen and Astellas," said K. Peony Yu, M.D., Chief Medical Officer, FibroGen. "By bringing roxadustat to adult patients living

with anemia of CKD, both on dialysis and not on dialysis, we are continuing our efforts to meet the significant unmet medical need of patients in this community."

The approval of the supplementary New Drug Application (sNDA) for roxadustat in Japan for the treatment of anemia of CKD in adult patients not on dialysis triggers a milestone payment of $15 million by Astellas to FibroGen.

As a first-in-class orally administered inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase (PH), roxadustat increases Hb levels through a mechanism of action that is different from that of traditional ESAs. As a HIF-PH inhibitor, roxadustat activates the body's natural protective response to reduced oxygen levels in the blood. This response involves the regulation of multiple, coordinated processes that lead to the correction of anemia.

Product Information

PRODUCT NAME	EVRENZO® Tablets 20 mg EVRENZO® Tablets 50 mg EVRENZO® Tablets 100 mg
GENERAL NAME	Roxadustat
INDICATIONS	Renal anemia
DOSAGE AND ADMINISTRATION	*Patients not on erythropoiesis-stimulating agent treatment.* For adults, the usual dosage is 50 mg, the starting dose, as roxadustat orally administered three times weekly. The dosage thereafter should be adjusted according to the patient's condition; however, the maximum dose should not exceed 3.0 mg/kg. *Patients switching from erythropoiesis-stimulating agents.* For adults, the usual dosage is 70 or 100 mg, the starting dose, as roxadustat orally administered three times weekly. The dosage thereafter should be adjusted according to the patient's condition; however, the maximum dose should not exceed 3.0 mg/kg.
APPROVAL DATES	Renal anemia in patients on dialysis: September 20, 2019 Renal anemia in patients not on dialysis: November 27, 2020

About Clinical Trials

For more information about the clinical trials associated with this approval (1517-CL-0310, 1517-CL-0314, 1517-CL-0303), please visit www.clinicaltrials.gov.

About CKD and Anemia

CKD is characterized 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.[4,5] Worldwide, 1 in 10 people are living with CKD.[6] In Japan specifically, the prevalence of CKD has increased significantly over time.[7] Although CKD can occur at any age, it becomes more common in aging populations and the prevalence is increasing.[8] In

addition, CKD is predicted to become the fifth most common cause of premature death by 2040 globally.[9] It is a critical worldwide healthcare issue that represents a large and growing unmet medical need.

Anemia is a common complication of CKD,[10] resulting from the failing kidneys' ability to produce erythropoietin, reduced oxygen sensing, and increased hepcidin and iron deficiency resulting from chronic inflammation. Anemia affects approximately one-third of Japanese patients with Stage 3–5 CKD.[11] It is associated with significant morbidity and mortality in dialysis and non-dialysis populations, increasing in both prevalence and severity as kidney disease worsens.[12] Anemia of CKD increases the risk of adverse cardiovascular events, worsens renal outcomes and can negatively impact patients' quality of life.[13-15]

About Roxadustat
Roxadustat is a first-in-class orally administered inhibitor of HIF-PH, which increases hemoglobin levels through a mechanism of action that is different from that of traditional ESAs. As a HIF-PH inhibitor, roxadustat activates a response that occurs naturally when the body responds to reduced oxygen levels in the blood. Roxadustat promotes red blood cell production through increased endogenous production of erythropoietin; improved iron absorption, transport, and mobilization; and downregulation of hepcidin, which helps to overcome the negative impact of inflammation on hemoglobin synthesis and red blood cell production.

Roxadustat is approved and launched for the treatment of anemia of CKD in Japan and China in adult patients on dialysis (DD) and not on dialysis (NDD). A New Drug Application for the treatment of anemia of CKD in patients both DD and NDD is under review by the U.S. Food and Drug Administration with a decision expected in December 2020. The marketing authorisation application for roxadustat for the treatment of anemia of CKD in patients both DD and NDD was accepted by the European Medicines Agency for review. Several other licensing applications for roxadustat have been submitted by Astellas and AstraZeneca to regulatory authorities across the globe, which are currently in review.

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

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.

About FibroGen
FibroGen, Inc. is a biopharmaceutical company committed to discovering, developing and commercializing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology to advance innovative medicines for the treatment of unmet needs. The Company is currently developing and commercializing roxadustat, an oral small molecule inhibitor of HIF prolyl hydroxylase activity, for anemia associated with chronic kidney disease (CKD). Roxadustat is also in clinical

development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA). Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of idiopathic pulmonary fibrosis (IPF), locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and coronavirus (COVID-19). 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 the commercial plans 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 clinical, regulatory and commercial operations and results, 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 June 30, 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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