ASTRAZENECA PLC ANNOUNCES MARKETING AUTHORISATION APPLICATION FOR GOUT TREATMENT LESINURAD ACCEPTED BY EUROPEAN MEDICINES AGENCY

AstraZeneca today announced the European Medicines Agency has accepted the Marketing Authorisation Application (MAA) for lesinurad 200mg tablets. Lesinurad is a selective uric acid reabsorption inhibitor (SURI) developed for the chronic treatment of hyperuricaemia in combination with xanthine oxidase (XO) inhibitors allopurinol or febuxostat in gout patients when additional therapy is warranted.

The MAA filing was based on data from the CLEAR1, CLEAR2 and CRYSTAL pivotal Phase III combination therapy studies. CLEAR1 and CLEAR2 were 12-month, multicentre, randomised, placebo-controlled studies that evaluated the efficacy and safety of a once daily dose of lesinurad in combination with allopurinol versus allopurinol alone, in symptomatic gout patients not achieving target serum uric acid (sUA) levels on their current allopurinol therapy. CRYSTAL was a 12-month, multicentre, randomised, placebo-controlled study that evaluated the efficacy and safety of a once daily dose of lesinurad in combination with febuxostat compared to febuxostat alone in gout patients with tophi (deposits of uric acid crystals in joints and skin).

Between 40 to 80% of patients do not achieve recommended sUA goals with the current standard of care of an XO inhibitor alone. XO inhibitors including allopurinol and febuxostat reduce the production of uric acid. Lesinurad works by inhibiting the uric acid transporter URAT1 in the kidney, thereby increasing uric acid excretion resulting in lower sUA.Combination therapy with lesinurad and an XO inhibitor provides a dual mechanism approach targeting both excretion and production of uric acid which effectively lowers sUA and enables significantly more patients to achieve and maintain target treatment goals to control their disease.

The CLEAR1, CLEAR2 and CRYSTAL studies were conducted by Ardea Biosciences, a member of the AstraZeneca Group.

About Lesinurad
Lesinurad is a selective uric acid reabsorption inhibitor (SURI) that inhibits the URAT1 transporter and is being studied as an investigational agent for the treatment of gout. URAT1 is responsible for the majority of the reabsorption of filtered uric acid from the renal tubular lumen. By inhibiting URAT1, lesinurad increases uric acid excretion and thereby lowers sUA. Lesinurad also inhibits OAT4, a uric acid transporter involved in diuretic-induced hyperuricaemia.

About Gout

Gout is a serious, chronic and debilitating form of inflammatory arthritis. There are more than 15.8 million diagnosed cases of gout in major markets. Gout is caused by a metabolic disorder, hyperuricaemia (elevated sUA), which leads to the deposition of crystals in musculoskeletal structures including joints, in the kidneys, and in other tissues.

About Ardea Biosciences

Ardea Biosciences, Inc. was acquired by AstraZeneca in June 2012. It is located in San Diego, California and is a member of the AstraZeneca Group. Ardea is leading the development of AstraZeneca's gout portfolio, including lesinurad and RDEA3170.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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22 January 2015

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