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AZ' gout therapy gets FDA approval

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AstraZeneca announced that the US Food and Drug Administration (US FDA) has approved ZURAMPIC (lesinurad) 200mg tablets in combination with a xanthine oxidase inhibitor (XOI) for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with an XOI alone.

ZURAMPIC inhibits the urate transporter, URAT1, which is responsible for the majority of the renal reabsorption of uric acid. By inhibiting URAT1, ZURAMPIC increases uric acid excretion and thereby lowers sUA.

In combination with the current standard of care, XOIs allopurinol or febuxostat, ZURAMPIC provides a dual mechanism of action to increase excretion and decrease production of uric acid, enabling more patients with inadequately controlled gout to achieve target treatment goals.

Mr Sean Bohen, executive vice president of Global Medicines Development and Chief Medical Officer, AstraZeneca, said, "With the FDA approval of ZURAMPIC, we are pleased to offer a new treatment option for the many patients who are suffering from the effects of gout and who are not reaching the recommended serum uric acid treatment targets with the current standard of care."

The FDA approval is based on data from three pivotal Phase III studies, CLEAR1, CLEAR2 and CRYSTAL, which represent the largest clinical trial data set of gout patients (n=1,537 total) treated with combination urate lowering therapy.

Gout is a serious and debilitating form of inflammatory arthritis caused by hyperuricemia (elevated sUA). It affects millions of people around the globe, many of whom do not reach recommended sUA treatment goals on XOIs, which decrease production of uric acid. For those inadequately controlled patients, the addition of a urate-lowering therapy to increase

excretion of uric acid may help them achieve treatment goals.

ZURAMPIC is also under regulatory review in the European Union and other territories.