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AstraZeneca’s roxadustat reveals positive results against anaemia

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AstraZeneca and FibroGen China, a wholly-owned subsidiary of FibroGen Inc., are collaborating on thedevelopment and commercialisation of roxadustat in China

AstraZeneca has announced that data from two Phase III trials evaluating the efficacy and safety of roxadustat in China.

The trials, Study 806 and 808, evaluated roxadustat in Chinese patients with anaemia caused by chronic kidney disease (CKD) who are either dialysis-dependent (DD) or non-dialysis-dependent (NDD), respectively. In both trials, the primary efficacy endpoints were met. Results were previously presented at the American Society of Nephrology Kidney Week Annual Meeting in 2018.

In Study 806, DD-CKD patients with anaemia previously treated with erythropoiesis-stimulating agents (ESAs), the current standard of care for these patients, were randomised to receive roxadustat or epoetin alfa, an ESA, over 26 weeks. The trial met its primary efficacy endpoint of a mean change in haemoglobin (Hb) from baseline averaged over weeks 23-27 for patients treated with roxadustat compared to epoetin alfa. Roxadustat showed a numerically greater mean change in Hb in patients receiving roxadustat compared to epoetin alfa, showing it was statistically non-inferior. In a subgroup analysis of patients with inflammation marked by elevated c-reactive protein (CRP), roxadustat achieved consistent Hb control regardless of the patients' inflammation status, compared to epoetin alfa.

In Study 808, for the first eight weeks, NDD-CKD patients with anaemia were randomised to receive roxadustat or placebo. For the following 18 weeks, all patients were treated with roxadustat. The trial met its primary efficacy endpoint of mean change in Hb from baseline to weeks seven to nine. Patients randomised to roxadustat had a statistically significant greater mean change in Hb from baseline compared to patients randomised to placebo.

The safety profile of roxadustat in both studies was consistent with previous clinical trials of roxadustat in the CKD patient population.

AstraZeneca and FibroGen China, a wholly-owned subsidiary of FibroGen Inc., are collaborating on the development and commercialisation of roxadustat in China. Roxadustat is currently approved in China for the treatment of patients with anaemia in DD-CKD. The submission for NDD-CKD patients is under review by China’s National Medical Product Administration (NMPA).