

AstraZeneca announces phase III trials for roxadustat

03 January 2019 | News

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AstraZeneca has announced that the Phase III OLYMPUS and ROCKIES trials for roxadustat each met their primary efficacy endpoints for the treatment of patients with anaemia in chronic kidney disease (CKD) that are either non-dialysis-dependent or dialysis-dependent, respectively.

Roxadustat is a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) and a potential first-in-class new medicine to treat anaemia in CKD being jointly developed and commercialised by AstraZeneca and FibroGen, Inc.

OLYMPUS is a Phase III, randomised, double-blinded, placebo-controlled trial designed to evaluate the efficacy and safety of roxadustat vs. placebo for the treatment of patients with anaemia in CKD stages 3, 4 and 5 whose disease progression is moderate to severe and who are non-dialysis dependent.

The trial met its primary efficacy endpoint by demonstrating a statistically-significant and clinically-meaningful improvement in mean change from baseline in haemoglobin (Hb) levels averaged over weeks 28 to 52 vs. placebo. The trial evaluated 2,781 patients in 26 countries.

ROCKIES is a Phase III, randomised, open-label, active-controlled trial designed to assess the efficacy and safety of roxadustat vs. epoetin alfa, for the treatment of patients with anaemia in CKD who are dialysis dependent. The trial met its primary efficacy endpoint by demonstrating a statistically-significant improvement in mean change from baseline in Hb levels averaged over weeks 28 to 52 vs. epoetin alfa. The trial evaluated 2,133 patients in 18 countries.

Sean Bohen, Executive Vice-President, Global Medicines Development and Chief Medical Officer, said: "These results add to the growing body of evidence for roxadustat, which is part of the largest clinical programme worldwide in evaluating the novel class of HIF-PHI. This is a significant milestone in the role roxadustat can play to help address a high unmet need in anaemia associated with chronic kidney disease, which today is under diagnosed and in many cases under treated."

Data from the Phase III OLYMPUS and ROCKIES trials, together with the efficacy and pooled safety data from the global Phase III programme, will be part of the regulatory submission package in the US and other major countries. Results from these trials will be presented at forthcoming medical meetings.

AstraZeneca and FibroGen, Inc. are collaborating on the development and commercialisation of roxadustat for the treatment of anaemia in patients with CKD in the US, China, and other global markets. FibroGen and Astellas are collaborating on the development and commercialisation of roxadustat for the treatment of anaemia in patients with CKD in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.