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Roxadustat Phase III study shows positive efficacy in patients with anaemia from CKD

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In non-dialysis-dependent patients receiving roxadustat, the risk of MACE, MACE+ and all-cause mortality was comparable to placebo Dialysis-dependent patients receiving roxadustat had a lower risk of MACE+ and no increased risk of MACE or all-cause mortality versus epoetin alfa In incident dialysis patients, roxadustat had a lower risk of MACE and MACE+ and showed a trend towards a lower risk of all-cause mortality relative to epoetin alfa

AstraZeneca and FibroGen Inc. (FibroGen) have presented pooled efficacy and cardiovascular (CV) safety analyses from the pivotal Phase III programme assessing roxadustat for the treatment of patients with anaemia from chronic kidney disease (CKD).

The pooled CV safety analyses showed that roxadustat, an oral first-in-class hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), did not increase the risk of MACE, MACE+ and all-cause mortality in non dialysis-dependent (NDD) patients compared to placebo and dialysis-dependent (DD) patients compared to epoetin alfa, a current medicine used to treat anaemia.

In a clinically important predefined subgroup of incident dialysis (ID) patients, defined as patients who have been on dialysis for four months or less, roxadustat reduced the risk of MACE and MACE+ and showed a trend towards a lower risk of all-cause mortality relative to epoetin alfa.

Key safety endpoints consisted of time to major adverse CV events (MACE), defined as all-cause mortality, stroke and myocardial infarction, and time to MACE+, defined as MACE, unstable angina requiring hospitalisation and congestive heart failure requiring hospitalisation.

The results were presented in an oral late-breaking abstract session at the American Society of Nephrology (ASN) Kidney Week 2019 in Washington, D.C., US.

Mene Pangalos, Executive Vice President, BioPharmaceuticals, R&D, said: “These highly-anticipated results reinforce our confidence in the potential of roxadustat to address significant unmet medical needs among patients with anaemia from

chronic kidney disease, particularly for those who have recently started dialysis. The pooled analyses showed incident dialysis patients receiving roxadustat had a lower risk of cardiovascular events which is important as these patients may experience higher rates of morbidity and mortality than those on stable dialysis."

Robert Provenzano, MD, Associate Professor of Medicine, Wayne State University, Detroit, Michigan, US and a primary investigator on the global Phase III programme, said: "Roxadustat is the first in a new class of medicines for the treatment of anaemia from chronic kidney disease. This pooled cardiovascular safety data, together with strong efficacy data, support its potential as an important new treatment option for patients with anaemia from chronic kidney disease who have seen little to no innovation in decades."

The primary efficacy endpoint was achieved in the pooled analyses for NDD and DD patients and in all individual Phase III trials. Data from the pooled efficacy and CV safety analyses, together with other statistical analyses, will form part of the regulatory submission in the US, which is anticipated in Q4 2019.

The pooled efficacy analyses in the NDD population showed roxadustat was superior to placebo, regardless of iron-repletion, with a mean increase from baseline in haemoglobin (Hb) levels averaged over weeks 28 to 52 of 1.85 g/dL in patients treated with roxadustat compared to 0.13 g/dL with placebo ($p<0.001$).

The pooled efficacy analyses in the DD population showed roxadustat demonstrated a statistically significant mean increase from baseline in Hb levels averaged over weeks 28 to 52 with 1.22 g/dL in patients treated with roxadustat compared to 0.99 g/dL with epoetin alfa ($p<0.001$).

Roxadustat is currently approved in China for the treatment of anaemia in patients with CKD, regardless of whether they require dialysis, and in Japan for the treatment of dialysis patients with anaemia from CKD.