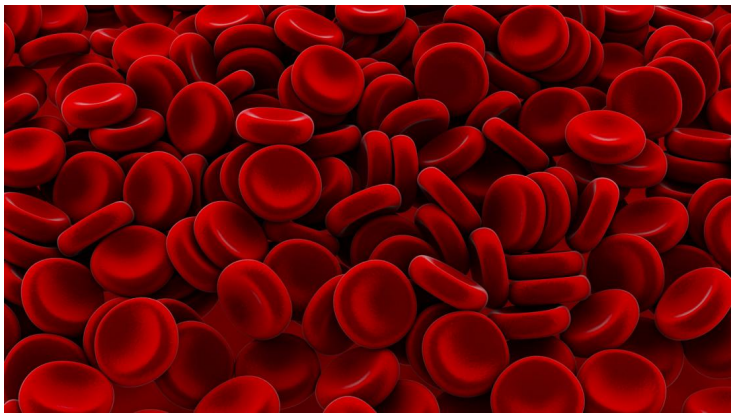
BioSpectrum the business of Bio & Health Sciences ASIA EDITION

China approves AstraZeneca drug to treat anaemia in CKD patients

23 August 2019 | News

China becomes the first country to approve roxadustat for all chronic kidney disease (CKD) patients with anaemia



AstraZeneca has announced that its partner FibroGen (China) Medical Technology Development Co., Ltd. (FibroGen China) has received marketing authorisation for roxadustat in China for the treatment of anaemia caused by chronic kidney disease (CKD) in non-dialysis-dependent (NDD) patients.

This approval, granted by the National Medical Products Administration, is primarily supported by a Phase III trial in NDD-CKD patients with anaemia, in which roxadustat demonstrated a statistically-significant improvement in haemoglobin levels from baseline averaged over weeks seven to nine of treatment, with a mean change of 1.9 g/dL compared to -0.4 g/dL with placebo. This marketing authorisation follows the approval of roxadustat in China in December 2018 for anaemia in CKD patients who are on dialysis. AstraZeneca and FibroGen China expect to launch roxadustat in China during the second half of 2019.

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: “With this approval for roxadustat in China, we are now able to provide this first-in-class medicine to all patients living with chronic kidney disease who experience anaemia, regardless of whether they require dialysis. This is a significant milestone and we look forward to bringing the medicine to patients later this year.”

Anaemia caused by CKD is associated with cardiovascular disease, hospitalisation, cognitive impairment and reduced quality of life, and has been shown consistently to increase the risk of death in patients with CKD. Anaemia becomes increasingly common in patients with CKD as their disease progresses.