

Zydus starts phase II trial of ZYAN1 for treating anemia in patients with CKD

Ahmedabad, India, July 5, 2017

Zydus today announced the initiation of a phase II trial investigating ZYAN1, an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), as a treatment for anemia associated with chronic kidney disease (CKD).

ZYAN1 is an oral small molecule that has been designed to inhibit hypoxia-inducible factor prolyl hydroxylase, and thereby increase the natural production of hemoglobin and RBCs in anemic patients. ZYAN1 has been shown to improve iron mobilization and has the potential to reduce or eliminate the need for iron supplementation.

“We have observed desired pharmacokinetic & safety profile in addition to positive signals in biomarker responses, including erythropoietin increase with ZYAN1 in the two phase I trials that were conducted in Australia and India” said, Pankaj Patel, Chairman & Managing Director, Zydus Cadila, and added, “ZYAN1 has the potential to bring about a paradigm shift in the management of patients with anemia as it could provide an oral, safer alternative to currently available erythropoietin-stimulating agents (ESAs), which are associated with an increased risk of CV events, and must be given via injections. Zydus is committed to bring this therapy to millions of patients suffering from anemia”.

Anemia is a global public health problem affecting both developing and developed countries. Anemia commonly arises in kidney disease patients, because the kidneys no longer produce sufficient amounts of erythropoietin, a hormone which stimulates red blood cell production. Symptoms of anemia may include fatigue, skin pallor, shortness of breath, light-headedness, dizziness or a fast heartbeat. The Global ESA Market was estimated at USD 7 billion worldwide.

Two phase I trials of ZYAN1 have been concluded in Australia and India, and results were recently published in *Clinical Pharmacokinetics*. ZYAN1 was safe and well-tolerated in healthy volunteers following single escalating oral doses (10–300 mg) and multiple escalating oral doses (100–300 mg). The measurement of serum erythropoietin (EPO) levels in healthy volunteers confirmed the pharmacodynamic effect as EPO increased with increasing ZYAN1 doses in relation to placebo.

About Zydus

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics and vaccines. The group employs over 20,000 people worldwide, including 1200 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com