

## **Zydus completes single rising dose Phase I studies for its oral HIF-PH inhibitor, ZYAN1 for treating Anemia and initiates multiple dosing studies**

- *ZYAN1 is an orally bioavailable hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor, designed to increase the natural production of erythropoietin and match the efficacy of injectable EPO stimulating agents*
- *First-in-man, double blind, multicentric study is underway in Australia.*
- *Single ascending dose (SAD) study has now been completed in Australia. The multiple dosing studies are expected to be completed by Q2 2015*

Ahmedabad, February 16, 2015

Zydus Cadila today announced that it has completed the single ascending dose (SAD) range finding studies of ZYAN1 in healthy human volunteers as a part of the Phase I study currently ongoing in Australia. The molecule, ZYAN1 is an orally bioavailable hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor being developed for the treatment of anemia. ZYAN1 has been designed to increase the natural production of erythropoietin (EPO) in anemic patients.

Anemia is a condition of having lower red blood cells or lower hemoglobin levels than is normal. Anemia is a serious medical condition linked to increased morbidity and mortality, and is commonly observed in patients with chronic kidney disease (CKD). Currently available agents for the treatment of anemia include injectable EPO stimulating agents (ESA's) and intravenous iron supplements. The estimated global market for treatments for anemia related to CKD is \$ 10 billion.

“This is an important innovation that will radically change the treatment paradigm in anemia”, said Mr. Pankaj R. Patel, Chairman and Managing Director, Zydus Cadila. “ZYAN1 has the potential to become an oral therapy for treating patients with anemia with significant advantages over currently available injectable EPO stimulating agents (ESAs)”, he added.

The Phase I study was designed to evaluate the safety, tolerability and pharmacokinetics of single ascending doses of ZYAN1 in healthy volunteers. During the dose ranging study, ZYAN1 was administered up to 150 mg orally, once-a-day to healthy human volunteers as part of single ascending dose finding studies. Pharmacokinetics, Erythropoietin and other biomarker responses were also measured in the healthy volunteers as part of this study. Now the multiple ascending doses of ZYAN1 in healthy human volunteers have been initiated. In addition, the effect of food and gender on the pharmacokinetics of ZYAN1 will also be studied.

**About Zydus**

Headquartered in Ahmedabad, India, Zydus Cadila is an innovative, global pharmaceutical company that discovers, manufactures and markets a broad range of healthcare therapies. The group employs over 16,000 people worldwide including over 1200 scientists engaged in R & D and is dedicated to creating healthier communities globally. As a leading healthcare provider, it aims to become a global research based pharmaceutical company by 2020. The group has a strong research pipeline of NCEs, biologics and vaccines which are in various stages of clinical trials including late stage.