Zydus and ICMR initiate a Phase 2 proof-of-concept trial of Desidustat in patients with Sickle Cell Disease

The partnership marks a pivotal step towards developing new therapies for combating Sickle Cell Disease

Ahmedabad, India, 14 October, 2024

In a significant stride towards strengthening India's clinical research ecosystem, Zydus Lifesciences Limited has formalized the Memorandum of Agreement (MoA) with Indian Council of Medical Research (ICMR) to initiate Phase 2 clinical trials of Desidustat in patients with Sickle Cell Disease.

This Phase IIa, double blind, randomized, placebo controlled, parallel, multi-centre, proof-of-concept study, co-funded and co-monitored by INTENT, Indian National Clinical Trial and Education Network, Clinical Studies and Trial Unit, Division of Development Research, ICMR, will evaluate the efficacy and safety of Desidustat oral tablet for treatment of sickle cell disease. Proportion of patients with Hb response (defined as ≥ 1 g/dL increase in Hb from baseline) compared to placebo will be measured at week 4 and week 8 as the primary end-point. The trial will also evaluate Key Secondary Endpoints including Mean change in haemoglobin, proportion of patients requiring blood transfusions, proportion of patients experiencing vaso-occlusive crisis and mean change in percentage of HbSS [CTRI Registration : CTRI/2024/06/068363].

Dr. Rajiv Bahl, Secretary, Department of Health Research & Director General, ICMR, emphasized the transformative potential of the project, stating, "This collaboration reflects our commitment to advancing clinical research in India through strategic public-private partnerships. Desidustat was invented in India, and patients with Sickle Cell disease need therapies in addition to currently available drug, hydroxyurea, our vision is to ensure that India continues to lead in the development of innovative and affordable healthcare solutions."

Mr. Pankaj Patel, Chaiman of Zydus Lifesciences Limited, mentioned that "Public-private partnerships in the healthcare sector is essential to deliver novel drug to achieve the goals of the National Sickle Cell Anaemia Elimination Mission. The initiation of this study reaffirms hope for the 20 million Sickle Cell affected patients in the country for a high potential novel treatment."

PRESS RELEASE

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About Sickle Cell Disease

In India, Sickle Cell Disease is a significant public health concern, particularly among certain tribal populations where the prevalence is higher. According to the National Health Mission NHM estimates, there are approximately 20 Million sickle cell-affected patients in the country. Every year, 50,000 children with sickle cell anemia are estimated to be born in India. The Government of India recognizes the significant impact of Sickle Cell Disease SCD on public health, particularly among tribal populations where the prevalence of the disease is higher. Therapeutic options for management of SCD are limited. Hydroxyurea, reduced frequency of painful crisis in SCD, but is not universally effective and associated with side-effects like neutropenia and thrombocytopenia. Blood transfusions are expensive, not uniformly accessible, and are accompanied by risks including alloimmunization, hemolysis, and transfusion iron overload.

About Desidustat

Desidustat is a hypoxia inducible factor (HIF)-prolyl hydroxylase inhibitor (PHI) and stimulates EPO production in a similar manner that happens in response to hypoxia. Desidustat has been discovered at Zydus' R&D labs, and was recently approved for treatment of anemia in Chronic Kidney Disease patients not-on-dialysis and patients on-dialysis. DCGI has recently granted permission to conduct a Phase IIa POC trial to evaluate efficacy and safety of Desidustat oral tablet for treatment of sickle cell disease [CTRI Registration : CTRI/2024/06/068363].

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