

Zydus announces positive Phase 2 Proof-of-Concept of NLRP3 inhibitor, ZYIL1 in patients with Cryopyrin Associated Periodic Syndrome (CAPS)

- *First Phase 2 Proof-of-Concept (POC) study demonstrating rapid clinical improvement and remission within days when Cryopyrin Associated Periodic Syndrome (CAPS) patients with flare ups were treated with ZYIL1, a novel oral small molecule NLRP3 inhibitor*
- *Phase 1 study in Healthy Human volunteers published in “Clinical Pharmacology in Drug Development” Journal of American College of Clinical Pharmacology*

Ahmedabad, India, 07 September 2022,

Zydus Lifesciences Ltd. (formerly known as Cadila Healthcare Ltd.), a discovery-driven, global lifesciences company today announced that it has achieved a positive Proof-of-Concept in its Phase 2 clinical study of ZYIL1, in patients with CAPS.

CAPS is a rare, life-long, auto-inflammatory condition, caused by NLRP3 activating mutations and is classified as an orphan disease. The chronic inflammation due to IL-1beta release in CAPS patients leads to urticaria-like rash, fever, arthralgia, and increased risk of amyloidosis. CAPS patients also experience multiple neurological complications like sensorineural hearing loss, migraine, headache, aseptic meningitis and myalgia. Bone deformities and neurological impairments have been reported in Neonatal Onset Multisystem Inflammatory Disease (NOMID), the most severe form of CAPS.

The Phase 2 trial conducted in Australia, evaluated the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of ZYIL1 in Subjects with Cryopyrin Associated Periodic Syndromes (CAPS) [ClinicalTrials.gov Identifier: NCT05186051]. ZYIL1 showed rapid oral absorption. ZYIL1 is extremely potent (IC50 in nanomolar range) in human whole blood and suppressed inflammation caused by the NLRP3 inflammasome. Robust effect on disease biomarkers including CRP, Serum Amyloid A (SAA), IL-6, WBC, was also observed.

ZYIL1 was safe and well-tolerated and there were no Serious Adverse Events (SAE's) observed in this Phase 2 trial. Liver and kidney function tests also did not show any abnormalities in this Phase 2 trial. CAPS patients with confirmed NLRP3 mutation suffering from CAPS-related flare up, when treated with ZYIL1 in Phase 2 Proof-of-Concept trial showed rapid clinical improvement as early as day 3 which sustained till the end of treatment.



**PRESS
RELEASE**

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Lauding the positive proof-of-concept results achieved in CAPS patients as a significant milestone, Mr. Pankaj R. Patel, Chairman, Zydus Lifesciences Ltd. said, “As an innovation driven organization, we have been focussed on making a meaningful difference in the lives of patients. This top-line result from the Phase 2 clinical trial has demonstrated for the first time that ZYIL1, an oral small molecule NLRP3 inhibitor is beneficial in treating chronic inflammation in CAPS patients. Zydus is now planning to conduct further pivotal clinical trials and is committed to develop ZYIL1 for patients living with CAPS and other chronic inflammatory diseases.”

Reference:

1. ClinicalTrials.gov Identifier: NCT04972188 A Phase I, Prospective, Open Label, Multiple Dose Study of ZYIL1 Administered Via Oral Route to Investigate The Safety, Tolerability, Pharmacokinetics And Pharmacodynamics In Healthy Adult Subjects
2. ClinicalTrials.gov Identifier: NCT04731324 A Phase 1, Prospective Open Label, Single Dose, Single Arm Study of ZYIL1 Administered Via Oral Route to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics in Healthy Adult Human Subjects
3. ClinicalTrials.gov Identifier: NCT05186051 A Phase 2a, Prospective, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of ZYIL1 in Subjects With Cryopyrin Associated Periodic Syndromes (CAPS)
4. Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of the Oral NLRP3 Inflammasome Inhibitor ZYIL1: First-in-human Phase 1 studies (Single Ascending Dose and Multiple Ascending Dose), Clinical Pharmacology in Drug Development, 2022. DOI: 10.1002/cpdd.1162

About Zydus

The Zydus Group with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 23000 people worldwide and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. For more details visit www.zyduslife.com



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