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Zydus to begin Phase II (a) clinical trial of ZYIL1, a novel oral NLRP3 inflammasome inhibitor in patients with Cryopyrin-Associated Periodic Syndrome (CAPS) in Australia

- *CAPS is a rare life-long auto-inflammatory condition, caused by NLRP3 activating mutations and is classified under orphan diseases.*

Ahmedabad, India, 13th December, 2021

Zydus, a leading discovery-based, global pharmaceutical company announced today that it has received permission to initiate the Phase II (a) clinical study of its NLRP3 inhibitor "ZYIL1" in patients with Cryopyrin-Associated Periodic Syndrome (CAPS) in Australia. Phase II (a) clinical trial in Australia will study the safety, tolerability, pharmacokinetics and pharmacodynamics in patients with Cryopyrin-Associated Periodic Syndrome (CAPS).

Cryopyrin-Associated Periodic Syndrome (CAPS) is caused by NLRP3 activating mutations that cause activation of the cryopyrin inflammasome and release of inflammatory cytokines including IL-1β. Selective inhibition of NLRP3 could be beneficial, as NLRP3 inflammasomes are primarily involved in the inflammation process in these patients.

CAPS is a rare life-long auto-inflammatory condition, and is classified under orphan diseases. 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 impairment have been reported in Neonatal Onset Multisystem Inflammatory Disease (NOMID), the most severe form of CAPS.

Mr. Pankaj R. Patel, Chairman, Cadila Healthcare Ltd. said, "The Cryopyrin Associated Periodic Syndromes (CAPS) patient community has very limited treatment options and there is a huge unmet medical need. We are committed to develop novel therapies, and ZYIL1 has potential to treat several autoimmune diseases."

ZYIL1 is a novel oral small molecule NLRP3 inhibitor. Studies have demonstrated that ZYIL1 has high binding affinity in human whole blood, and can selectively supress inflammation caused by the NLRP3 inflammasome. In non-clinical species including mice, rats and non-human primates, ZYIL1 has demonstrated brain penetration. The efficacy of ZYIL1 has been established in a number of validated pre-clinical models of Neuroinflammation, Parkinson's Disease, Inflammatory Bowel Disease (IBD), Multiple Sclerosis (MS), Sepsis and acute lung injury models of Acute Respiratory Distress Syndrome (ARDS). The candidate, ZYIL1, has an acceptable ADME profile, with good safety margin.

ZYIL1 was found to be safe and well-tolerated in Phase I trials [NCT04731324]. In the second Phase I trial, Multiple-dose studies of ZYIL1 was conducted to evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) following repeated dosing for 14 days in healthy subjects [NCT04972188]. ZYIL1 showed rapid oral absorption and steady state was achieved at 48h. Inhibition of IL-1beta biomarker in Phase I trial demonstrated proof-of-biology.

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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 23,000 people worldwide, including 1400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com

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