Zydus receives approval from USFDA to initiate Phase II clinical trial of ZYIL1 in patients with Parkinson's disease

Ahmedabad, India, Dec 16, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as "Zydus") a leading discovery-based, global pharmaceutical company, announced today that it has received permission from USFDA, to initiate the Phase II clinical study of NLRP3 inhibitor "ZYIL1" in patients with Parkinson's disease.

Parkinson's is a devastating disease with patients steadily losing the control on movements leading to unintended or uncontrollable movements, such as shaking, stiffness and difficulty with balance and co-ordination. It is estimated that there are more than 8.5 mn people in the world suffering from Parkinson's disease, with 1 mn suffering from the disease in the US. Each year 90,000 new cases of Parkinson's disease are reported in the US. Analysts estimate that the treatment costs of Parkinson's disease amounts to almost U.S. $52 billion every year, and by 2037 this disease is estimated to touch U.S. $80 billion every year.

Speaking on the development Mr. Pankaj R. Patel, Chairman, Zydus Lifesciences Ltd. said, "Our researchers have been working on path-breaking discoveries that can unlock new possibilities and help patients lead more healthier and fulfilled lives. Our team is developing a novel, disease modifying approach through inhibiting the activation of NLRP3 inflammasome with ZYIL1, which could potentially reduce neuroinflammation and neuro-degeneration in patients suffering from Parkinson's disease."

ZYIL1 is a novel oral small molecule NLRP3 inhibitor. Studies have demonstrated that ZYIL1 is highly potent and can suppress inflammation caused by NLRP3 inflammasome activation. ZYIL1 was found distributed in the brain & CSF of various nonclinical species including mice, rats and non-human primates. The efficacy of ZYIL1 has been established in a number of validated pre-clinical models of neuro-inflammation and Parkinson's disease. ZYIL1, has demonstrated desirable ADME profile, with good safety margin. In phase I studies, ZYIL1 was found to be safe and well-tolerated in human volunteers [NCT04731324, NCT04972188]. The Phase 2 study will evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics in patients with Parkinson's Disease.

Previously, Zydus had demonstrated efficacy of ZYIL1 in CAPS (Cryopyrin Associated Periodic Syndrome) patients [NCT05186051], and was the first to establish the phase 2 proof of-concept with an oral small molecule NLRP3 inhibitor in CAPS patients. The phase-2 data

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)
Regd. Office : 'Zydus Corporate Park',
Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar),
Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382
481, Gujarat, India. | Phone : +91-79-71800000,
+91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878

of ZYIL1 in CAPS has now been published in "Clinical Pharmacology in Drug Development". Zydus has been granted an 'Orphan Drug Designation' by the US FDA for ZYIL1 in treatment of patients with CAPS, a rare auto-inflammatory disease.

Additionally Zydus has also initiated Phase 2 clinical trial of ZYIL1 in patients with Amyotrophic Lateral Sclerosis (ALS), a neurodegenerative disease [ClinicalTrials.gov Identifier: NCT05981040].

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. ClinicalTrials.gov Identifier: NCT05981040. Efficacy, Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ZYIL1 in Patients With Amyotrophic Lateral Sclerosis
5. 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
6. Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of ZYIL1 in Three Patients with Cryopyrin-Associated Periodic Syndromes, Clinical Pharmacology in Drug Development, 2023, 0(0) 1–8. DOI: 10.1002/cpdd.1318.
7. Identification of ZYIL1, a novel NLR family pyrin domain containing protein inhibitors: a potential disease modifier in Parkinson's disorder -- Abstract Number: 1346 --Abstract Category: Parkinson's Disease: Pharmacology and Therapy. International Congress of Parkinson's Disease and Movement Disorders.

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)
Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878

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 25,000 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.

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)
Regd. Office : 'Zydus Corporate Park',
Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar),
Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382
481, Gujarat, India. | Phone : +91-79-71800000,
+91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878