

Zydus Lifesciences receives approval for the name ‘Usnoflast’ as recommended name for ZYIL1 from the WHO International Non-proprietary Names (INN)

- *Usnoflast (ZYIL1) is a novel oral small molecule NLRP3 inhibitor discovered at Zydus Research Centre, the R&D arm of Zydus Lifesciences Ltd.*
- *Usnoflast is under clinical development in 4 indications : Cryopyrin-Associated Periodic Syndromes (CAPS), Amyotrophic Lateral Sclerosis (ALS), Parkinson’s disease and Ulcerative Colitis*

Ahmedabad, April 1, 2024

Zydus, a leading discovery-based, global pharmaceutical company, announced today that it has received approval from WHO International Non-proprietary Names (INN) for “Usnoflast” as the recommended name for ZYIL1. The INN system aims to provide healthcare professionals with a unique and universal designated name for each pharmaceutical substance.

Usnoflast (ZYIL1) is a novel oral small molecule NLRP3 inhibitor discovered at Zydus. Studies have demonstrated that ZYIL1 is highly potent in human whole blood assay and can suppress inflammation caused by the NLRP3 inflammasome. ZYIL1 was found distributed in the brain and CSF of various nonclinical species including mice, rats and non-human primates. The efficacy of Usnoflast (ZYIL1) has been established in several validated pre-clinical models of neuroinflammation, Parkinson’s disease, Inflammatory Bowel Disease (IBD) and Multiple Sclerosis (MS). The candidate, Usnoflast (ZYIL1), has an acceptable ADME profile, with a good safety margin. In Phase I studies, ZYIL1 was found to be safe and well-tolerated [NCT04731324, NCT04972188].

The Chairman of Zydus Lifesciences, Mr. Pankaj Patel said, “In keeping with our mission of creating healthier communities globally, we discovered the novel oral NLRP3 inhibitor ‘Usnoflast’ with potential to provide “Pipeline-in-a-pill” treatment owing to the number of different patient populations NLRP3 mechanism can target. We are currently conducting clinical development in indications including rare autoinflammatory diseases, neurological diseases like Amyotrophic Lateral Sclerosis (ALS), Parkinson’s Disease, as well as Ulcerative Colitis”.

Zydus was the first to establish the Phase 2 proof-of-concept in Cryopyrin-associated periodic syndromes (CAPS) patients [NCT05186051], and published the Phase 2 results in ‘Clinical Pharmacology in Drug Development’. The USFDA has granted Zydus an ‘Orphan Drug Designation’

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for Usnoflast (ZYIL1) to treat patients with Cryopyrin Associated Periodic Syndrome (CAPS), a rare auto-inflammatory disease.

Usnoflast (ZYIL1) is under Phase 2 clinical trial in patients with Amyotrophic Lateral Sclerosis (ALS) [ClinicalTrials.gov Identifier: NCT05981040]. ALS affects approximately 31,000 people in the U.S.A. and on average 5,000 new patients are diagnosed every year with this disease in USA as per statistics from Centers for Disease Control and Prevention (CDC). More than 30,000 people are estimated to be living with ALS in Europe (European Union and United Kingdom), while India has an estimated 75,000 people living with ALS. People living with ALS have a median survival of approximately two years from diagnosis.

Zydus has initiated Phase 2 proof-of-concept study in patients with Ulcerative Colitis [CTRI/2024/02/062456]. Ulcerative Colitis is characterized by an irregular, chronic immune response that creates inflammation and ulcers in the mucosa of the large intestine or rectum. In 2023, the prevalence of ulcerative colitis was estimated to be 5 million cases around the world, and the incidence is increasing worldwide [The Lancet, (2023), 402, 10401, 571-584, DOI : [https://doi.org/10.1016/S0140-6736\(23\)00966-2](https://doi.org/10.1016/S0140-6736(23)00966-2)].

Usnoflast (ZYIL1) has also received permission from USFDA, to initiate the Phase II clinical study in patients with Parkinson's disease. 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 USA. Each year 90,000 new cases of Parkinson's disease are reported in the USA. Analysts estimate that the treatment costs of Parkinson's disease amounts to almost USD 52 billion every year, and by 2037 this disease is estimated to touch U.S. \$80 billion every year.

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 ID NCT05981040. A Phase 2, Proof-of-concept, Placebo Controlled, Randomized, Multi-centre, Double Blind Study of ZYIL1 to Evaluate



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- the Efficacy, Safety, Tolerability, Pharmacokinetics and Pharmacodynamics in Patients With Amyotrophic Lateral Sclerosis (ALS)
5. 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. CTRI Identifier : CTRI/2024/02/062456. A randomised, double blind, parallel, interventional phase IIa proof of concept trial to evaluate the efficacy and safety of ZYIL1 for the treatment of patients with mild to moderately active Ulcerative Colitis resistant or intolerant to oral aminosalicylates.
 7. 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.
 8. 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.
 9. Recommended INN: List 91. International Nonproprietary Names for Pharmaceutical Substances (INN). WHO Drug Information, Vol. 38, No. 1, 2024.

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 26,000 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.

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