March 21, 2023

BSE Limited **Code: 532321**
1st Floor,
P J Towers,
Dalal Street,
Mumbai-400001

National Stock Exchange of India Limited **Code: Zyduslife**
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated March 21, 2023 titled **"Zydus granted Orphan Drug Designation by the USFDA for ZYIL1 in treatment of patients with Cryopyrin Associated Periodic Syndrome (CAPS)"**.

The contents of the press release give full details.

Please bring the aforesaid news to the notice of the members of the exchange and the investors' at large.

Thanking you,

Yours faithfully,
For, **ZYDUS LIFESCIENCES LIMITED**

DHAVAL NARENDRA SONI
Digitally signed by DHAVAL NARENDRA SONI
Date: 2023.03.21 10:12:03 +05'30'

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

Zydus granted Orphan Drug Designation by the USFDA for ZYIL1 in treatment of patients with Cryopyrin Associated Periodic Syndrome (CAPS)

- *Orphan drug designation by USFDA for ZYIL1, provides eligibility for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and seven-year marketing exclusivity upon FDA approval.*

Ahmedabad, India, 21 March 2023

Zydus Lifesciences Ltd. (formerly known as Cadila Healthcare Ltd.), a discovery-driven, global lifesciences company today announced that the United States Food and Drug Administration (USFDA) has granted 'Orphan Drug Designation' (ODD) to ZYIL1, for treatment of patients with Cryopyrin Associated Periodic Syndrome (CAPS). The FDA's Office of Orphan Drug Products grants orphan status to support development of medicines for the treatment of rare diseases that affect fewer than 200,000 people in the United States.

ZYIL1 is a novel oral small molecule NLRP3 inhibitor which has demonstrated CSF penetration in non-human primates. In September 2022, Zydus had announced positive Phase 2 proof-of-concept (POC) study in CAPS patients, and publication of Phase 1 study results in Clinical Pharmacology in Drug Development, supporting the advancement of ZYIL1 into pivotal clinical trials in CAPS patients.

Mr. Pankaj R. Patel, Chairman, Zydus Lifesciences Ltd., said, "This Orphan Drug Designation from the USFDA underlines the urgent need to develop ZYIL1 to address this rare and critical chronic inflammatory condition CAPS, a high unmet medical need. ZYIL1 demonstrated Phase 2 proof-of-concept in CAPS patients showing rapid clinical improvement as early as day 3 which sustained till the end of the treatment, in addition to the improvement in inflammatory markers like Serum Amyloid A (SAA), CRP, IL-6. There were no Serious Adverse Events (SAE's) observed."

CAPS is a rare, life-long auto-inflammatory condition, caused by NLRP3 activating mutations 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.

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

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 group 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 life-sciences 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