April 20, 2024

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 April 20, 2024 titled **"Sentynl Therapeutics receives marketing authorization for NULIBRY® (fosdenopterin) from the UK MHRA for treatment of MoCD Type A"**.

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: 2024.04.20 15:19:57 +05'30'

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

Sentynl Therapeutics receives marketing authorization for NULIBRY® (fosdenopterin) from the UK MHRA for treatment of MoCD Type A

- *NULIBRY® is the first and only treatment in the United Kingdom (UK) for patients with Molybdenum Cofactor Deficiency (MoCD) Type A. MoCD Type A is an ultra-rare, life-threatening genetic disorder that often progresses rapidly in infants with a median overall survival age of about four years.*
- *NULIBRY® has also received an Orphan Drug status from the UK MHRA*
- *NULIBRY® is already approved by the FDA in the US and it also has an Orphan Drug designation.*

Ahmedabad, April 20, 2024

Zydus Lifesciences Ltd. (Zydus), today announced that its wholly-owned subsidiary Sentynl Therapeutics, Inc. (Sentynl), has received marketing authorisation from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for NULIBRY® (fosdenopterin) for Injection as the first therapy for the treatment of patients in Great Britain (GB) with Molybdenum Cofactor Deficiency (MoCD) Type A. This is an ultra-rare, life-threatening genetic disorder that often progresses rapidly in infants. It is known to impact fewer than 150 patients globally with a median survival age of four years.

NULIBRY® is a first-in-class synthetic cPMP substrate replacement therapy that was approved by the U.S. Food and Drug Administration (FDA) in 2021 to reduce the risk of mortality in patients with MoCD Type A. Following this decision by the UK MHRA, NULIBRY® is the first and only approved therapy in GB for MoCD Type A.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Zydus Lifesciences Ltd., said, "We are happy that with the UK MHRA approval of NULIBRY® which will enable access to this critical drug and treat an ultra-rare disorder. Healthcare providers in Great Britain can now bridge the unmet needs of patients with this innovative treatment."

Matt Heck, President & Chief Executive Officer of Sentynl said, "This approval advances our mission to make a positive impact in the lives of patients suffering from rare diseases, especially one as devastating as MoCD Type A."

NULIBRY®'s MHRA approval was supported by data from three clinical trials that demonstrated the safety and efficacy of NULIBRY for the treatment of patients with MoCD Type A compared to data from a natural history study. These studies showed that NULIBRY-treated patients had a 5.5 times lower risk of death than that of the untreated patients. Moreover, the survival probability at 3 years of age was 85.5% for NULIBRY®-treated patients and 55.1% for untreated control patients.

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

In March 2022, Sentynl acquired the global rights to NULIBRY® from BridgeBio Pharma, Inc. and is responsible for the ongoing development, manufacturing and commercialization of fosdenopterin globally.

About Molybdenum Cofactor Deficiency (MoCD) Type A

MoCD Type A is an autosomal recessive, inborn error of metabolism caused by mutations in the molybdenum cofactor synthesis 1 gene and characterized by a deficiency in molybdenum cofactor production, leading to a lack of molybdenum-dependent enzyme activity.1,2 The lack of activity leads to decreased sulfite oxidase activity with buildup of sulfite and secondary metabolites (such as S-sulfocysteine) in the brain, which causes irreversible neurological damage.2

MoCD Type A is an ultra-rare disease. The incidence and prevalence of MoCD Type A in Great Britain are not known, but the estimated prevalence is 0.005 per 10,000. Based on these estimates, MoCD Type A is likely to be underdiagnosed.

The most common presenting symptoms of MoCD Type A are seizures, feeding difficulties and encephalopathy. Patients with MoCD Type A who survive beyond infancy typically suffer from progressive brain damage, which presents in characteristic patterns on magnetic resonance imaging (MRI). This damage leads to severe psychomotor impairment and an inability to make coordinated movements or communicate with their environment.

About NULIBRY® (fosdenopterin) for Injection

NULIBRY® (fosdenopterin) for Injection is a substrate replacement therapy that provides a synthetic source of cPMP, which is converted to molybdopterin. Molybdopterin is then converted to molybdenum cofactor, which is needed for the activation of molybdenum-dependent enzymes, including sulfite oxidase, an enzyme that reduces levels of neurotoxic sulfites. NULIBRY® was approved by the U.S. FDA in February 2021, and by the Israel Ministry of Health in July 2022 and is indicated to reduce the risk of mortality in patients with MoCD Type A. NULIBRY® was also approved by the EMA in September 2022, with an indication for treatment of patients with MoCD Type A.

References

1 Mechler K et al. Genet Med. 2015;17(12):965-970.

2 Schwarz G. Cur Op in Che Bio. 2016;31:179-187.

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About Zydus Group

Zydus Lifesciences Limited 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 has a significant presence in cancer related therapies and offers a wide range of solutions with cytotoxic, supportive & targeted drugs. The group employs over 26,000 people worldwide, including 1,400 scientists engaged in R & D, 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 information, visit https://www.zyduslife.com/zyduslife/.

About Sentynl Therapeutics

Sentynl Therapeutics is a U.S.-based biopharmaceutical company focused on bringing innovative therapies to patients living with rare diseases. The company was acquired by the Zydus Group in 2017. Sentynl's experienced management team has previously built multiple successful pharmaceutical companies. With a focus on commercialization, Sentynl looks to source effective and well-differentiated products across a broad spectrum of therapeutic areas to address unmet needs. Sentynl is committed to the highest ethical standards and compliance with all applicable laws, regulations and industry guidelines. For more information, visit https://sentynl.com.

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