December 15, 2025

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

National Stock Exchange of India Limited **Code: Zyduslife**
Exchange Plaza,
C/1, Block G,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated December 15, 2025, titled **"Sentynl Therapeutics Announces FDA Acceptance of CUTX-101 NDA Resubmission"**.

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.

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

DHAVAL NARENDRA SONI
Digitally signed by DHAVAL NARENDRA SONI
Date: 2025.12.15 18:10:09 +05'30'

DHAVAL N. SONI
COMPANY SECRETARY AND COMPLIANCE OFFICER
MEMBERSHIP NO. FCS7063

Encl.: As above

Sentynl Therapeutics Announces FDA Acceptance of CUTX-101 NDA Resubmission

The investigational copper histidinate candidate receives new PDUFA

Target Action Date of January 14, 2026

Solana Beach, CA – December 15, 2025 – Sentynl Therapeutics, Inc. ("Sentynl"), a U.S.-based biopharmaceutical company wholly-owned by Zydus Lifesciences, Ltd. ("Zydus Group"), today announced that the U.S. Food and Drug Administration (FDA) has accepted the resubmission of its New Drug Application ("NDA") for copper histidinate (CUTX-101), intended to treat Menkes disease in pediatric patients. The resubmission has been accepted as a Class I response and as a result, the Company has received January 14, 2026 as the new PDUFA date.

"We appreciate the Agency's partnership and commitment to expeditiously reviewing our NDA resubmission," said Matt Heck, CEO, Sentynl. "The acceptance of the application brings us one step closer to a milestone for patients and families who are living with Menkes disease."

Sentynl resubmitted its revised NDA on November 14, 2025 after receiving a complete response letter (CRL) from the FDA on September 30, 2025, which cited observations regarding the manufacturing site's cGMP compliance. The CRL did not cite any other approvability concerns, nor did it identify any deficiencies in CUTX-101's efficacy and safety data, which demonstrate improvement in overall survival for Menkes disease subjects who received early treatment with the therapy.

If approved, CUTX-101 will be the first and only FDA approved treatment available for Menkes disease, a rare X-linked recessive pediatric genetic disease that impacts an estimated 1 in 34,810 to as high as 1 in 8,664 live male births. (Estimated birth prevalence of Menkes disease and ATP7A-related disorders based on the Genome Aggregation Database (gnomAD)).

About CUTX-101 (Copper Histidinate)
CUTX-101 is an investigational drug currently under NDA review with the U.S. FDA to treat patients with Menkes disease. CUTX-101 is a subcutaneous injectable formulation of copper histidinate manufactured under current good manufacturing practice ("cGMP") that is intended to improve tolerability due to its physiological pH. In a Phase 1/2 clinical trial conducted by Stephen G. Kaler, M.D., M.P.H., at the National Institutes of Health ("NIH"), early treatment of patients with Menkes disease with CUTX-101 led to an improvement in neurodevelopmental outcomes and survival. Cyprium previously reported positive topline clinical efficacy results for CUTX-101, demonstrating statistically significant improvement in overall survival for Menkes disease subjects who received early treatment (ET) with CUTX-101, compared to an untreated historical control cohort, with a nearly 80% reduction in the risk of death. Median overall survival (OS) was 177.1 months for CUTX-101 ET cohort compared to 16.1 months for the untreated historical control cohort. (Copper Histidinate Treatment for Menkes Disease (Kinky Hair Syndrome) | Pediatrics | American Academy of Pediatrics) CUTX-101 has been granted FDA Breakthrough Therapy, Fast Track, Rare Pediatric Disease and FDA Orphan Drug Designations. Additionally, the European Medicines Agency granted Orphan Designation for CUTX-101. An expanded access protocol for patients with Menkes disease is ongoing at multiple U.S. medical centers. (Study Details | NCT04074512 | Copper Histidinate Treatment for Menkes Disease | ClinicalTrials.gov)

About Menkes Disease
Menkes disease is a rare X-linked recessive pediatric disease caused by gene mutations of the copper transporter ATP7A. The minimum birth prevalence for Menkes disease is believed to be 1 in 34,810 live

male births, and potentially as high as 1 in 8,664 live male births, based on recent genome-based ascertainment. (Estimated birth prevalence of Menkes disease and ATP7A-related disorders based on the Genome Aggregation Database (gnomAD)). The condition is characterized by distinctive clinical features, including sparse and depigmented hair ("kinky hair"), connective tissue problems, and severe neurological symptoms such as seizures, hypotonia, failure to thrive, and neurodevelopmental delays. Mortality is high in untreated Menkes disease, with many patients dying between 2-3 years of age. (Early clinical signs and treatment of Menkes disease - ScienceDirect). Milder versions of ATP7A mutations are associated with conditions other than Menkes Disease, such as Occipital Horn Syndrome and *ATP7A*-related Distal Motor Neuropathy.

About Zydus Lifesciences Limited

Zydus Lifesciences Limited is an innovation-led life-sciences company with leadership positions across pharmaceuticals and consumer wellness, supported by an emerging MedTech franchise and a global footprint across the United States, India and other international markets. As of September 30, 2025, the group employs 27,000 people worldwide, including 1,500 scientists engaged in R&D, 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

About Sentynl Therapeutics

Sentynl Therapeutics, Inc. ("Sentynl") is a commercial stage U.S.-based biopharmaceutical company focused on bringing innovative therapies to patients living with rare diseases. Recognized for its commitment to the rare disease community, Sentynl leverages its global operations as well as its parent organization, Zydus Group, to advance the development, manufacturing, and delivery of treatments to patients who need them in numerous countries worldwide. Sentynl is dedicated to improving patient outcomes and access while upholding ethical standards and operating in compliance with applicable laws, regulations, and industry guidelines. For more information, visit https://sentynl.com.

Contacts

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