October 1, 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 October 1, 2025, titled **"Sentynl Therapeutics updates on its NDA for CUTX-101"**.

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: 2025.10.01 17:43:23 +05'30'

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

Encl.: As above

Sentynl Therapeutics updates on its NDA for CUTX-101

Solana Beach, CA – OCTOBER 1, 2025 – Sentynl Therapeutics, Inc. ("Sentynl"), a U.S.-based biopharmaceutical company wholly-owned by Zydus Lifesciences, Ltd. ("Zydus"), announced today that the U.S. Food and Drug Administration (USFDA) has issued a Complete Response Letter (CRL) relating to its New Drug Application (NDA) for copper histidinate (CUTX-101), intended to treat Menkes disease in pediatric patients.

The USFDA provided findings within the CRL that Sentynl and Zydus Lifesciences will need to address to clarify the path forward. Specifically, the USFDA mentioned a CGMP inspection of the facility where CUTX-101 is manufactured. Zydus recently provided responses to USFDA's September 2025 re-inspection demonstrating the facility's CGMP compliance and is awaiting USFDA's Establishment Inspection Report (EIR). Sentynl will request a meeting with USFDA to discuss the CRL and resubmission of the CUTX-101 NDA. The CRL did not cite any other approvability concerns, nor did it identify any deficiencies in CUTX-101's efficacy and safety data.

"We recognize the USFDA's decision and remain dedicated to working with the Agency to clarify next steps. Our commitment to patients is unchanged. We believe in the promise of our therapy and are prepared to address the feedback and pursue resubmission promptly," said Matt Heck, CEO, Sentynl.

Menkes disease is 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.[1] Patients with Menkes disease are born with the inability to absorb dietary copper and subsequently have impaired copper transport across the blood-brain barrier.[1,2] CUTX-101 is a subcutaneous injectable formulation of copper histidinate that restores copper homeostasis and maintains copper levels in patients with Menkes disease.

The CUTX-101 NDA was initially granted Priority Review by the FDA and is supported by positive topline clinical efficacy results for CUTX-101, demonstrating significant improvement in overall survival for Menkes disease subjects who received early treatment with CUTX-101.

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[1]. 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. Milder versions of *ATP7A* mutations are associated with other conditions, including Occipital Horn Syndrome and *ATP7A*-related Distal Motor Neuropathy.

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 deep 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 transformative treatments to patients who need them in numerous countries worldwide. Sentynl is dedicated to improving patient outcomes and access while upholding the highest ethical standards and operating in full compliance with all applicable laws, regulations, and industry guidelines. For more information, visit https://sentynl.com.

About Zydus Group

Zydus Lifesciences Ltd. with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global life sciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 29,000 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 information, visit https://www.zyduslife.com/zyduslife.

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