October 8, 2021

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

National Stock Exchange of India Limited **Code: Cadilahc**
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 October 8, 2021 titled "**Fortress Biotech and Cyprium Therapeutics with support from its licensing partner Sentynl Therapeutics, Inc. a wholly owned subsidiary of Cadila Healthcare Limited ("Zydus") Announce Positive Clinical Data for CUTX-101, Copper Histidinate for the treatment of Menkes Disease**".

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, **CADILA HEALTHCARE LIMITED**

DHAVAL NARENDRA SONI
Digitally signed by DHAVAL NARENDRA SONI
Date: 2021.10.08 16:57:06 +05'30'

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

Fortress Biotech and Cyprium Therapeutics Announce Positive Clinical Data for CUTX-101, Copper Histidinate, Presented at 2021 American Academy of Pediatrics National Conference & Exhibition

Cyprium Therapeutics, a partner company of Fortress Biotech, is developing CUTX-101 for the treatment of Menkes disease

Overall survival significantly improved in patients treated with CUTX-101

Rolling submission of New Drug Application to the FDA for CUTX-101 planned to begin in fourth quarter of 2021; potential to be first FDA-approved treatment for Menkes disease

New York, NY, and Solana Beach, CA, October 8, 2021 – Cyprium Therapeutics, Inc. ("Cyprium"), a Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress") partner company, with support from its licensing partner Sentynl Therapeutics, Inc. ("Sentynl"), a wholly owned subsidiary of Cadila Healthcare Limited ("Zydus"), today announced positive results from an efficacy and safety analysis of data integrated from two completed pivotal studies in patients with Menkes disease treated with CUTX-101, copper histidinate (CuHis). In both pre-specified primary and secondary efficacy analyses, treatment with CUTX-101 demonstrated a significantly greater median overall survival (OS) compared to untreated historical control patients. These data will be presented as a virtual poster at the 2021 American Academy of Pediatrics National Conference & Exhibition. More information on the poster is listed below:

Virtual Poster Title: Copper Histidinate Treatment for Menkes Disease (Kinky Hair Syndrome)
Presentation Date: Friday, October 08, 2021
Session: (VH1410) Section on Advances in Therapeutics and Technology Program
Authors: Stephen G. Kaler, M.D., M.P.H., Shama Munim, M.S., Michael Chen, Ph.D., Robert Niecestro, Ph.D., Lung S. Yam, M.D., Ph.D.

"There is a significant unmet need for an approved treatment for patients with Menkes disease. These positive data demonstrate the potential of CUTX-101 to be an effective therapy for patients with this devastating disease. We look forward to working with the U.S. Food and Drug Administration ("FDA") to begin our rolling submission of a new drug application ("NDA") for CUTX-101 in the fourth quarter of this year," said Lung S. Yam, M.D., Ph.D., President and Chief Executive Officer of Cyprium.

In two completed open-label, single-arm, single-site studies, 129 patients with Menkes disease were treated with CUTX-101 (1450 mcg CUTX-101, equivalent to 250 mcg elemental copper) administered subcutaneously twice daily until 12 months of age, and once daily thereafter, for a total duration of up to three years. Sixty-six patients born after 1999 and with severe loss-of-function *ATP7A* mutations from these two studies were combined and categorized into an Early Treatment cohort (CuHis-ET; treatment initiated within 4 weeks of birth, corrected for prematurity, n=31) and a Late Treatment cohort (CuHis-LT; treatment initiated after 4 weeks of birth, n=35). A historical control cohort of 18 Menkes disease patients who had not been treated with CUTX-101 were enrolled (including 18 in historical control-early treatment cohort (HC-ET); 17 of whom were also included in historical control-late treatment (HC-LT)). Efficacy of CUTX-101 was assessed by comparing CuHis-ET to untreated HC-ET, and CuHis-LT to untreated HC-LT, using OS as the primary and secondary efficacy endpoints, respectively.

The primary efficacy endpoint comparing CuHis-ET to HC-ET and the secondary efficacy endpoint comparing CuHis-LT to HC-LT were both met. Overall, a 79% reduction in risk of death was observed in CuHis-ET patients compared with HC-ET patients and median OS was 177.1 and 16.1 months, respectively with a hazard ratio (HR) of (95% CI) = 0.208 (0.094, 0.463) $p<0.0001$. A 75% reduction in the risk of death was also observed in CuHis-LT patients compared with HC-LT subjects and median OS was 62.4 and 17.6 months, respectively; HR (95% CI) = 0.253 (0.119, 0.537); $p<0.0001$.

Clinical benefit was greater for patients who were treated within four weeks of birth with CUTX-101, emphasizing the importance of early identification, including newborn screening and prompt initiation of treatment. A newborn screening test for Menkes disease is currently in development.

CUTX-101 was shown to be well tolerated. In CuHis-ET and CuHis-LT cohorts, the most common treatment emergent adverse events were pneumonia (30.3%), seizures (21.2%), dehydration (18.2%), failure to thrive (16.7%), and respiratory distress (15.2%) and no patient discontinued due to an adverse event considered related to treatment.

Stephen G. Kaler, M.D., M.P.H., a physician-scientist in the Center for Gene Therapy in the Abigail Wexner Research Institute at Nationwide Children's Hospital, is Principal Investigator of the clinical studies and is also a professor of Pediatrics and Genetics at The Ohio State University College of Medicine.

"We are grateful to the patients and their families who have participated in the clinical studies over the years. We would also like to thank Dr. Kaler for his ongoing efforts and dedication to improving therapies for this devastating pediatric disease. We commend the Cyprium team who has worked diligently to advance the CUTX-101 program and will remain steadfast and focused on bringing this therapy to patients," said Dr. Yam.

Cyprium has partnered with Sentynl Therapeutics, Inc., a U.S.-based specialty pharmaceutical company owned by the Zydus Group, to bring CUTX-101 to market. Cyprium will retain development responsibility of CUTX-101 through approval of the NDA by the FDA, and Sentynl will be responsible for commercialization of CUTX-101 as well as progressing newborn screening activities.

"We are encouraged by the clinical data presented at the 2021 American Academy of Pediatrics National Conference & Exhibition and are excited to continue to support Cyprium's efforts to advance CUTX-101 through NDA approval as we parallel significant efforts in Disease Awareness education and Newborn Screening. These developments support the group's ongoing endeavor to address unmet healthcare needs," said Matthew Heck, President and Chief Executive Officer of Sentynl.

About Menkes Disease

Menkes disease is a rare X-linked recessive pediatric disease caused by gene mutations of 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 (Kaler SG, Ferreira CR, Yam LS. Estimated birth prevalence of Menkes disease and *ATP7A*-related disorders based on the Genome Aggregation Database (gnomAD). Molecular Genetics and Metabolism Reports 2020 June 5;24:100602). 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 before the age of three years old. Milder versions of *ATP7A* mutations are associated with other conditions, including Occipital Horn Syndrome and *ATP7A*-related Distal Motor Neuropathy. Currently, there is no FDA-approved treatment for Menkes disease and its variants.

About CUTX-101 (Copper Histidinate)
CUTX-101 is in clinical development to treat patients with Menkes disease. CUTX-101 is a subcutaneous injectable formulation of Copper Histidinate manufactured under current good manufacturing practice ("cGMP") and 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. In August 2020, Cyprium 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 (HC) cohort, with a nearly 80% reduction in the risk of death. A Cyprium-sponsored expanded access protocol for patients with Menkes disease is ongoing at multiple U.S. medical centers.

About Cyprium Therapeutics
Cyprium Therapeutics, Inc. ("Cyprium") is focused on the development of novel therapies for the treatment of Menkes disease and related copper metabolism disorders. In March 2017, Cyprium entered into a Cooperative Research and Development Agreement ("CRADA") with the Eunice Kennedy Shriver National Institute of Child Health and Human Development ("NICHD"), part of the NIH, to advance the clinical development of CUTX-101 (Copper Histidinate injection) for the treatment of Menkes disease. In addition, Cyprium and NICHD entered into a worldwide, exclusive license agreement to develop and commercialize adeno-associated virus (AAV)-based gene therapy, called AAV-ATP7A, to deliver working copies of the copper transporter that is defective in patients with Menkes disease, and to be used in combination with CUTX-101. CUTX-101 was granted FDA Breakthrough Therapy, Fast Track and Rare Pediatric Disease Designations, and both CUTX-101 and AAV-ATP7A have received FDA Orphan Drug Designation previously. Additionally, the European Medicines Agency previously granted Orphan Drug Designation to CUTX-101. Cyprium was founded by Fortress Biotech, Inc. (Nasdaq: FBIO) and is based in New York City. For more information, visit www.cypriumtx.com.

About Fortress Biotech
Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company that was ranked in Deloitte's 2019 and 2020 Technology Fast 500™, annual rankings of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentages of fiscal year revenue growth over three-year periods. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has seven marketed prescription pharmaceutical products and over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and at partners it founded and in which it holds significant minority ownership positions. Such product candidates span six large-market areas, including oncology, rare diseases and gene therapy, which allow it to create value for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand the company's portfolio of product opportunities. Fortress has established partnerships with some of the world's leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including Alexion Pharmaceuticals, Inc., AstraZeneca, City of Hope, Fred Hutchinson Cancer Research Center, St. Jude Children's Research Hospital, Nationwide Children's Hospital and Sentynl Therapeutics, Inc. For more information, visit www.fortressbiotech.com.

About Sentynl Therapeutics
Sentynl Therapeutics is a San Diego-based commercial-stage specialty pharma company that specializes in acquiring, developing and launching unique products. The company was acquired by the Zydus Group in 2017. Sentynl's highly experienced and knowledgeable 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. Sentynl is committed to the highest ethical standards and compliance with all applicable laws, regulations, and industry guidelines. For more information, visit www.sentynl.com.

About Zydus
Zydus is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics and vaccines. The group employs over 23,000 people worldwide, including 1,400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. For more information, visit www.zyduscadila.com.

Forward-Looking Statements
This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this press release, the words "we", "us" and "our" may refer to Fortress individually or together with one or more partner companies, as dictated by context. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees' and consultants' ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

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