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Cyprium Therapeutics, a Fortress Biotech Subsidiary Company, Completes Asset Transfer of CUTX-101 Copper Histidinate Product Candidate for Treatment of Menkes Disease, to Sentynl Therapeutics, a Wholly-owned Subsidiary of Zydus Lifesciences Ltd.

Cyprium received $4.5 million payment upon closing and remains eligible to receive royalties and up to $129 million in aggregate development and sales milestones

Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101

MIAMI, Dec. 06, 2023 (GLOBE NEWSWIRE) -- Cyprium Therapeutics, Inc. ("Cyprium"), a Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress") subsidiary company, today announced that it executed an Assignment and Assumption Agreement (the "Agreement") with Sentynl Therapeutics, Inc. ("Sentynl"), a U.S.-based specialty pharmaceutical company wholly owned by the Zydus Lifesciences Ltd., in which, Cyprium completed the transfer of its proprietary rights and assigned its FDA documents pertaining to CUTX-101, Copper Histidinate product candidate for the treatment of Menkes disease, to Sentynl.

Cyprium received $4.5 million at closing and remains eligible to receive up to $129 million in aggregate development and sales milestones under the Agreement, in addition to royalties on net sales of CUTX-101 as follows: (i) 3% of annual net sales up to $75 million; (ii) 8.75% of annual net sales between $75 million and $100 million; and (iii) 12.5% of annual net sales in excess of $100 million. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

"We are pleased to complete the CUTX-101 asset transfer with Sentynl. Cyprium has made progress with the CUTX-101 rolling NDA submission, and we expect that Sentynl will complete the filing in 2024. The transfer of the CUTX-101 program to Sentynl will result in a reduction in Cyprium's development-related spend, while potentially expediting commercialization upon FDA approval. The drug has demonstrated a compelling safety and

efficacy profile for the treatment of Menkes disease and, if approved, CUTX-101 will fill a significant unmet need for children suffering from this rare, fatal pediatric disease," said Fortress' Chairman, President and Chief Executive Officer and Cyprium's Chairman, Lindsay A. Rosenwald, M.D.

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. 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. 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 Drug Designation for CUTX-101. A Cyprium-sponsored expanded access protocol for patients with Menkes disease is ongoing at multiple U.S. medical centers and will be administered by Sentynl subsequent to the transfer.

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 two 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 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 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 2023, Cyprium completed the transfer of its proprietary rights and assigned its FDA documents pertaining to CUTX-101 Copper Histidinate product candidate for the treatment of Menkes disease, to Sentynl Therapeutics, Inc. Cyprium and NICHD also previously 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; AAV-ATP7A gene therapy is currently in pre-clinical development. 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 Miami. For more information, visit www.cypriumtx.com.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company focused on efficiently acquiring, developing and commercializing or monetizing promising therapeutic products and product candidates. The company has eight marketed prescription pharmaceutical products and over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and subsidiaries and at partners and subsidiaries 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 focused on leveraging its significant biopharmaceutical industry expertise and network 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 AstraZeneca, City of Hope, Fred Hutchinson Cancer Center, St. Jude Children's Research Hospital, Nationwide Children's Hospital and Sentynl. For more information, visit www.fortressbiotech.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, ability to generate shareholder value, ability of our products to receive necessary approvals, including FDA approval, ability of our products and therapies to help patients 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; financing and strategic agreements and relationships; Sentynl's ability to successfully develop and obtain regulatory approval for CUTX-101; our need for substantial additional funds and uncertainty relating to financings; our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis; our ability to attract, integrate and retain key personnel; the early stage of products under development; 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; the ability to secure and maintain third-party manufacturing, marketing and distribution of our and our partner companies' products and product candidates; 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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