September 17, 2024

Capricor Therapeutics Signs Binding Term Sheet with Nippon Shinyaku for European Expansion and Commercialization of Deramiocel for the Treatment of Duchenne Muscular Dystrophy

-Capricor to Receive $15 Million Equity Investment at a 20% Premium, as well as $20 Million Upfront Payment upon Signing Definitive Agreement with up to $715 Million in Potential Milestones and a Double-Digit Percentage of Product Revenue-

-Upfront Payment and Investment Extends Cash Runway into 2026-

-Potential Milestones from Combined Distribution Agreements Now Total approximately $1.5 Billion-

-Capricor Preparing to Meet with EMA to Discuss European Expansion for Deramiocel-

SAN DIEGO, Sept. 17, 2024 (GLOBE NEWSWIRE) -- Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for the treatment of rare diseases, today announced it has entered into a binding term sheet with Nippon Shinyaku Co., Ltd., a Japanese pharmaceutical company listed on the TYO, for the commercialization and distribution in Europe of Capricor's lead asset, deramiocel, for the treatment of Duchenne muscular dystrophy (DMD), a rare neuromuscular disease with limited treatment options. The potential transaction covered by the term sheet is similar to the existing Commercialization and Distribution Agreements with Nippon Shinyaku in the United States and Japan with an opportunity for further product reach globally. In addition, Nippon Shinyaku has agreed to purchase approximately $15 million of Capricor common stock at a 20% premium to the 60-day VWAP.

Under the terms of the binding term sheet and further subject to finalization of a Definitive Agreement, which is expected to occur in the fourth quarter of 2024, Capricor will be responsible for the development and manufacturing of deramiocel for potential approval in all countries in the European Union, United Kingdom and several other countries in the region. Nippon Shinyaku will be responsible for the sales and distribution of deramiocel in those territories. Capricor will also receive an upfront payment of $20 million subject to execution of the Definitive Agreement and there are potential additional development and sales-based milestone payments to Capricor of up to $715 million and Capricor will receive a double-digit share of product revenue.

"Our expanded partnership with Nippon Shinyaku into the European region marks a pivotal

moment for Capricor as we work together to bring deramiocel to DMD patients worldwide," said Linda Marbán, Ph.D., Capricor's Chief Executive Officer. "With the addition of the upfront payment and equity investment, we will be able to extend our runway into 2026 and be well positioned to advance toward potential approval of deramiocel in the United States and beyond. Furthermore, these funds will provide necessary capital for commercial launch preparations, manufacturing scale-up and product development for Europe, as we envision high global demand for deramiocel."

Dr. Marbán continued, "As previously reported, we held a successful pre-BLA meeting with the U.S. Food and Drug Administration (FDA) in August. Since that meeting, we have now had several additional informal meetings with the agency to continue to refine our approval pathway for deramiocel in the United States and we plan to provide further updates as they become available."

Toru Nakai, President of Nippon Shinyaku, commented, "We look forward to building deramiocel's commercial footprint around the world and this partnership would allow us to continue to invest in Nippon Shinyaku's DMD franchise and to potentially advance life-changing therapies for patients in need."

Contemporaneously with the term sheet, Nippon Shinyaku has also agreed to purchase 2,798,507 shares of common stock at a price of $5.36 per share, which price represents a 20% premium to the 60-day volume-weighted average price (VWAP) of Capricor's common stock, for an aggregate purchase price of approximately $15 million. The closing of the offering is expected to take place on or about September 20, 2024. The Company expects to use the proceeds from the transaction primarily to support product development as well as general, administrative and corporate purposes.

The offer and sale of the foregoing securities are being made in a transaction not involving a public offering and have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or applicable state securities laws. Accordingly, the securities may not be reoffered or resold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act and such applicable state securities laws. As part of the transaction, the Company has agreed to file a registration statement with the Securities and Exchange Commission for purposes of registering the resale by the investors of the shares of common stock purchased by such investors.

This press release does not constitute an offer to sell or the solicitation of an offer to buy any securities. Any offering of the securities under the resale registration statement will only be by means of a prospectus.

About Deramiocel (CAP-1002)

Deramiocel consists of allogeneic cardiosphere-derived cells (CDCs), a population of stromal cells that have been shown in preclinical and clinical studies to exert potent immunomodulatory, antifibrotic and regenerative actions in dystrophinopathy and heart failure. CDCs act by secreting extracellular vesicles known as exosomes, which target macrophages and alter their expression profile so that they adopt a healing, rather than a pro-inflammatory, phenotype. CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 200 human subjects across

several clinical trials. Deramiocel for the treatment of DMD has received Orphan Drug Designation and the regulatory pathway for deramiocel is supported by RMAT (Regenerative Medicine Advanced Therapy Designation). In addition, if Capricor were to receive FDA marketing approval for deramiocel for the treatment of DMD, Capricor would be eligible to receive a Priority Review Voucher (PRV) based on its previous receipt of a rare pediatric disease designation.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a devastating genetic disorder characterized by progressive weakness and chronic inflammation of the skeletal, heart and respiratory muscles with mortality at a median age of approximately 30 years. It is estimated that DMD occurs in approximately one in every 3,500 male births and that the patient population is estimated to be approximately 15,000-20,000 in the United States. DMD pathophysiology is driven by the impaired production of functional dystrophin, which normally functions as a structural protein in muscle. The reduction of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. Treatment options are limited and there is no cure.

About Nippon Shinyaku

Based on Nippon Shinyaku's business philosophy, "Helping people lead healthier, happier lives," we aim to be an organization trusted by the community through creating unique medicines that will bring hope to patients and families suffering from illness. Please visit our website (https://www.nippon-shinyaku.co.jp/english/) for products or detailed information.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a biotechnology company dedicated to advancing transformative cell and exosome-based therapeutics to redefine the treatment landscape for rare diseases. At the forefront of our innovation is our lead product candidate, deramiocel (CAP-1002), an allogeneic cardiac-derived cell therapy. Extensive preclinical and clinical studies have shown deramiocel to demonstrate immunomodulatory, antifibrotic, and regenerative actions specifically tailored for dystrophinopathies and heart disease. Deramiocel is currently advancing through Phase 3 clinical development for the treatment of Duchenne muscular dystrophy. Capricor is also harnessing the power of its exosome technology, using its proprietary StealthX™ platform in preclinical development focused on the areas of vaccinology, targeted delivery of oligonucleotides, proteins and small molecule therapeutics to potentially treat and prevent a diverse array of diseases. At Capricor, we stand committed to pushing the boundaries of possibility and forging a path toward transformative treatments for those in need. For more information, visit capricor.com, and follow Capricor on Facebook, Instagram and Twitter.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release regarding the efficacy, safety, and intended utilization of Capricor's product candidates; the initiation, conduct, size, timing and results of discovery efforts and clinical trials; the pace of enrollment of clinical trials; plans regarding regulatory filings, future research and clinical trials; regulatory developments involving products, including the ability to obtain regulatory approvals or otherwise bring products to market;

manufacturing capabilities; dates for regulatory meetings; statements about our financial outlook; the ability to achieve product milestones and to receive milestone payments from commercial partners; plans regarding current and future collaborative activities and the ownership of commercial rights; potential future agreements; scope, duration, validity and enforceability of intellectual property rights; future revenue streams and projections; expectations with respect to the expected use of proceeds from the recently completed offerings and the anticipated effects of the offerings; and any other statements about Capricor's management team's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements that are not statements of historical fact (including statements containing the words "believes," "plans," "could," "anticipates," "expects," "estimates," "should," "target," "will," "would" and similar expressions) should also be considered to be forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by such forward-looking statements. More information about these and other risks that may impact Capricor's business is set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on March 11, 2024, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on August 8, 2024. All forward-looking statements in this press release are based on information available to Capricor as of the date hereof, and Capricor assumes no obligation to update these forward-looking statements.

Capricor has entered into an agreement for the exclusive commercialization and distribution of deramiocel (*CAP-1002) for DMD in the United States and Japan with Nippon Shinyaku Co., Ltd. (U.S. subsidiary: NS Pharma, Inc.), subject to regulatory approval. Deramiocel is an Investigational New Drug and is not approved for any indications. None of Capricor's exosome-based candidates have been approved for clinical investigation.*

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