June 25, 2024

CORRECTION: Capricor Therapeutics

SAN DIEGO, June 25, 2024 (GLOBE NEWSWIRE) -- In a release issued under the headline "Capricor Therapeutics Announces for the Treatment of Duchenne Muscular Dystrophy" on Tuesday, June 25th by Capricor Therapeutics, please note that the words "Pre-BLA Meeting with FDA for Deramiocel" were omitted from the headline. The corrected release follows.

Capricor Therapeutics Announces Pre-BLA Meeting with FDA for Deramiocel for the Treatment of Duchenne Muscular Dystrophy

Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for the treatment of rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has scheduled a Pre-BLA (Biologics License Application) meeting with the Company in the third quarter of 2024 for deramiocel (CAP-1002), for the treatment of Duchenne Muscular Dystrophy (DMD). Capricor's goal for this meeting will be to finalize its BLA filing plans based on all currently available data as well as to work with the FDA to outline the rolling BLA submission timeline.

"We continue to move rapidly towards potential approval of deramiocel for the treatment of DMD," said Linda Marbán, Ph.D., Capricor's chief executive officer. "We now have formally scheduled our Pre-BLA meeting with the FDA, which will finalize our BLA filing plans and discuss available options to expedite the filing of our BLA. We recognize the FDA's willingness to bring impactful therapies to market as quickly as possible due to the enormous unmet needs of patients with DMD. While we are delighted with the approval of gene therapy for DMD, we believe that it will take multiple therapies to combat DMD effectively. Based on the need to address the secondary consequences of DMD, we believe deramiocel can serve as a potential anchor therapy for DMD patients."

Additionally, Capricor will present its latest update of the HOPE-2 open label extension (OLE) 36-month data, both skeletal and cardiac, at the upcoming Parent Project Muscular Dystrophy (PPMD) 30th Annual Conference being held June 27-29, 2024.

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 to 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 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 (DMD). Capricor is also harnessing the power of our exosome technology, using our 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; 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 March 31, 2024, as filed with the Securities and Exchange Commission on May 14, 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.

For more information, please contact:

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Source: Capricor Therapeutics