June 7, 2023

Capricor Therapeutics Announces Follow-up Type-B Clinical Meeting with the FDA for CAP-1002 for the Treatment of Duchenne Muscular Dystrophy

Upcoming Meeting Planned in Early Q3 2023 to Discuss CAP-1002's Pathway Towards Potential Biologics License Application Submission

SAN DIEGO, June 07, 2023 (GLOBE NEWSWIRE) -- Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company focused on the development of transformative cell and exosome-based therapeutics for the treatment and prevention of muscular and other select diseases, today announced an upcoming Type-B clinical meeting with the U.S. Food and Drug Administration (FDA), planned in early Q3 2023. During the planned meeting with the FDA, Capricor will outline its proposed path towards submission of a potential Biologics License Application (BLA) and further discuss its ongoing HOPE-3 clinical trial with the agency.

"We are appreciative of the FDA's guidance and are encouraged by ongoing discussions as we determine the most expeditious path forward for CAP-1002 for the treatment of Duchenne muscular dystrophy (DMD) and align on key features of our Phase 3 HOPE-3 trial," said Linda Marbán, Ph.D., Capricor's chief executive officer. "Advancing therapies such as CAP-1002 towards potential commercialization to help patients in need is of critical importance, and we look forward to working closely with the FDA to achieve this goal. Further, with over 50% of patients enrolled across 16 active sites in HOPE-3, we expect to complete enrollment by the second half of 2023. Building on this momentum and the team's strategic execution, we plan to report the interim analysis for HOPE-3 in the fourth quarter of 2023. Since time is muscle, we will continue to work closely with the FDA to bring CAP-1002 to patients as quickly as possible."

The regulatory pathway for CAP-1002 is supported by RMAT (Regenerative Medicine Advanced Therapy Designation) as well as Orphan Drug Designation. If Capricor were to receive market approval for CAP-1002 by the FDA, Capricor would be eligible to receive a Priority Review Voucher based on its designation as a rare pediatric disease.

About HOPE-3

HOPE-3, the Company's Phase 3 clinical trial of CAP-1002 is a multi-center, randomized, double-blind, placebo-controlled study (NCT05126758) which is designed to treat up to 68 subjects in the United States.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy is a devastating genetic disorder characterized by progressive weakness and chronic inflammation of the skeletal, heart and respiratory muscles. Patients suffering from DMD typically lose their ability to walk in their teenage years and generally die of cardiac or respiratory complications by age 30. It occurs in one in every 3,600 live male births across all races, cultures and countries. DMD afflicts approximately 200,000 boys and young men around the world. Treatment options are limited and there is no cure.

About CAP-1002

CAP-1002 consists of allogeneic cardiosphere-derived cells (CDCs), a type of progenitor cell that has been shown in pre-clinical and clinical studies to exert potent immunomodulatory activity and is being investigated for its potential to modify the immune system's activity to encourage cellular regeneration. 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.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a biotechnology company focused on the development of transformative cell and exosome-based therapeutics for the treatment and prevention of muscular and other select diseases. Capricor's lead candidate, CAP-1002, is an allogeneic cardiac-derived cell therapy that is currently in late-stage clinical development for treating Duchenne muscular dystrophy. Capricor is also developing its exosome technology as a next-generation therapeutic platform. Capricor's focus is on developing exosomes capable of delivering nucleic acids, including mRNA, as well as proteins to treat or prevent a variety of diseases. 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; 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 royalty streams and revenue 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, 2022, as filed with the Securities and Exchange Commission on March 17, 2023 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, as filed with the Securities and Exchange Commission on May 12, 2023. 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.

CAP-1002 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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