July 25, 2019

Capricor Therapeutics Announces Positive DSMB Safety and Futility Review and Continuation of its HOPE-2 Study in Duchenne Muscular Dystrophy

--Independent Data Safety Monitoring Board recommends to continue HOPE-2 study--

--Capricor to resume treating currently enrolled patients--

LOS ANGELES, July 25, 2019 (GLOBE NEWSWIRE) -- Capricor Therapeutics, Inc. (NASDAQ: CAPR), a clinical-stage biotechnology company, today announced that its independent Data and Safety Monitoring Board (DSMB) completed its safety assessment and futility analysis review of the company's ongoing Phase II HOPE-2 study with CAP-1002 in boys and young men who are in advanced stages of Duchenne muscular dystrophy (DMD) and recommended that the trial continue. Earlier this month, Capricor announced positive results from its interim analysis in the HOPE-2 Trial.

"We are pleased with the DSMB's recommendation to continue the HOPE-2 clinical trial and supports our understanding of the safety of CAP-1002 in the DMD patient population, which is an important step toward establishing a potential new treatment to help these boys. We look forward to sharing updates from the HOPE-2 trial in the coming months, including additional analyses and guidance from the FDA based on our ongoing discussions with the agency," said Linda Marbán, president and CEO of Capricor.

HOPE-2 is a randomized, double-blind, placebo-controlled, Phase II clinical trial of the company's lead investigational therapy, CAP-1002 in steroid-treated boys and young men who are in advanced stages of DMD, a debilitating genetic disorder. DMD is characterized by progressive weakness and chronic inflammation of the skeletal, heart, and respiratory muscles. Study patients are being treated via intravenous delivery with either CAP-1002 (150 million cells per infusion) or placebo every 3 months.

The FDA has granted Capricor RMAT and Orphan Drug Designation for CAP-1002 for the treatment of DMD. Additionally, the FDA has granted a Rare Pediatric Disease Designation to CAP-1002 for treatment of DMD. Upon receiving market approval for CAP-1002 by the FDA, Capricor would be eligible to receive a Priority Review Voucher.

About Duchenne Muscular Dystrophy

DMD is a devastating genetic disorder that causes muscle degeneration and leads to death, generally before the age of 30, most commonly from heart failure. 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, or CDCs, a type of progenitor cell that has been shown in pre-clinical and clinical studies to exert potent immuno-modulatory 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 approximately 150 human subjects across several clinical trials.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class biological therapeutics for the treatment of rare disorders. Capricor's lead candidate, CAP-1002, is an allogeneic cell therapy that is currently in clinical development for the treatment of DMD. Capricor is also exploring the potential of CAP-2003, a cell-free, exosome-based candidate, to treat a variety of disorders. For more information, visit www.capricor.com.
Keep up with Capricor on social media:www.facebook.com/capricortherapeutics, www.instagram.com/capricortherapeutics/ and https://twitter.com/capricor

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; 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, 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, 2018 as filed with the Securities and Exchange Commission on March 29, 2019, and as amended by its Amendment No. 1 to Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on April 1, 2019 and in its Quarterly Report on Form 10-Q as filed with the Securities and Exchange Commission on May 14, 2019. 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. CAP-2003 has not yet been approved for clinical investigation.

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