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Capricor Therapeutics Announces DSMB Recommendation to Continue Phase II INSPIRE Trial for Severe COVID-19 Patients

Trial Assessing Ability of Capricor's Cardiac Cell Therapy, CAP-1002, to Reduce the Cytokine Storm Associated with Severe COVID-19

LOS ANGELES, Dec. 29, 2020 (GLOBE NEWSWIRE) -- Capricor Therapeutics, Inc. (NASDAQ: CAPR), a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class cell- and exosome-based therapeutics for the treatment and prevention of a variety of diseases and disorders, announced today that the independent Data and Safety Monitoring Board (DSMB) has completed its safety review for Capricor's Phase II INSPIRE study. The DSMB recommended that the study continue as designed with Capricor's cardiac cell therapy, CAP-1002, for treating patients with severe COVID-19. In addition, an independent prespecified review of the safety data was conducted on an initial group of INSPIRE patients and the study is continuing according to the study protocol.

"As hospitalizations continue to steadily increase heading into the New Year, the DSMB's recommendation is vital as we continue this study to potentially help patients who are at a high risk for significant morbidity or even death," said Linda Marbán, Ph.D., Capricor's President and CEO. "Given that CAP-1002 polarizes macrophages to an anti-inflammatory, healing immunomodulatory phenotype, it may subsequently attenuate the effects of the cytokine storm associated with severe COVID-19."

The INSPIRE trial (NCT04623671) is a Phase 2, randomized, double-blind, placebo-controlled study that will enroll up to 60 patients with a COVID-19 clinical diagnosis confirmed by laboratory testing who are in severe or critical condition as indicated by life-support measures. The study's primary objectives are to determine the safety and effectiveness of the intravenously infused CAP-1002 for improving clinical outcomes. Patients will be randomized to either the CAP-1002 or placebo group (1:1 ratio) and undergo baseline safety and efficacy assessments approximately one to three days prior to administering the investigational product.

Dr. Marbán continued, "Based on data from the initial emergency use cases, we are encouraged by the potential of our cell-based therapy, CAP-1002, for treating COVID-19. Many patients are now suffering from COVID-19's long-term cardiac consequences. As CAP-1002 directly targets cardiac dysfunction, it has the potential to serve as an important tool in treating the virus's cardiac complications – an unmet medical need in today's patient

population. We are now actively enrolling subjects in Texas and California where case levels continue to rise. We expect to have data available in the first half of 2021 and will continue to evaluate potential partnering opportunities for this program."

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 cell- and exosome-based therapeutics for the treatment and prevention of diseases. Capricor's lead candidate, CAP-1002, is an allogeneic cell therapy that is currently in clinical development for the treatment of Duchenne muscular dystrophy and the cytokine storm associated with COVID-19. Capricor is also investigating the field of extracellular vesicles and exploring the potential of exosome-based candidates to treat or prevent a variety of disorders. The Company is now developing two potential vaccines for COVID-19 as part of its exosome platform. For more information, visit www.capricor.com, and follow the Company 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; 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, 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, 2019 as filed with the Securities and Exchange Commission on March 27, 2020 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 as filed with the Securities and Exchange Commission on November 13, 2020. 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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