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Capricor Therapeutics Commences Dosing Patients in Phase 2 Trial of CAP-1002 in Patients with Severe COVID-19

- Data Expected Second Quarter 2021 -

- The INSPIRE Trial Is Designed to Assess the Ability of CAP-1002 to Modulate the Cytokine Storm Associated With Severe COVID-19 -

LOS ANGELES, Nov. 24, 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 first two patients have been dosed in its Phase 2 study evaluating intravenous infusion of CAP-1002 – its lead clinical asset - using its allogeneic cardiosphere-derived cells (CDC) technology as a treatment option for patients with COVID-19. The study is now enrolling patients who have been diagnosed with SARS-CoV-2 and require supplemental oxygen. The study is being conducted at multiple sites in the United States and will enroll up to 60 patients.

“This trial represents a significant milestone for Capricor, as we expand the scope of our CAP-1002 program to treat patients with severe COVID-19. As hospitalizations continue to increase, we have a therapeutic under investigation for patients at a high-risk for significant morbidity or even death,” said Linda Marbán, Ph.D., President and Chief Executive Officer of Capricor. “It is important to remember that many patients are suffering from long term cardiac consequences from COVID-19. As CAP-1002 directly targets cardiac dysfunction, CAP-1002 potentially may also be an important tool in the treatment of the cardiac complications of COVID-19.”

Within the framework of SARS-CoV-2 pathogenesis, multiple pathways known to be CAP-1002 sensitive may serve as therapeutic targets. These targets include pro-inflammatory pathways (TNF-α, interferon γ, IL-1, and IL-6) and anti-inflammatory pathways (regulatory T cells and IL-10) that have been explored with CAP-1002 in preclinical models of myocardial ischemia, myocarditis, heart failure, muscular dystrophy and pulmonary hypertension. Given that CAP-1002 polarizes macrophages to an anti-inflammatory (healing) immunomodulatory phenotype, CAP-1002 may subsequently attenuate cytokine storm.

The INSPIRE trial (NCT04623671) is a Phase 2, randomized, double-blind, placebo-controlled study that will enroll subjects with a clinical diagnosis of COVID-19 confirmed by laboratory testing and are in severe or critical condition as indicated by life-support measures. The primary objectives of the study are to determine the safety and effectiveness of intravenously infused CAP-1002 for improving clinical outcomes in severe to critical

patients with COVID-19. Eligible subjects 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 the administration of investigational product (IP).

“We remain committed to developing therapeutic options for patients diagnosed with severe COVID-19 in parallel to the exciting developments recently reported on our exosome platform technology. We look forward to announcing more updates on these programs as they become available,” concluded Dr. Marbán.

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. We are now developing two potential vaccines for COVID-19 as part of our exosome platform. For more information, visit www.capricor.com and follow the Company on Facebook, Instagram and Twitter.

About CAP-1002

CAP-1002 consists of allogeneic cardiosphere-derived cells, or CDCs, a type of cardiac cell therapy that has been shown in pre-clinical and clinical studies to exert potent immunomodulatory activity. It is being investigated for its potential to modify the immune system’s activity to encourage cellular regeneration. The cells function by releasing exosomes that are taken up largely by macrophages and T-cells and begin a cycle of repair. CDCs have been the subject of over 100 peer-reviewed scientific publications and administered to approximately 200 human subjects across several clinical trials.

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.

For more information, please contact:

Media Contact:
Caitlin Kasunich / Raquel Cona
KCSA Strategic Communications
ckasunich@kcsa.com / rcona@kcsa.com
212.896.1241 / 212.896.1204

Investor Contact:
Joyce Allaire
LifeSci Advisors, LLC
jallaire@lifesciadvisors.com
617.435.6602

Company Contact:
AJ Bergmann, Chief Financial Officer
abergmann@capricor.com
310.358.3200

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