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Capricor Therapeutics Announces Key Updates on its Vaccine and Therapeutic Programs for COVID-19

Capricor's Exosome-based mRNA Vaccine for SARS-CoV-2
-In-Vivo Preclinical Data Published in the Journal of Biological Chemistry-
-Preclinical Data Demonstrates Strong T-Cell Response for High Conserved N Protein which may Confer Longer Lasting Immunity-
-Completing Non-Clinical Studies for IND Submission-

CAP-1002 – Capricor's Cell Therapy Program for Severe COVID-19 Patients
-Phase 2 Trial Enrollment Complete with 63 Patients Randomized-
-Data Expected in First Quarter 2022-

SAN DIEGO, Dec. 13, 2021 (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 a broad spectrum of diseases, today announced new updates on its vaccine and therapeutic development programs focused on COVID-19. The preclinical data describes, for the first time, the potential for Capricor's multivalent exosome mRNA vaccine candidate for SARS-CoV-2 to generate a strong T-cell response against viral infection in addition to eliciting an antibody response. In addition, Capricor will announce topline data from its Phase 2 clinical trial, INSPIRE, in the first quarter of 2022. This study is designed to assess the ability of CAP-1002 to modulate the cytokine storm and attenuate the sequelae caused by severe COVID-19 disease.

Capricor's multivalent mRNA vaccine utilizes exosomes, which are the body's own drug delivery vehicle, produced by all cells, abundant in all biofluids, and demonstrated to be safe by decades of transfusion and transplantation medicine. This proprietary SARS-CoV-2 vaccine is multivalent, delivering both the highly mutagenic S protein (Spike) and the more conserved N protein (Nucleocapsid) which may offer broader immunity against SARS-CoV-2. Utilization of a multivalent vaccine may potentially offer enhanced protection against future coronavirus variants and may be critical in ensuring long-term management of the COVID-19 pandemic.

"This published study represents a significant milestone in Capricor's efforts to develop mRNA-loaded exosomes for the prevention and treatment of human disease," said Dr. Linda Marbán, Ph.D., CEO of Capricor. "Exosomes have been demonstrated to be safe and effective for mRNA delivery by this new study. This new report, which arises from a close collaboration with Dr. Stephen J. Gould and colleagues of Johns Hopkins University, lays the foundation for our platform by demonstrating how to make clinical-grade exosomes, how to load them at high efficiency with synthetic mRNAs, and, once formulated, how they are able

to drive functional expression of the encoded proteins over sustained cycles of weekly and semi-weekly injections for more than two months. Further, it demonstrates that this approach can be used to simultaneously deliver multiple mRNAs encoding both Spike and Nucleocapsid, a dual immunization approach that has recently emerged as key to protecting against both proximal and distal COVID-19 disease. At this time, we plan to file an IND and position this vaccine as a potential booster to currently available vaccines."

Capricor's therapeutic approach to COVID-19 is based on multiple published peer-reviewed studies of CAP-1002 demonstrating favorable modulation of various inflammatory cytokines and regulation of the immune response. COVID-19's more severe presentation is thought to be due to overstimulation of the immune system, which triggers a cytokine storm in which the body is overwhelmed with pro-inflammatory molecules. This immune response may become excessive and pathologic, inducing ARDS, multi-system organ failure and death.

Dr. Marbán continued, "Our ability to leverage a therapeutic CAP-1002 program to intervene in the progression of the cytokine storm in COVID-19 patients may reduce the need for ventilatory support and may potentially not only save lives but also reduce long-term morbidity that can occur after severe respiratory compromise. We look forward to sharing the results from this double-blind, placebo-controlled Phase 2 study in the first quarter of 2022 and then moving rapidly to discuss this program with FDA if a pathway towards further development becomes clear."

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a biotechnology company focused on developing transformative cell- and exosome-based therapeutics and vaccines for treating and preventing a broad spectrum of diseases. Capricor's lead candidate, CAP-1002, is an allogeneic cardiac-derived cell therapy that is currently in clinical development for treating Duchenne muscular dystrophy and the cytokine storm associated with COVID-19. Capricor is also developing its exosome technology as a next-generation therapeutic platform. The Company's current focus is on developing exosomes loaded with nucleic acids, including mRNA, to treat or prevent a variety of diseases. 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, 2020, as filed with the Securities and Exchange Commission on March 15, 2021, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission on November 12, 2021. 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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