April 3, 2020

Capricor Initiates Compassionate Use Program for Severe COVID-19 Patients using CAP-1002, its Novel Cell Therapy

-CAP-1002 Aims to Mitigate Severe Inflammatory Response Associated with COVID-19-

-Expanded Access Protocol Submitted to FDA-

LOS ANGELES, April 03, 2020 (GLOBE NEWSWIRE) -- Capricor Therapeutics (NASDAQ: CAPR) a clinical-stage biotechnology company focused on the development of first-in-class biological therapeutics for the treatment or prevention of serious diseases, today announced it is providing CAP-1002, its novel cell therapy to patients with advanced COVID-19 under the compassionate use pathway. Two patients were treated last week at a leading healthcare center in Los Angeles, California with additional patients planned in the coming weeks. Infusions of CAP-1002 were administered safely and patients are currently clinically stable.

“Physicians leading the fight against COVID-19 patients approached Capricor to discuss the use of CAP-1002 due to its strong immunomodulatory capabilities. They believe that the use of CAP-1002 for the treatment or attenuation of ARDS pneumonia in COVID-19 patients is based on solid scientific rationale and pre-clinical data. We know from previously published pre-clinical data that CAP-1002 mitigates the release of anti-inflammatory cytokines as well as macrophage activation in a number of models of inflammation including sepsis and autoimmune diseases. It is believed that COVID-19 induced ARDS pneumonia is a response to exaggerated and sustained cytokine storm. As such, we are hopeful that CAP-1002 will be of value to patients with respect to the treatment of COVID-19,” said Linda Marbán, Ph.D., Capricor’s president and chief executive officer.

The compassionate use act allows FDA to immediately collect information on experimental treatments and then make the appropriate decisions about the safety and efficacy of those treatments. Physicians plan to re-dose patients as well as treat additional patients in the coming weeks. Additionally, Capricor has submitted an expanded access Investigational New Drug (IND) application to investigate the use of CAP-1002 in certain COVID-19 patients which is currently under review with the FDA.

Dr. Marbán added, “In addition, we are continuing our efforts in developing our exosome platform technology as a potential COVID-19 vaccine and remain committed to advancing our DMD program. We expect to have data available this quarter from our HOPE-2 trial and look forward to sharing those results,” said Dr. Marbán.

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 and 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 have been administered to over 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 or prevention of serious 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. Capricor is also investigating the field of extracellular vesicles and is exploring the potential of exosome-based candidates to treat or prevent 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, 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. 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:

Investor Contact:
Joyce Allaire - Managing Director
LifeSci Advisors, LLC
jallaire@lifesciadvisors.com
(617) 435-6602

Company Contact:
AJ Bergmann, Chief Financial Officer
+1-310-358-3200
abergmann@capricor.com

Source: Capricor Therapeutics