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Capricor Therapeutics Announces Manufacturing Scale-Up of CAP-1002 Production at New San Diego Facility as it Continues Plans Toward Commercialization

-Cohort B of HOPE-3, Phase 3 Clinical Trial Expected to Complete Enrollment in Second Quarter 2024-

SAN DIEGO, Feb. 20, 2024 (GLOBE NEWSWIRE) -- Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for the treatment and prevention of rare diseases, announced today the scale-up to expand manufacturing capacity of CAP-1002 to its new state-of-the-art manufacturing facility, intended for commercial use, subject to regulatory approval, located in San Diego. Furthermore, the Company announced that Cohort B of its HOPE-3, Phase 3 clinical study is enrolling rapidly and is expected to complete full enrollment (n=44) in the second quarter of 2024.

“We are extremely pleased with the progress of our manufacturing scale-up efforts in connection with our new San Diego facility which brings us one step closer towards a successful launch of CAP-1002, should we obtain approval, to meet the significant unmet need in this broad and underserved patient population. This facility was designed to be a versatile and cost-effective way to bring CAP-1002 to market efficiently and it is expected that our enhanced manufacturing capacity to increase our supply capabilities and improve our margins,” said Linda Marbán, Ph.D., Capricor’s chief executive officer. “Furthermore, with Cohort A of the HOPE-3 trial being fully enrolled and topline data readout expected in the fourth quarter of 2024, we plan to meet with the U.S. Food & Drug Administration (FDA) with the aim to discuss possible expedited pathways to approval.”

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a biotechnology company dedicated to advancing transformative cell and exosome-based therapeutics to redefine the treatment landscape for rare diseases. At the forefront of our innovation is our lead product candidate, CAP-1002 — an allogeneic cardiac-derived cell therapy. Extensive preclinical and clinical studies have shown CAP-1002 to demonstrate immunomodulatory, antifibrotic, and regenerative actions specifically tailored for dystrophinopathies and heart disease. CAP-1002 is currently advancing through Phase 3 clinical development for the treatment of Duchenne muscular dystrophy (DMD). Capricor is also harnessing the power of our exosome technology, using our proprietary StealthX™ platform which is focused on the

areas of vaccinology, targeted delivery of oligonucleotides, proteins and small molecule therapeutics to potentially treat and prevent a diverse array of diseases. At Capricor, we stand committed to pushing the boundaries of possibility and forging a path toward transformative treatments for those in need. For more information, visit capricor.com, and follow Capricor 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; manufacturing capabilities; the ability to achieve product milestones and to receive milestone payments from commercial partners; 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 and 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, 2022, as filed with the Securities and Exchange Commission on March 17, 2023 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on November 14, 2023. 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.

Capricor has entered into a partnership for the exclusive commercialization and distribution of CAP-1002 for DMD in the United States and Japan with Nippon Shinyaku Co., Ltd. (U.S. subsidiary: NS Pharma, Inc.), subject to regulatory approval. 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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