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Capricor Therapeutics and Nippon Shinyaku Enter Partnership for Exclusive Commercialization and Distribution of CAP-1002 for the Treatment of Duchenne Muscular Dystrophy in Japan

-Expands Partnership with Nippon Shinyaku to Japan to Leverage Deep Experience in Drug Development for Rare Diseases and Commercial DMD Franchise-

-Capricor to Receive an Upfront Payment of $12 Million, Additional Potential Milestone Payments of up to $89 Million as well as Meaningful Double-Digit Percentage of Revenue Based on Product Sales-

SAN DIEGO, Feb. 16, 2023 (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 muscular and other select diseases, announced today that it has entered into a partnership with Nippon Shinyaku Co., Ltd., a Japanese pharmaceutical company listed on the TYO, for the exclusive commercialization and distribution in Japan of Capricor's lead asset, CAP-1002, for the treatment of Duchenne muscular dystrophy (DMD), a rare neuromuscular disease with limited treatment options. This follows the exclusive Commercialization and Distribution Agreement entered into with Nippon Shinyaku in the United States in January 2022.

"Nippon Shinyaku is a proven leader in developing therapeutics for rare diseases, specifically DMD, and an ideal partner for us to maximize the opportunity with CAP-1002 in Japan and the U.S.," said Dr. Linda Marbán, CEO of Capricor. "With the addition of non-equity capital from this transaction, we are well positioned to advance and execute on our milestones including the execution of the HOPE-3 Phase 3 trial in the United States. CAP-1002 has shown clinical benefits for both the cardiac and skeletal muscle myopathy, which few therapies have demonstrated. The data from our recently announced 18-month HOPE-2 open label extension study showed evidence of disease modification and showed statistically significant differences in the Performance of the Upper Limb (PUL). This continues to build upon CAP-1002's safety and efficacy profile and to potentially establish it as an anchor therapy for DMD patients. Furthermore, we remain committed to securing strategic partners that will further strengthen our balance sheet and help us achieve our goal of bringing our therapies to the global patient community as quickly as possible."

Under the terms of the agreement, Capricor will receive an upfront payment of $12 million and in addition, Capricor will potentially receive additional development and sales-based milestone payments of up to approximately $89 million and a meaningful, double-digit share

of product revenue. This agreement is similar to the terms of the U.S. agreement with Nippon Shinyaku, in that Capricor will be responsible for clinical development and Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan, once approved. Capricor will sell commercial product to Nippon Shinyaku. In addition, Capricor will hold the Marketing Authorization in Japan, if the product is approved in that territory.

Toru Nakai, President of Nippon Shinyaku, commented, “We look forward to further strengthening our partnership with Capricor as CAP-1002 moves towards potential commercialization. This agreement provides an opportunity to expand Nippon Shinyaku’s DMD franchise and to advance potentially life-changing therapies for patients with Duchenne Muscular Dystrophy. In Japan, we already have launched Viltepso®, an exon skipping agent for the treatment of DMD and will leverage our established commercial infrastructure to deliver on our shared mission of bringing hope to more patients with the addition of CAP-1002 to our pipeline.”

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy is a devastating genetic disorder characterized by progressive weakness and chronic inflammation of the skeletal, heart and respiratory muscles. Patients suffering from DMD typically lose their ability to walk in their teenage years and generally die of cardiac or respiratory complications by age 30. It occurs in one in every 3,600 live male births across all races, cultures and countries. DMD afflicts approximately 200,000 boys and young men around the world. Treatment options are limited and there is no cure.

About CAP-1002

CAP-1002 consists of allogeneic cardiosphere-derived cells (CDCs), a type of progenitor cell that has been shown in pre-clinical and clinical studies to exert potent immuno-modulatory activity and is being investigated for its potential to modify the immune system’s activity to encourage cellular regeneration. CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 200 human subjects across several clinical trials.

About Nippon Shinyaku

Based on Nippon Shinyaku’s business philosophy, “Helping people lead healthier, happier lives,” we aim to be an organization trusted by the community through creating unique medicines that will bring hope to patients and families suffering from illness. Please visit our website (https://www.nippon-shinyaku.co.jp/english/) for products or detailed information.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a biotechnology company focused on the development of transformative cell and exosome-based therapeutics for the treatment and prevention of muscular and other select diseases. Capricor’s lead candidate, CAP-1002, is an allogeneic cardiac-derived cell therapy that is currently in late-stage clinical development for treating Duchenne muscular dystrophy. Capricor is also developing its exosome technology as a next-generation therapeutic platform. Capricor’s focus is on developing exosomes capable of delivering nucleic acids, including mRNA, as well as proteins to treat or

prevent a variety of diseases. 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; 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, 2021, as filed with the Securities and Exchange Commission on March 11, 2022 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 as filed with the Securities and Exchange Commission on November 10, 2022. 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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