NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

December 4, 2025

CAP-1002：Capricor Therapeutics Announces Positive Topline Results from Pivotal Phase III HOPE-3 Study in Duchenne Muscular Dystrophy

Kyoto, Japan, December 4, 2025 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku, Headquarters: Kyoto, Japan, President: Toru Nakai) announced that Capricor Therapeutics, Inc. (Capricor, Headquarters: California, USA, CEO: Linda Marbán, NASDAQ: CAPR) has issued a press release regarding the topline results of the Phase III clinical trial (HOPE-3 trial) of CAP-1002 (Deramiocel), which is currently under development in the United States for patients with Duchenne muscular dystrophy (DMD).

- HOPE-3 study met the primary endpoint, performance of upper limb (PUL v2.0) and the key secondary cardiac endpoint, left ventricular ejection fraction (LVEF), both achieving statistical significance (p=0.03 and p=0.04, respectively)
- CAP-1002 maintained a favorable safety and tolerability profile consistent with prior clinical experience
- Results supporting CAP-1002 as a potential first-in-class therapy for Duchenne cardiomyopathy.
- Capricor plans to submit its response to the Complete Response Letter incorporating HOPE-3 data, following prior alignment with FDA

For more details, please see the press release from Capricor.
https://www.capricor.com/investors/news-events/press-releases/detail/331/capricor-therapeutics-announces-positive-topline-results

If Capricor obtains the BLA approval in the U.S., NS Pharma, Inc. (New Jersey, USA, President: Yukiteru Sugiyama), a wholly owned subsidiary of Nippon Shinyaku, will market CAP-1002. Nippon Shinyaku will continue to work closely with Capricor and prepare to deliver CAP-1002 to patients in the United States at the earliest possible opportunity.

About CAP-1002(Deramiocel)

CAP-1002 consists of allogeneic cardiosphere-derived cells (CDCs), a rare population of cardiac cells that have been shown in preclinical and clinical studies to exert potent immunomodulatory and anti-fibrotic actions in the preservation of cardiac and skeletal muscle function in muscular dystrophies such as DMD. CDCs act by secreting extracellular vesicles known as exosomes, which target macrophages and alter their expression profile to adopt a healing rather than pro-inflammatory phenotype. CAP-1002 has received Orphan Drug Designation for the treatment of DMD from both the U.S. FDA and the European Medicines Agency (EMA). In addition, it has been granted Regenerative Medicine Advanced Therapy (RMAT) designation in the U.S., Advanced Therapy Medicinal Product (ATMP) designation in Europe, and Rare Pediatric Disease Designation from the FDA.

About the HOPE-3 Phase 3 Trial

HOPE-3 is a Phase 3, multi-center, randomized, double-blind, placebo-controlled clinical trial evaluating the safety and efficacy of CAP-1002 in participants with DMD. Non-ambulatory and ambulatory boys who meet eligibility criteria are randomly assigned to receive either CAP-1002 or placebo every 3 months for a total of four doses during the first 12 months of the trial. A total of 106 eligible subjects were randomized in the trial. For more information, please visit ClinicalTrials.gov (NCT05126758).

About Capricor Therapeutics, Inc.

Capricor (NASDAQ: CAPR) is a biotechnology company dedicated to advancing transformative cell and exosome-based therapeutics to redefine the treatment landscape for rare diseases. Capricor is also harnessing the power of its exosome technology, using its proprietary StealthX™ platform in preclinical development 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. For more information, https://www.capricor.com.

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