# *NEWS RELEASE*

NIPPON SHINYAKU CO., LTD.

March 5, 2025

**CAP-1002: The U.S. FDA has accepted the Biologics License Application for Duchenne Muscular Dystrophy Cardiomyopathy**

**KYOTO, Japan, March 5, 2025** - Nippon Shinyaku Co., Ltd. (Headquarters: Kyoto, Japan, President: Toru Nakai) announced that Capricor Therapeutics, Inc. (Headquarters: California, USA, CEO: Linda Marbán, NASDAQ: CAPR) has received the acceptance letter from the U.S. Food and Drug Administration (FDA) for its Biologics License Application (BLA) filing for CAP-1002 (also referred to as deramiocel) for the expected indication of Duchenne Muscular Dystrophy (DMD) cardiomyopathy. Additionally, the FDA granted the BLA Priority Review with a Prescription Drug User Fee Act ("PDUFA") target action date of August 31, 2025 (U.S. time).

For more details, please see the press release from Capricor.
https://www.capricor.com/investors/news-events/press-releases/detail/305/capricor-therapeutics-announces-fda-acceptance-and-priority

Nippon Shinyaku and Capricor have entered into an exclusive distribution agreement for CAP-1002 for the U.S. and Japan in January 2022 and February 2023, respectively. 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.

DMD is a progressive muscular dystrophy caused by a deficiency of the dystrophin protein leading to weakness of skeletal, cardiac, and pulmonary muscles. In DMD patients, heart muscle cells progressively die and are replaced with scar tissue, leading to cardiomyopathy. This DMD cardiomyopathy eventually leads to heart failure, which is currently the leading cause of death among those with DMD. Treatment options are limited, and effective therapies are required to be developed.

CAP-1002 is comprised of human allogenic cardiosphere derived cells that is potentially expected to be effective in a wide range of DMD patients, regardless of the type of genetic mutation. Exosomes (extracellular vesicles) secreted by CAP-1002 are known to be the mechanism of action of CAP-1002 and have been shown to reduce oxidative stress, inflammation and fibrosis. The filing of BLA for CAP-1002 for DMD cardiomyopathy in the U.S. is based on the results of its Phase II HOPE-2 and HOPE-2 Open Label Extension trials.

Nippon Shinyaku is focusing on the field of intractable, rare disorders, and has commercialized our in-house developed DMD treatment, Viltepso® (an antisense exon skipping agent) in Japan and the U.S. We expect that the approval of CAP-1002, a cell therapy product, by the FDA will contribute further to the treatment of patients suffering from DMD.

**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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