

NEWS RELEASE



March 11, 2026

CAP-1002: Capricor Therapeutics Announces Establishment of New PDUFA Date

KYOTO, Japan, March 11, 2026 - Nippon Shinyaku Co., Ltd. (Headquarters: Kyoto, Japan, President: Toru Nakai) announces that it has been notified by Capricor Therapeutics, Inc. (Headquarters: California, USA, CEO: Linda Marbán, NASDAQ: CAPR) that the U.S. Food and Drug Administration (FDA) has resumed the review of the Biologics License Application (BLA) for CAP-1002 (deramiocel), for which Duchenne muscular dystrophy (DMD) cardiomyopathy is the proposed indication. In addition, the FDA has newly set the Prescription Drug User Fee Act date (PDUFA date) for August 22, 2026 (U.S. time).

Capricor received a Complete Response Letter (CRL) from the FDA in July 2025. Following submission of data and supporting documentation from the HOPE-3 clinical trial, the FDA has lifted the previously issued CRL and resumed review of the application and assigned a PDUFA target action date of August 22, 2026.

For more details, please see the press release from Capricor.

<https://www.capricor.com/investors/news-events/press-releases/detail/338/capricor-therapeutics-announces-establishment-of-new-pdufa>

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 for DMD are limited, and effective therapies are needed 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.

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 DMD patients.

About Capricor Therapeutics

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, visit <https://www.capricor.com>.

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