

NEWS RELEASE



NIPPON SHINYAKU CO., LTD.

September 18, 2024

Nippon Shinyaku and Capricor Therapeutics Execute Letter of Intent for Commercialization and Distribution of CAP-1002 for the Treatment of Duchenne Muscular Dystrophy in Europe

KYOTO, Japan, September 18, 2024 - Nippon Shinyaku Co., Ltd. (Headquarters: Kyoto, Japan, President: Toru Nakai) announced today that Nippon Shinyaku and Capricor Therapeutics, Inc. (Headquarters: California, USA, CEO: Linda Marbán, NASDAQ: CAPR) have executed a Letter of Intent stipulating the exclusive right to negotiate over the next few months an exclusive distribution agreement for CAP-1002 (also referred to as deramiocel) for the treatment of Duchenne Muscular Dystrophy (DMD) in the territory of Europe.

DMD is a progressive muscular dystrophy caused by a deficiency of the dystrophin protein leading to weakness of skeletal, cardiac, and pulmonary muscles. DMD has a variety of genotypic variants, and therapeutic agents have been developed for patients with DMD caused by specific genetic mutations, thus contributing to the fulfillment of unmet medical needs. However, these treatment options are limited to select genetic mutations and additional treatments, in particular for relatively older, DMD patients represents an area of significant unmet medical need, 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. A Phase II study (HOPE-2), conducted in the U.S. showed improved upper limb and cardiac function in late-stage DMD patients. Capricor is currently conducting a Phase III study (HOPE-3) at multiple U.S. health institutions.

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. Nippon Shinyaku has entered into an exclusive distribution agreement for CAP-1002 for the U.S. and Japan in January 2022 and February 2023, respectively. Following the successful execution of the exclusive distribution agreement in the territory of Europe with Capricor, Nippon Shinyaku will continue to contribute further to the treatment for patients suffering from DMD in Japan, the U.S., and Europe.

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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