

# NEWS RELEASE



**NIPPON SHINYAKU CO., LTD.**

February 16, 2023

## **Nippon Shinyaku and Capricor Therapeutics enter into an Exclusive Partnership for Commercialization and Distribution of CAP-1002 for the Treatment of Duchenne Muscular Dystrophy in Japan**

**KYOTO, Japan, February 16, 2023** - 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 entered into an exclusive distribution agreement for CAP-1002 for the treatment of Duchenne muscular dystrophy (DMD) in the territory of Japan. This agreement builds upon the exclusive distribution agreement in the territory of the United States signed in January 2022.

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 an allogeneic cell therapy that is expected to be effective in a wide range of DMD patients, regardless of the type of genetic mutation. A Phase II study (HOPE-2 study), 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 study) at multiple U.S. health institutions. Capricor also plans to conduct clinical development in Japan. CAP-1002 is comprised of human allogeneic cardiosphere-derived cells. Exosomes (extracellular vesicles) secreted by CAP-1002 are thought to be the mechanism of action of CAP-1002 and has been shown to reduce oxidative stress, inflammation, fibrosis and increase myocyte generation.

Nippon Shinyaku is focusing on the field of intractable, rare disorders, and have commercialized our in-house developed DMD treatment, Viltepso® (an antisense exon skipping agent) in Japan and the U.S. By executing this agreement with Capricor, Nippon Shinyaku aims to contribute further to the treatment for patients suffering from DMD in both countries.

**About exosomes**

Exosomes (extracellular vesicles) are vesicles of about 30 to 150 nanometers in diameter surrounded by a lipid- bilayer membrane that are secreted by cells. Exosomes were previously considered relating to the excretion of intracellular waste products, but in recent years, it has been discovered and well known that exosomes contain proteins and nucleic acids and act as important mediators of intercellular communication. Research and development of clinical applications, such as therapeutic, diagnostic, and DDS, using this function has been actively pursued.

**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 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 <https://www.capricor.com>.

**Contact**

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