NEWS RELEASE

NS Pharma, Inc.
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Paramus, NJ 07652

FDA Accepts Biologics License Application for Duchenne Muscular Dystrophy Cardiomyopathy Treatment

PARAMUS, NJ: March 4, 2025 – NS Pharma, Inc. (NS Pharma), a subsidiary of Nippon Shinyaku Co., Ltd. (Nippon Shinyaku), announced today that acceptance has been received by Capricor Therapeutics, Inc. (Headquarters: California, USA, CEO: Linda Marbán, NASDAQ: CAPR) from the U.S. Food and Drug Administration (FDA) for the Biologics License Application (BLA) filing for deramiocel, an investigational cell therapy, as a treatment for patients diagnosed with Duchenne muscular dystrophy ("DMD") cardiomyopathy. The FDA granted the BLA Priority Review with a Prescription Drug User Fee Act ("PDUFA") target action date of August 31, 2025, and at this time, the FDA has not identified any potential review issues.

Nippon Shinyaku and Capricor entered into an exclusive distribution agreement for deramiocel for the U.S. in January 2022. NS Pharma will be exclusively responsible for commercialization and distribution of deramiocel in the U.S.

"Deramiocel has the potential to address a clear, unmet medical need for patients diagnosed with DMD," said NS Pharma President, Yukiteru Sugiyama, Ph.D. "We are excited for the possibility to bring additional treatment options and renewed hope to families of the rare disease community."

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

About Deramiocel

Deramiocel consists of allogeneic cardiosphere-derived cells ("CDCs"), a population of stromal cells that have been shown in preclinical and clinical studies to exert potent immunomodulatory, antifibrotic and regenerative actions in dystrophinopathy and heart failure. CDCs act by secreting extracellular vesicles known as exosomes, which target macrophages and alter their expression profile so that they adopt a healing, rather than a pro-inflammatory, phenotype. CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 200 human subjects across several clinical trials.

About Duchenne Muscular Dystrophy (Duchenne)

Duchenne is a form of muscular dystrophy that occurs primarily in males. It causes progressive weakness and loss of skeletal, cardiac, and respiratory muscles. Early signs of Duchenne may include delayed ability to sit, stand or walk. There is a progressive loss of mobility, and by adolescence, patients with Duchenne may require the use of a wheelchair. Cardiac and respiratory muscle problems begin in the teenage years and lead to serious, life-threatening complications. For more information about Duchenne, please visit wespeakduchenne.com.

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

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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.

About NS Pharma, Inc.

NS Pharma, Inc., is a wholly owned subsidiary of Nippon Shinyaku Co., Ltd. NS Pharma is a registered trademark of the Nippon Shinyaku Co., Ltd. For more information, please visit nspharma.com.

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