

NEWS RELEASE



July 14, 2025

CAP-1002: Capricor Therapeutics received Complete Response Letter from the U.S. FDA for Biologics License Application for Duchenne Muscular Dystrophy Cardiomyopathy

KYOTO, Japan, July 14, 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 a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its Biologics License Application (BLA) filing for CAP-1002 (also referred to as deramioce) for the expected indication of Duchenne Muscular Dystrophy (DMD) cardiomyopathy.

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

<https://www.capricor.com/investors/news-events/press-releases/detail/319/capricor-therapeutics-provides-regulatory-update-on>

Capricor Therapeutics is currently reviewing the contents of the CRL and plans to engage further with the FDA to determine the appropriate next steps. Nippon Shinyaku will discuss the regulatory schedule in close consultation with Capricor Therapeutics. While we currently anticipate that the impact on the consolidated business forecast for the current fiscal year and the medium-term management plan will be minimal, we will provide further information in due course.

About Complete Response Letters (CRLs)

CRLs are issued directly to product sponsors when the FDA completes its review cycle and determines that it cannot grant an approval of an application in its current form.

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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