NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

November 24, 2026

CAP-1002: FDA Issues Complete Response Letter for Biologics License Application

KYOTO, Japan, November 24, 2026 – Nippon Shinyaku Co., Ltd. (Headquarters: Kyoto, Japan; President: Toru Nakai) announces that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) submitted by Capricor Therapeutics, Inc. (Headquarters: San Diego, California, U.S.; Chief Executive Officer: Linda Marbán) for CAP-1002 (deramiocel) as a treatment for Duchenne muscular dystrophy (DMD).

For further details, please visit the FDA website.
https://www.fda.gov/vaccines-blood-biologics/whats-new-biologics/statement-deramiocel-bla-duchenne-muscular-dystrophy

About Complete Response Letters (CRLs)

A CRL is sent directly to the product sponsor when the FDA completes its review of an application and determines that it cannot be approved in its current form.

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