NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

August 25, 2026

CAP-1002 (deramiocel): Notice Regarding Extension of the PDUFA Date

KYOTO, Japan, August 25, 2026 - Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku"; Headquarters: Kyoto, Japan; President: Toru Nakai) hereby announces that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) target action date for CAP-1002 (deramiocel) from August 22, 2026, to November 22, 2026. CAP-1002 (deramiocel) is currently under review pursuant to a Biologics License Application (BLA) submitted by Capricor Therapeutics, Inc. ("Capricor"; Headquarters: San Diego, California, USA; Chief Executive Officer: Linda Marbán).

Following discussions with the FDA, Capricor submitted additional data and analyses related to its BLA as a BLA amendment. The FDA accepted the submission as a Major Amendment, indicating that it constituted a significant modification to the application.

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