

NEWS RELEASE



NIPPON SHINYAKU CO., LTD.

February 10, 2026

RGX-121: REGENXBIO received Complete Response Letter from the U.S. FDA for Biologics License Application for mucopolysaccharidosis type II

KYOTO, Japan, February 10, 2026 - Nippon Shinyaku Co., Ltd. (Headquarters: Kyoto, Japan, President: Toru Nakai) announced that REGENXBIO Inc. (REGENXBIO; Headquarters: Rockville, Maryland, USA; CEO: Curran M. Simpson, NASDAQ: RGNX) has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its Biologics License Application (BLA) filing for RGX-121 (clemidsogene lanparvovec) for the expected indication of mucopolysaccharidosis type II (MPS II, Hunter syndrome).

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

<https://ir.regenxbio.com/news-releases/news-release-details/regenxbio-announces-regulatory-update-rgx-121-bla-mps-ii>

REGENXBIO 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 REGENXBIO.

In January 2025, Nippon Shinyaku and REGENXBIO have entered a strategic partnership for RGX-111 and RGX-121, under which Nippon Shinyaku acquired exclusive commercialization rights in the U.S. and exclusive development and commercialization rights in Asia including Japan. Preparation for sales in the U.S. will continue to be handled by NS Pharma, Inc. (New Jersey, USA, President: Yukiteru Sugiyama), a wholly owned subsidiary of Nippon Shinyaku.

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 REGENXBIO Inc.

REGENXBIO is a leading clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. Since its founding in 2009, REGENXBIO has pioneered the development of AAV Therapeutics, an innovative class of gene therapy medicines. For more information, please visit www.regenxbio.com.

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