NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

January 29, 2026

Regulatory Update on RGX-111 and RGX-121

KYOTO, Japan, January 29, 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 notification that the U.S. Food and Drug Administration (FDA) placed a clinical hold on RGX-111 and RGX-121.

For more details, please see the press release from REGENXBIO.
https://ir.regenxbio.com/news-releases/news-release-details/regenxbio-announces-regulatory-update-ultra-rare-mps-programs

RGX-111 and RGX-121 are gene therapies being developed by REGENXBIO for the treatment of mucopolysaccharidosis type I (MPS I, Hurler syndrome) and mucopolysaccharidosis type II (MPS II, Hunter syndrome), respectively. The FDA has accepted the Biologics License Application (BLA) filing for RGX-121 in May 2025.

In January 2025, Nippon Shinyaku and REGENXBIO have entered into 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. After REGENXBIO obtains BLA approval for each product in the U.S., NS Pharma, Inc. (New Jersey, USA, President: Yukiteru Sugiyama), a wholly owned subsidiary of Nippon Shinyaku, will market them in the U.S.

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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