NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

August 25, 2026

Regulatory Update on RGX-121 for MPS II

KYOTO, Japan, August 25, 2026 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; 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-121.

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-mps-ii

REGENXBIO has not yet received the full clinical hold letter from the FDA. The path forward for RGX-121 will be determined following further feedback from the FDA.

RGX-121 is a gene therapy under development by REGENXBIO for the treatment of Mucopolysaccharidosis Type II (MPS II, Hunter syndrome). In January 2025, Nippon Shinyaku and REGENXBIO entered into a strategic partnership for RGX-121, under which Nippon Shinyaku acquired exclusive commercialization rights in the U.S., as well as exclusive development and commercialization rights in Asia including Japan.
Following potential FDA approval, the product will be commercialized by NS Pharma, Inc. (Paramus, New Jersey; President: Yukiteru Sugiyama), a wholly-owned subsidiary of Nippon Shinyaku, 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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