NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

June 23, 2026

REGENXBIO Announces Alignment with FDA on Path Forward for RGX-121 BLA Resubmission for Accelerated Approval

KYOTO, Japan, June 23, 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) announced it has aligned with the U.S. Food and Drug Administration (FDA) regarding the next steps needed for an accelerated approval of RGX-121, the gene therapy for Mucopolysaccharidosis 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-alignment-fda-path-forward-navsunlitm-bla

RGX-121 are gene therapies being developed by REGENXBIO for the treatment of MPS II. Through collaborative discussions as part of the Company's appeal of the February 2026 RGX-121 Complete Response Letter, the FDA acknowledged the current clinical data is sufficient to be considered for the accelerated approval pathway.

REGENXBIO expects the Type A meeting to take place in July and to rapidly resubmit the BLA following the meeting.

In January 2025, Nippon Shinyaku and REGENXBIO have entered into a strategic partnership for 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.

Contact

Corporate Communications Dept., Nippon Shinyaku Co., Ltd.
e_mail_kouhou@po.nippon-shinyaku.co.jp