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Andelyn Biosciences to Produce Gene Therapies for Rare Diseases

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Chosen by the FNIH's AMP BGTC, Andelyn will spearhead the manufacturing of AAV therapies, targeting rare retinal degenerations and advancing treatment accessibility.



Andelyn Biosciences, Inc., a pioneering and patient-focused cell and gene therapy Contract Development and Manufacturing Organization (CDMO), has been selected to manufacture adeno-associated vectors (AAV) therapies in its suspension platform for several programs under the Foundation for the National Institutes of Health (FNIH) Accelerating Medicines Partnership® (AMP®) Bespoke Gene Therapy Consortium (BGTC).

BGTC has chosen to focus on **eight rare disease programs**, with Andelyn selected to optimize and scale the AAV therapy processes for the treatments of CNGB1 Retinitis Pigmentosa 45 and NPHP5 retinal degeneration. Managed by the Foundation for the National Institutes of Health, AMP BGTC is a public-private partnership between the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), biopharmaceutical and life science companies, and nonprofit and other organizations with a mission to speed the development and delivery of AAV gene therapies that could treat the millions of people affected by rare diseases.

Matt Niloff, Chief Commercial Officer of Andelyn, commented, “As a long-standing pioneer in AAV gene therapies with a focus on patients, we have great synergies with the BGTC. Andelyn is privileged to work with the FNIH/BGTC on its first AMP which was established specifically to help overcome the major obstacles related to developing gene therapies for rare diseases.”

“We are pleased to have Andelyn Biosciences as a manufacturing partner for two programs in the BGTC’s clinical portfolio,” said Courtney Silverthorn, Associate Vice President for Science Partnerships at the FNIH and Director of the AMP program. “This is an important step toward reaching our ultimate goal of getting gene therapies to rare disease

patients in need sooner, and with fewer hurdles along the way.”

With exceptional quality and scalable end-to-end development and manufacturing capabilities across its three Columbus, Ohio facilities, Andelyn is enabling the progression of life-altering gene therapies for rare and prevalent diseases.