



NEWS RELEASE

Battelle, Andelyn Biosciences, and AmplifyBio Awarded Task Orders for Plasmid and Suspension AAV Vector Manufacturing and IND-enabling Studies from the National Institute of Neurological Disorders and Stroke (NINDS)

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COLUMBUS, Ohio--(BUSINESS WIRE)-- Battelle, **Andelyn Biosciences, Inc.**, and AmplifyBio, have been awarded a new task order from the National Institute of Neurological Disorders and Stroke (NINDS) to manufacture suspension process gene therapy for the transformative treatment of Aspartylglucosaminuria (AGU).

Battelle is the world's largest independent nonprofit research and development organization; **Andelyn Biosciences, Inc.** is a pioneering and patient focused cell and gene therapy Contract Development and Manufacturing Organization (CDMO), and AmplifyBio is a drug development and commercialization partner for advanced therapies.

NINDS, via its Ultra-rare Gene-based Therapy (URGenT) network, is funding a cooperative agreement for the manufacturing of plasmids and AAV gene therapy, and GLP preclinical studies, for AGU which is a severe and progressive genetic neurological disorder. Andelyn will manufacture the gene of interest plasmid, packaging/helper plasmids, and AAV vector, while AmplifyBio will perform IND-enabling GLP preclinical studies and Battelle will provide assay support for the ELISA and enzyme activity portions of the studies.

The task orders follow the announcement made earlier this year of the team of Battelle, AmplifyBio and Andelyn

Biosciences winning a seat on an eight-year, \$149 million indefinite delivery, indefinite quantity (IDIQ) contract vehicle from NINDS.

Matt Niloff, Chief Commercial Officer of Andelyn, said, “The path to gene therapy commercialization for the treatment of rare and prevalent genetic diseases requires innovators and expert service providers working collaboratively toward a common goal. The partnership formed here exemplifies such a model, maximizing the potential for curative therapies and providing hope for those suffering from debilitating genetic diseases like AGU.”

Dr. Mark J. Perry, Director of Business Development of AmplifyBio, said, “We are passionate to support acceleration of the advancement of novel therapeutics to waiting patients, and proud to be able to bring our expansive preclinical neuroscience study expertise to the partnership of our central Ohio based team.”

“We’re thrilled to be partnering with these two forward-thinking, innovative companies,” said Greg Kimmel, General Manager of Battelle’s Health business unit. “By combining our strengths, we have an opportunity to make a true impact using gene therapy to address this disease.”

With Andelyn’s GMP manufacturing capabilities now established at the state of the art 180,000 square foot Andelyn Corporate Center (ACC), Andelyn is proud to offer its clients exceptional quality and large-scale suspension clinical and commercial manufacturing in the Columbus, Ohio biotech hub. The ACC augments Andelyn’s two other Columbus facilities offering pre-clinical process development and plasmid manufacturing.

About Andelyn Biosciences, Inc.

Andelyn Biosciences is a full-service cell and gene therapy CDMO focused on the development, characterization and production of viral vectors for gene therapy. With more than 20 years of experience, Andelyn’s deep scientific expertise has resulted in the production of cGMP material for more than 450 clinical batches and 75 global clinical trials. Operating out of three Columbus, Ohio facilities, Andelyn supports its clients in developing curative cell and gene therapies from concept through plasmid development and manufacturing, process development, and cGMP clinical and commercial manufacturing. Andelyn’s versatile capabilities include cGMP manufacturing capacity for both adherent and suspension processes up to a 2,000-liter capacity. An advanced digital model, quality system, full regulatory support and supply chain vertical integration help Andelyn accelerate the development and manufacturing of its clients’ innovative cell and gene therapies. For more information, visit andelynbio.com.

About Battelle

Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world, Battelle conducts research and development, designs and

manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries. For more information, visit www.battelle.org

About AmplifyBio

AmplifyBio is a drug development and commercialization partner for advanced therapies. Launched out of Battelle in 2021, they provide industry-leading preclinical toxicology, safety, and pharmacology testing in an agile environment with analytics capabilities that serve the dynamic safety requirements of modern modalities. AmplifyBio further expanded in 2022 to offer R&D services with a particular focus on drug characterization services that de-risk scale-up and manufacturing. In 2023, they opened their first fully customizable manufacturing suites for lease in staffing models that range from full “hoteling” to more traditional outsourcing partnerships. In any service program, AmplifyBio clients harness decades of experience in drug development, safety testing, and manufacturing support services to reduce risks, timelines, and costs of bringing life-saving cures to patients. www.amplify-bio.com

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