Andelyn Biosciences, a cell and gene therapy contract development and manufacturing (CDMO) born out of Nationwide Children's Hospital, said that the U.S. FDA has accepted its GMP plasmid DNA drug master file (DMF), which enables the organization to vertically integrate its clients' manufacturing process, condensing timelines for developers to begin manufacturing to just three months.

Most of today's gene therapies—including adeno-associated virus- and lentivirus-based therapies—depend on plasmid DNA as either a critical starting material or an API. With the rapid growth of the gene therapy development pipeline and massive quantities of plasmid DNA required for the global mRNA COVID-19 vaccination effort, timelines for securing this essential material have escalated dramatically, causing large delays.

With industry capacity restrictions and throughput bottlenecks, gene therapy manufacturers wait, on average, ten months for production, analytical analysis, and release of plasmids. This wait, combined with delays associated with fragmented materials suppliers and CDMOs, often results in a gene therapy commercial manufacturing timeline of approximately 18 months.

"For Andelyn, 18 months is too long to deliver the life-saving promise of gene therapies to patient populations with unmet medical needs," said Wade Macedone, COO, Andelyn Biosciences. "Andelyn's mission is to enable gene therapy developers to deliver therapeutics to patients much faster, and developers working with us can now begin commercial manufacturing in just three months."

While Andelyn Biosciences' scientific team has decades of experience working with plasmid DNA, the company began offering research-grade plasmids in 2019 and clinical-grade plasmids in 2021. The accepted DMF will allow Andelyn Biosciences' clients to leverage important intellectual property information resulting in speed and efficiency when filing an IND or BLA with the FDA.

While the GMP plasmid DNA offering is key to vertically integrating the complete gene therapy manufacturing process for Andelyn's clients, increased production capacity is another factor. By the end of the first quarter of 2022, the company expects to double its plasmid DNA production capacity and quintuple that capacity by the end of 2023.

"Our clinical-grade plasmid DNA enables end-to-end manufacture of GMP gene therapies for our clients, and the regulatory filing efficiency created by the DMF adds fuel to our fire," said Kristin Heller, plasmid manager, Andelyn Biosciences. "We already have experienced quality assurance and quality control teams in place, but the plasmid DNA scale and capacity we are bringing online is game-changing, providing our clients with immediate access to starting materials and product

manufacturing."

Macedone expanded, "The tremendous expertise and experience made possible by our founding within Nationwide Children's Hospital have led to rapid growth. However, to achieve the capacity and capabilities urgently required by the gene therapy sector, we needed to increase our production footprint significantly. Our new 185,000 square-foot commercial-scale gene therapy manufacturing plant housed within the Ohio State University's Innovation District is coming online in July 2022, along with the new Andelyn Development Center in Dublin, OH, opening in Q2 2022 will do precisely this. Capacity expansions coupled with our clinical-grade plasmid DNA offering allows us to be a fully vertically integrated gene therapy CDMO continuing to contribute to the capacity and capabilities required to advance the gene therapy sector."

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