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Viralgen Receives cGMP Certification from European Medicines Agency

Certification confirms Viralgen's commitment to high operational standards with the world's most flexible and robust AAV manufacturing capability

San Sebastián, Spain/Research Triangle Park, N.C. (27 Aug., 2019) – Viralgen and AskBio announced that Viralgen has received Current Good Manufacturing Practices (cGMP) compliance accreditation and Pharmaceutical Laboratory authorization by the AEMPS (Spanish Agency for Medicines and Health Products) and certification from the European Medicines Agency (EMA). Based in San Sebastián, Spain, Viralgen is a leading contract development and manufacturing organization (CDMO) that specializes in developing, validating and manufacturing adeno-associated virus (AAV) gene therapies.

"We have gone from a bare concrete floor to a fully certified, world-class facility in less than two years," said Javier García, Viralgen's CEO. "The quality of our facility, scaled-up manufacturing processes, and this certification underscore our commitment to helping our clients develop safer and more effective therapies for genetic disease. We have an amazing facility and a highly skilled team focused on delivering technology that produces higher yields of rAAV vectors, ultimately contributing to lowering the cost of potentially life-saving therapeutics for patients in need."

Adherence to the cGMP regulations guides the proper quality, monitoring, safety, efficacy and information accuracy of medicines and health products for manufacturing processes and facilities in the interest of protecting and promoting people's health.

A key benefit of Viralgen's technology is the cGMP production of high-quality rAAV in large batches through a unique and robust manufacturing platform. AskBio, which owns 50 percent of Viralgen, has developed the world's foremost clinical stage gene therapy platform that includes an industry-leading proprietary cell line manufacturing process known as Pro10™. This allows Viralgen to scale cGMP manufacturing of rAAV vectors at levels that exceed what other CMOs can produce and enables flexible, scalable clinical manufacturing faster than current industry standards.

According to Mr. García, Viralgen's current cGMP capacity is comprised of:

- Three independent, state-of-the-art cGMP production suites (>1800m2), providing the capability to continuously and simultaneously manufacture three different products
- 50L scale to supply toxicology/biodistribution studies with full support for research, toxicology and GMP production in parallel
- 50L, 250L and 500L single-use stirred-tank bioreactors for culture of suspension cells with a total capacity of 1,250 liters of dedicated AAV production
- In-house quality control labs for critical release assays

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Mr. García also noted that Viralgen plans to expand its current footprint with support for up to 2000L scale for commercial use by the end of 2021. This will enable full life cycle support and maximized flexibility to serve a wide range of AAV capsids for manufacturing potentially curative therapeutics.

“Viralgen is a focused and highly capable organization with an unparalleled depth of resources devoted to being the world’s best AAV CDMO,” said Sheila Mikhail, CEO and co-founder of AskBio. “Viralgen delivers its clients a superior level of quality to ensure safe, reliable AAV vectors for clinical use that are commercially ready for large-scale production. Together, we look forward to solving many of the gene therapy cost and scale issues that face our industry today.”

Dr. Jude Samulski, co-founder of AskBio and considered the founder of AAV gene therapeutics, adds, “Viralgen plays a critical role in our mission as one of the three pillars required for successful AAV gene therapy (i.e., production, promoters and capsids). The production pillar is absolutely necessary to erase genetic disease and make therapeutics accessible without limits.”

About Viralgen
Founded in 2017 as a joint venture between AskBio and Columbus Venture Partners (a Spanish venture capital group), Viralgen is a world-class AAV cGMP. Viralgen licenses AskBio’s Pro10™ cell line technology that allows for greater scale, higher yields and increased accuracy of AAV therapeutics. Based at the Miramon Parke in San Sebastián, Spain, Viralgen is a CDMO (Contract Development and Manufacturing Organization) that produces AAV gene therapy treatments to enable pharmaceutical and biotechnology companies to accelerate the delivery of novel treatments to improve patient lives.

About AskBio
Asklepios BioPharmaceutical, Inc. (AskBio) is a privately held, clinical stage gene therapy platform company dedicated to improving the lives of children and adults with rare genetic disorders. AskBio’s gene therapy platform includes an industry-leading proprietary cell line manufacturing process known as Pro10™, an extensive AAV capsid library, and synthetic promoter technology. The company has generated hundreds of proprietary third generation gene vectors, several of which have entered clinical testing, and maintains a portfolio of development programs across a range of indications, including Pompe, Limb Girdle Muscular Dystrophy, Cystic Fibrosis, Myotonic Muscular Dystrophy and Huntington’s; other programs that use AskBio’s technology include Hemophilia (Chatham Therapeutics/Takeda) and Duchenne Muscular Dystrophy (Bamboo Therapeutics/Pfizer). For more information, visit www.askbio.com.

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