PRESS RELEASE

Viralgen receives cGMP certification to produce rAAV commercial grade product at new facility in San Sebastian, Spain

-- Certification expands Viralgen's capacity threefold and positions the company as a world-leading CDMO --

-- New facility operates single-use bioreactors from 50 to 2,000 liters and manufactures research, clinical and commercial grade rAAV vectors using Pro10™, the leading cell line on the market --

09/01/23. San Sebastian. Viralgen Vector Core (Viralgen), an independently operated subsidiary of Asklepios BioPharmaceutical, Inc. (AskBio), and a member of the Bayer worldwide group of companies, has received Certified Good Manufacturing Practices (cGMP) certification for the manufacture of human medicinal products, investigational medicinal products and sterile or biological active substances. This certification was granted following a successful inspection by the Spanish Agency for Medicines and Medical Devices (AEMPS), a part of the European Medicines Agency (EMA) network. The company now operates two facilities in San Sebastian, Spain, with seven state-of-the-art single-use suites that have up to 2,000 liters of manufacturing capacity, making it a world-leading contract development and manufacturing organization (CDMO).

Viralgen is now licensed for the commercial manufacturing of recombinant adeno-associated virus (rAAV) gene therapies up to 2,000 liters and has completed seven successful runs at this maximum scale. This first phase of the expansion of the new facility, which has added 300,000 square feet of clinical and commercial rAAV manufacturing, is now complete. The new facility currently has three independent state-of-the-art quality control labs and commercial manufacturing suites with 500- and 2,000-liter single-use bioreactors. Viralgen anticipates opening additional manufacturing, science and technology (MSAT) and analytical development space at the same facility at the end of Q1 2023.

"Being a fully integrated CDMO, we offer a continuum of products and services, including process, analytical development, stability studies and fill and finish for all types of rAAV serotypes," said Jimmy Vanhove, CEO of Viralgen. "This can significantly shorten the time to market, help with predictable cost of goods and reduce the waiting time experienced by patients who have run out of options and hope for breakthrough treatments."

With this approval, Viralgen expands its ability to partner with customers in the rAAV space that are initiating Phase III studies and seeking approvals to commercialize their products. This builds on the company's achievement of its 2022 pivotal milestone, which was the manufacturing over 135 batches of clinical and preclinical material, and its enabling more than 24 INDs since its inception in 2019.

“With this certification, we have three times the rAAV production capacity we had previously. This solidifies our position as a global leader in the CDMO rAAV field”, said Javier García, co-founder and Chairman of the Board of Viralgen. “We are now able to manufacture at the industry's largest scale and supply Phase III and commercial products for our global customers.”

Viralgen was created in 2017 to respond to the unmet need for the manufacturing of gene therapies, with the goal of helping broaden access to these life-saving therapeutics around the world. Viralgen specializes in the production of rAAV vectors and has built an optimized facility that maximizes the throughput and efficiency of the proprietary Pro10™ based suspension manufacturing platform, enabling industry-leading yields, scalability and speed to market. Viralgen is a fully integrated company, which supplies research, cGMP and commercial grade material from 250 to 2,000 liters in scale, including process development, formulation and filling.

About Viralgen

Viralgen, an independently operated Contract Development and Manufacturing Organization (CDMO), was founded in 2017 as a joint venture between AskBio and Columbus Venture Partners (a venture capital firm based in Spain). As one of the world’s leading manufacturers of cGMP-certified AAV, Viralgen uses the Pro10™ based suspension manufacturing platform, a technology licensed from AskBio and developed by co-founder R. Jude Samulski, PhD, at University of North Carolina. It is believed that Pro10™ increases scalability, performance and precision of AAV therapies. Located in Spain, in the Gipuzkoa Science and Technology Park, Viralgen produces AAV gene therapy treatments for pharmaceutical and biotech companies with the aim of accelerating the delivery of new treatments that can improve patients’ lives.

The company's clinical facilities have four cGMP manufacturing suites, with 250-liter and 500-liter bioreactors. In 2020, Viralgen expanded within the Scientific Park by constructing a new building for increased manufacturing capacity. The new space includes three additional cGMP suites with a manufacturing capacity of 2,000 liters each.

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Viralgen has more than 420 employees, with three quarters of these holding advanced degrees. This talented workforce supports a range of core capabilities in quality assurance, quality control, analytical development and process development, all of which are critical to shortening the time to market and supporting customers with the regulatory process.

For more information, visit viralgenvc.com.

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