



MASSACHUSETTS
EYE AND EAR



MASSACHUSETTS
GENERAL HOSPITAL

MEDIA CONTACT

Ryan Jaslow | Senior Manager of Media Relations | Mass. Eye and Ear
617-573-4385 | Ryan_Jaslow@meei.harvard.edu

EMBARGOED FOR RELEASE: TK.

AAVCOVID Vaccine Program Expands Manufacturing Agreements with Gene Therapy Industry Partners Viralgen, Aldevron, and Catalent

[The AAVCOVID vaccine program](#) at Massachusetts Eye and Ear and Massachusetts General Hospital has entered into manufacturing agreements with [Viralgen](#), [Aldevron](#) and [Catalent](#) in order to support manufacturing of the experimental vaccine for clinical studies in the second half of 2020.

Viralgen, Aldevron and Catalent are three leading commercial biologics manufacturing organizations with deep AAV expertise. Their partnership with AAVCOVID provides immediate support toward clinical trial readiness, production of vaccine dose under Good Manufacturing Practice (GMP) conditions, and scalable processes to address future supply.

The AAVCOVID vaccine program was developed in the laboratory of [Luk H. Vandenberghe, PhD](#), director of the Grousbeck Gene Therapy Center at Massachusetts Eye and Ear and Associate Professor at Harvard Medical School. The experimental vaccine uses an adeno-associated virus (AAV) vector to deliver and express the Spike gene of the SARS-CoV-2 virus, which causes COVID-19, to elicit an immune response.

“One important aspect of our vaccine is that it can leverage the extensive and established AAV industry that currently supports dozens of gene therapy products and programs. The expertise, capacity, and capabilities in terms of manufacturing that these companies offer will help us reach our goal of a widely distributed vaccine,” said Dr. Vandenberghe. “These partners allow us to initiate production of this vaccine with commercial and scalable processes. Their responsiveness to this program and the broader crisis is truly humbling and speaks to the collective threat and mission we as a society are fighting together against.”

AAVCOVID is currently in preclinical development with a plan to begin clinical testing in humans later this year. [Mason Freeman, MD](#), director and founder of the MGH Translational Research Center and a Professor of Medicine at Harvard Medical School, is leading the efforts to develop the clinical studies intended to establish safety and efficacy of the experimental vaccine.

Mass. Eye and Ear and Mass General are member hospitals of Mass General Brigham.

Leaders in AAV gene therapies respond to COVID-19 Crisis

[Viralgen](#), a leading contract development and manufacturing organization (CDMO) that specializes in developing, validating and manufacturing AAV gene therapy viral vectors, has agreed to join the

AAVCOVID program's team of manufacturers. The company, based in San Sebastian, Spain mobilized quickly as the pandemic crisis was happening in their own country, by leveraging its Pro10(TM) platform and deep expertise in AAV manufacturing.

The Pro10 platform was first developed at Askbio, and is built to produce high volumes of any AAV as quickly as possible, and designed to be accepted by global regulators. Viralgen's facilities, supply chain, and workflows were all purpose-built for this platform to supply hundreds of trillions of viral particles per batch to support treatment of diseases with very high demand for AAV, which is exactly what COVID vaccination will require. By leveraging combined expertise in vector design and optimization with the AAVCOVID scientists in the academic research laboratories, the scalability and strength of the Pro10 platform at Viralgen supports the potential to help bring down manufacturing costs and provide broader access to the vaccine.

[Aldevron](#), headquartered in Fargo, N.D, is a leading plasmid DNA manufacturing company which also manufactures an AAV with GMP standards. The company is lending expertise and its plasmid technology to help in the manufacturing of the AAVCOVID vaccine. Plasmid DNA from Aldevron is used in thousands of different applications to help carry a genetic code to the cell in order to fix a defect.

[Catalent](#) is a leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products based in Somerset, N.J. Catalent joined the AAVCOVID vaccine program to assist with manufacturing and testing capacity. Catalent Gene Therapy is a full-service partner for AAV vectors.

About AAVCOVID Vaccine Program

The AAVCOVID vaccine program is a gene-based vaccine strategy that seeks to deliver genetic sequences of the SARS-CoV-2 using an AAV vector. Vaccination delivers genetic DNA fragments SARS-CoV-2 which generates an antigen protein, which is designed to elicit an immune response to prevent infection. This approach is supported by extensive experience with the safety of the AAV technology platform in other diseases, including the use of AAVs in two FDA-approved medications.

AAVCOVID is an academia-industry collaboration is led by Dr. Vandenberghe, the Grousbeck Family Chair in Gene Therapy at Mass. Eye and Ear, who is a world-renowned leader and pioneer of viral gene transfer and therapeutic gene transfer. Dr. Vandenberghe is working in conjunction with a clinical partner in Dr. Freeman, who serves as Director of the Translational Medicine Group of the MGH Center for Computational and Integrative Biology and is Professor of Medicine at Harvard Medical School.

Dr. Vandenberghe and his laboratory began work on the vaccine in mid-January following the Wuhan outbreak and the first publication of genetic sequences of the new coronavirus. Using a specific AAV with desirable vaccine properties, the program seeks to induce immunity to prevent infection and or disease in healthy populations, leveraging the existing manufacturing capabilities of the AAV industry.

AAV is also a rapidly adaptable technology. If a new strain of the SARS-CoV-2 virus emerges, the genetic code inside the AAVCOVID vaccine can be exchanged for an updated genetic code and processed into an updated vaccine in weeks, according to the researchers.

About Massachusetts Eye and Ear

Massachusetts Eye and Ear, founded in 1824, is an international center for treatment and research and a teaching hospital of Harvard Medical School. A member of Mass General Brigham, Mass. Eye and Ear specializes in ophthalmology (eye care) and otolaryngology—head and neck surgery (ear, nose and throat care). Mass. Eye and Ear clinicians provide care ranging from the routine to the very complex. Also home to the world's largest community of hearing and vision researchers, Mass. Eye and Ear scientists are driven by a mission to discover the basic biology underlying conditions affecting the eyes, ears, nose, throat, head and neck and to develop new treatments and cures. In the 2019–2020 “Best Hospitals Survey,” *U.S. News & World Report* ranked Mass. Eye and Ear #4 in the nation for eye care and #2 for ear, nose and throat care. For more information about life-changing care and research at Mass. Eye and Ear, visit our blog, [Focus](#), and follow us on [Instagram](#), [Twitter](#) and [Facebook](#).

About Massachusetts General Hospital

Massachusetts General Hospital, founded in 1811, is the original and largest teaching hospital of Harvard Medical School. The [MGH Research Institute](#) conducts the largest hospital-based research program in the nation, with an annual research budget of more than \$1 billion and comprises more than 8,500 researchers working across more than 30 institutes, centers and departments. In August 2019 the MGH was once again named #2 in the nation by *U.S. News & World Report* in its list of "America's Best Hospitals."

About Harvard Medical School Department of Ophthalmology

The Harvard Medical School [Department of Ophthalmology](#) is one of the leading and largest academic departments of ophthalmology in the nation. Composed of nine affiliates (Massachusetts Eye and Ear, which is home to Schepens Eye Research Institute; Massachusetts General Hospital; Brigham and Women's Hospital; Boston Children's Hospital; Beth Israel Deaconess Medical Center; Joslin Diabetes Center/Beetham Eye Institute; Veterans Affairs Boston Healthcare System; Veterans Affairs Maine Healthcare System; and Cambridge Health Alliance) and several international partners, the department draws upon the resources of a global team to pursue a singular goal—eradicate blinding diseases so that all children born today will see throughout their lifetimes. Formally established in 1871, the department is committed to its three-fold mission of providing premier clinical care, conducting transformational research, and providing world-class training for tomorrow's leaders in ophthalmology.

About Viralgen

Viralgen Vector Core is a partnership uniquely positioned in the CDMO industry to bring forward a robust suspension platform for AAV production in a facility custom-designed to bring therapies to market as quickly as possible. Leveraging the technology platforms of Askbio, Viralgen is able to support every aspect of your AAV program from start to finish, including large-scale manufacturing, fill-finish, and quality control in a GMP-certified environment in San Sebastian, Spain.

Viralgen Vector Core becomes the convergence point from experienced specialized organizations in biotechnology and life sciences, united with the aim of creating a CDMO in the cutting-edge sector of gene therapy and innovative medicines.

Devoted to the Development and Manufacturing of viral vectors, in order to contribute to the progress in health and welfare of people.

About Aldevron

Aldevron serves the biotechnology industry with custom production of nucleic acids, proteins, and antibodies. Thousands of clients use Aldevron-produced plasmids, RNA and gene editing enzymes for projects ranging from research grade to clinical trials to commercial applications. Aldevron specializes in GMP manufacturing and is known for inventing the GMP-Source® quality system. Company headquarters are in Fargo, N.D., with additional facilities in Madison, Wisc., and Freiburg, Germany.

About Catalent

Catalent is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable global clinical and commercial product supply. Catalent employs over 13,500 people, including over 2,400 scientists and technicians, at more than 40 facilities, and in fiscal year 2019 generated over \$2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com

More products. Better treatments. Reliably supplied.™