



NEWS RELEASE

# Inovio Receives European Medicines Agency Certification For Quality and Non-Clinical Data for Its Phase 3 Product, VGX-3100

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PLYMOUTH MEETING, Pa., May 6, 2019 /PRNewswire/ -- Inovio Pharmaceuticals, Inc. (NASDAQ: INO) today announced that its lead Phase 3 product candidate, VGX-3100, has been granted an Advanced Therapy Medicinal Product Certificate for quality and non-clinical data. The procedure of certification of quality and non-clinical data involves an assessment of the available data in view of future registration and the related European Scientific Data Requirements, not including any clinical data or benefit-risk assessment. The granted EMA's certificate confirms that Inovio's chemistry, manufacturing and controls (CMC) data and nonclinical results available to date overall comply with the scientific and technical standards for evaluating an EU Marketing Authorization.

Dr. Ami Shah Brown, Inovio's Senior Vice President of Regulatory Affairs, said, "We are extremely pleased that the current CMC, coupled with the nonclinical data supporting our lead product, VGX-3100, meets stringent EMA requirements. This certification is a testament to Inovio's technical excellence, cross-functional development expertise, and high quality standards as applied for VGX-3100 and indirectly for Inovio's technology."

VGX-3100 is currently being tested in a pivotal, global Phase 3 program, which is assessing the efficacy of VGX-3100 to regress cervical HSIL (high-grade squamous intraepithelial lesions), a direct precursor to cervical cancer, and to eliminate the HPV infection that causes these lesions. In parallel, the final commercial manufacturing process will be validated yielding additional quality data by time of the EU filing.

## About VGX-3100

VGX-3100 is a DNA-based immunotherapy under investigation for the treatment of HPV 16 and HPV 18 infection and precancerous lesions of the cervix (Phase 3) and vulva and anus (Phase 2). VGX-3100 has the potential to be the first approved treatment for HPV infection of the cervix and the first non-surgical treatment for precancerous cervical lesions. VGX-3100 works by stimulating a specific immune response to HPV-16 and HPV-18, which targets the infection and causes destruction of precancerous cells. In a randomized, double-blind, placebo-controlled Phase 2b study in 167 adult women with histologically documented HPV 16/18

cervical HSIL (CIN2/3), treatment with VGX-3100 resulted in a statistically significantly greater decrease in cervical HSIL and clearance of HPV infection vs. placebo. The most common side effect was injection site pain, and no serious adverse events were reported. VGX-3100 utilizes the patient's own immune system to clear HPV 16 and HPV 18 infection and precancerous lesions without the increased risks associated with surgery, such as loss of reproductive health and negative psychosocial impacts.

## About Inovio Pharmaceuticals, Inc.

Inovio is a late-stage biotechnology company focused on the discovery, development, and commercialization of DNA-based immunotherapies and vaccines that transform the treatment and prevention of cancer and infectious disease. Inovio's proprietary technology platform applies antigen sequencing and DNA delivery to activate potent immune responses to targeted diseases. The technology functions exclusively in vivo, and has been demonstrated to consistently activate robust and fully functional T cell and antibody responses against targeted cancers and pathogens. Inovio's most advanced clinical program, VGX-3100, is in Phase 3 for the treatment of HPV-related cervical pre-cancer. Also in development are Phase 2 immuno-oncology programs targeting HPV-related cancers, bladder cancer, and glioblastoma, as well as platform development programs in hepatitis B, Zika, Ebola, MERS, and HIV. Partners and collaborators include AstraZeneca, Regeneron, Roche/Genentech, ApolloBio Corporation, The Wistar Institute, The Bill & Melinda Gates Foundation, the University of Pennsylvania, Parker Institute for Cancer Immunotherapy, CEPI, DARPA, GeneOne Life Science, Plumline Life Sciences, NIH, HIV Vaccines Trial Network, National Cancer Institute, Walter Reed Army Institute of Research, Drexel University, and Laval University. For more information, visit [www.inovio.com](http://www.inovio.com).

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This press release contains certain forward-looking statements relating to our business, including our plans to develop electroporation-based drug and gene delivery technologies and DNA vaccines, our expectations regarding our research and development programs, including the planned initiation and conduct of clinical trials and the availability and timing of data from those trials. Actual events or results may differ from the expectations set forth herein as a result of a number of factors, including uncertainties inherent in pre-clinical studies, clinical trials and product development programs, the availability of funding to support continuing research and studies in an effort to prove safety and efficacy of electroporation technology as a delivery mechanism or develop viable DNA vaccines, our ability to support our pipeline of SynCon® active immunotherapy and vaccine products, the ability of our collaborators to attain development and commercial milestones for products we license and product sales that will enable us to receive future payments and royalties, the adequacy of our capital resources, the availability or potential availability of alternative therapies or treatments for the conditions targeted by us or our collaborators, including alternatives that may be more efficacious or cost effective than any therapy or treatment that we and our collaborators hope to develop, issues involving product liability, issues involving patents and whether they or licenses to them will provide us with meaningful protection from others using the covered technologies, whether such proprietary rights are enforceable or defensible or infringe or allegedly infringe on rights of others or can withstand claims of invalidity and whether we can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of our technology by potential corporate or other partners

or collaborators, capital market conditions, the impact of government healthcare proposals and other factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2018 and other regulatory filings we make from time to time. There can be no assurance that any product candidate in our pipeline will be successfully developed, manufactured or commercialized, that final results of clinical trials will be supportive of regulatory approvals required to market licensed products, or that any of the forward-looking information provided herein will be proven accurate. Forward-looking statements speak only as of the date of this release, and we undertake no obligation to update or revise these statements, except as may be required by law.

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