NEWS RELEASE

INOVIO Highlights Key Updates on Phase 3 Program for VGX-3100, its DNA-based Immunotherapy for the Treatment of Cervical HSIL Caused by HPV-16 and/or HPV-18

12/14/2021

INOVIO completes enrollment of REVEAL2

Long-term data favorable from REVEAL1

PLYMOUTH MEETING, Pa., Dec. 14, 2021 /PRNewswire/ -- INOVIO (NASDAQ: INO), a biotechnology company focused on bringing to market precisely designed DNA medicines to help protect people from infectious diseases and treat cancer and HPV-associated diseases, today announced updates on the Phase 3 program for VGX-3100 for HPV-associated cervical high-grade squamous intraepithelial lesions (HSIL), including a one-year follow-up of efficacy and safety data in participants from REVEAL1, completing enrollment in REVEAL2, and advancing its pre-treatment biomarker candidate for VGX-3100 to be further developed with QIAGEN. In addition, INOVIO's development partner within Greater China (mainland China, Hong Kong, Macao, Taiwan), ApolloBio Corp. ("ApolloBio"), dosed the first participant in a separate Phase 3 trial in China.

Key Updates for VGX-3100:

- REVEAL2 – INOVIO's second global Phase 3 clinical trial of VGX-3100 for cervical HSIL is fully enrolled and top-line efficacy and safety data are expected to be available in 2H22.
- REVEAL1 – INOVIO completed the 52-week safety follow-up of participants in REVEAL1, INOVIO's first global Phase 3 trial of VGX-3100, and the safety profile of VGX-3100 observed at Week 36 remained well-tolerated through Week 88. In addition, participants treated with VGX-3100 who met the primary endpoint at Week 36 remained clear of HPV-16 and/or HPV-18 at Week 88.
- Pre-treatment Biomarker – INOVIO and QIAGEN have made progress in biomarker development by identifying candidate biomarker signatures for VGX-3100 with the intent of selecting a final signature in a pre-treatment in vitro diagnostic to improve the primary clinical outcome for biomarker-positive patients

with cervical HSIL.

- Phase 3 Trial in China – The first participant has been dosed in the Phase 3 trial of VGX-3100 for cervical HSIL in China. This trial is being run by ApolloBio and is similar in design to REVEAL2. The trial is expected to enroll up to 84 participants.

Dr. J. Joseph Kim, President and CEO of INOVIO, said, "We are making strong progress in developing INOVIO's immunotherapies treating HPV-associated cervical HSIL. Left untreated, cervical HSIL may progress to cancer. VGX-3100 has the potential to be the first approved immunotherapy and non-surgical alternative for women with cervical HSIL and we look forward to advancing our efforts from our Phase 3 studies through commercialization."

Dr. Jeffrey Skolnik, Senior Vice President of Clinical Development and Program Lead for VGX-3100, added, "Completing enrollment for REVEAL2, and reporting on our long-term data from REVEAL1, are important milestones for VGX-3100 and an opportunity to advance women's health, given the lack of a non-surgical therapeutic for cervical HSIL. With our two Phase 3 studies now fully enrolled, INOVIO remains on target for the topline efficacy readout from this study in the second half of 2022."

INOVIO's Phase 3 program in cervical HSIL is assessing the efficacy of VGX-3100 to regress cervical HSIL, a direct precursor to cervical cancer, and to eliminate the HPV-16 and/or HPV-18 infection that causes these lesions. The REVEAL studies are prospective, randomized, double-blind, placebo-controlled trials evaluating adult women with HPV-16 and/or HPV-18 positive biopsy-proven cervical HSIL. REVEAL1 provided one-year post-endpoint safety data for a minimum of 198 participants randomized, while REVEAL2 will provide efficacy and one-month safety data for a minimum of 198 participants. For more information on the REVEAL1 and REVEAL2 studies, please visit **clinicaltrials.gov** (search identifier NCT03185013 and NCT03721978, respectively).

INOVIO completed the 52-week safety follow-up of participants in REVEAL1 and showed that the safety profile of VGX-3100 at Week 36 remained well-tolerated through Week 88. In addition, participants treated with VGX-3100 who met the primary endpoint at Week 36 remained clear of HPV-16 and/or HPV-18 at Week 88. There was no substantial change in the per-protocol assessment of primary efficacy from the mITT analysis that was previously reported for REVEAL1 (**link**).

Additionally, INOVIO is advancing its partnership with QIAGEN to co-develop a liquid biopsy-based diagnostic product based on next-generation sequencing (NGS) technology to guide clinical decision-making for the use of VGX-3100 in cervical HSIL. This biomarker, if validated, has the potential to increase the probability of clinical response in biomarker-positive women with cervical HSIL. QIAGEN offers an extensive expertise in technologies from polymerase chain reaction (PCR) to NGS for diagnostic development. INOVIO anticipates having additional information on its biomarker development in 2022.

Separately, INOVIO's partner ApolloBio dosed the first participant in the Phase 3 clinical trial of VGX-3100 in China. The Phase 3 trial in China is similar in design to REVEAL1 and REVEAL2 – randomized, double-blinded, placebo-controlled. The trial is expected to enroll 84 participants. In 2018, the companies signed an agreement providing ApolloBio with the exclusive right to develop, manufacture and commercialize VGX-3100 within Greater China (**link**).

About INOVIO

INOVIO is a biotechnology company focused on rapidly bringing to market precisely designed DNA medicines to treat and protect people from infectious diseases, cancer, and diseases associated with HPV. INOVIO has clinically shown that a DNA vaccine candidate can be delivered directly into cells in the body via a proprietary smart device to produce a robust and tolerable immune response. INOVIO is evaluating candidate VGX-3100 in two Phase 3 trials for precancerous high-grade cervical dysplasia caused by HPV-16 and/or HPV-18. INOVIO is also evaluating INO-4800, a DNA vaccine candidate against COVID-19, in a Phase 2/3 clinical trial; the Phase 3 segment of which has received regulatory approvals to proceed in Colombia, Mexico, Brazil, Philippines, India, Thailand, and the United States. INOVIO's partners, Advaccine Biopharmaceuticals and International Vaccine Institute, are also evaluating INO-4800 in ongoing clinical trials in China and South Korea, respectively.

Partners and collaborators include Advaccine, ApolloBio Corporation, AstraZeneca, The Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations, Defense Advanced Research Projects Agency/Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense/Department of Defense, HIV Vaccines Trial Network, International Vaccine Institute, Kaneka Eurogentec, Medical CBRN Defense Consortium, National Cancer Institute, National Institutes of Health, National Institute of Allergy and Infectious Diseases, Ology Bioservices, the Parker Institute for Cancer Immunotherapy, Plumbline Life Sciences, Regeneron, Richter-Helm BioLogics, Thermo Fisher Scientific, University of Pennsylvania, Walter Reed Army Institute of Research, and The Wistar Institute. For more information, visit **www.inovio.com**.

CONTACTS:

Media: Jeff Richardson, 267-440-4211, **jrichardson@inovio.com**
Investors: Ben Matone, 484-362-0076, **ben.matone@inovio.com**

This press release contains certain forward-looking statements relating to our business, including our plans to develop DNA medicines, our expectations regarding our research and development programs, including the planned initiation and conduct of preclinical studies and clinical trials and the availability and timing of data from those studies and trials, and our ability to successfully manufacture and produce large quantities of our product candidates if they receive regulatory approval. 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,

product development programs and commercialization activities and outcomes, our ability to secure sufficient manufacturing capacity to mass produce our product candidates, 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 medicines, our ability to support our pipeline of DNA medicine 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, 2020, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 and other filings we make from time to time with the Securities and Exchange Commission. 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 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.

View original content:**https://www.prnewswire.com/news-releases/inovio-highlights-key-updates-on-phase-3-program-for-vgx-3100-its-dna-based-immunotherapy-for-the-treatment-of-cervical-hsil-caused-by-hpv-16-andor-hpv-18-301443997.html**

SOURCE INOVIO Pharmaceuticals, Inc.