



NEWS RELEASE

Inovio Pharmaceuticals Adds Dr. Prakash Bhuyan to VGX-3100 Leadership Team for HPV-Related Dysplasia

2016-01-04

Dr. Bhuyan's Accomplishments Include Successful Development of Vaccines at Pfizer and Merck

PLYMOUTH MEETING, Pa., Jan. 04, 2016 (GLOBE NEWSWIRE) -- Inovio Pharmaceuticals, Inc. (NASDAQ:INO) announced today it has appointed Prakash Bhuyan, M.D, Ph.D., as Vice President, Clinical Development. Dr. Bhuyan will lead the clinical development of Inovio's programs to treat HPV-related pre-cancers (dysplasia). Inovio will take VGX-3100, its treatment for cervical dysplasia caused by the human papillomavirus (HPV), into a phase 3 registration study this year. He will report to Dr. Mark Bagarazzi, Chief Medical Officer.

Prior to joining Inovio, Dr. Bhuyan was Senior Director, Pfizer Vaccine Research, where he led the pivotal clinical study that helped achieve FDA approval in 2014 of the first meningococcal B vaccine to be licensed in the U.S.

Prior to Pfizer, Dr. Bhuyan directed the development and execution of multiple vaccine clinical trials for 4 licensed vaccines at Merck and successfully led an investigational hexavalent pediatric vaccine from phase 2 into phase 3 trials. He earned his M.D. and his Ph.D. in Immunology from the University of Texas Southwestern Medical Center. He completed his fellowship in Infectious Diseases at the University of Pennsylvania, where he currently serves as adjunct assistant professor.

Dr. Mark Bagarazzi, Chief Medical Officer, said, "Dr. Prakash Bhuyan has demonstrated leadership in advancing vaccines to licensure and we are pleased to bring him to Inovio where he will focus on advancing the development of VGX-3100. He will be instrumental in guiding VGX-3100, our immunotherapy for cervical pre-cancer, into phase 3 later this year."

Inovio's phase 2b trial showed that histopathological regression of high grade cervical neoplasia (CIN2/3) to low grade neoplasia (CIN1) or no disease occurred in a significantly higher percentage of VGX-3100 recipients compared with placebo recipients. Furthermore, concomitant histopathological regression and clearance of HPV occurred in a significantly higher percentage of VGX-3100 recipients compared with placebo recipients. HPV-specific CD8+ "killer T cells" were also generated in the blood as well as a substantial infiltration of CD8+ cells in the cervical tissue of VGX-3100 recipients, underscoring the role played by Inovio's best-in-class T-cell responses. VGX-3100 was safe and generally well-tolerated.

In VGX-3100-treated women whose high grade dysplasia regressed, most (43 out of 53) completely cleared their lesions to normal (complete response). Moreover, eighty percent of VGX-3100-treated women whose dysplasia regressed also eradicated the infecting HPV genotype (i.e. 16 or 18) from the cervix. This is an important outcome as persistence of the virus is associated with recurrence of the disease.

In 2015, The Lancet reported on results of Inovio's phase 2b trial in an article entitled, "Safety, efficacy, and immunogenicity of VGX-3100, a therapeutic synthetic DNA vaccine targeting human papillomavirus 16 and 18 E6 and E7 proteins for cervical intraepithelial neoplasia 2/3: a randomized, double-blind, placebo-controlled phase 2b trial," by C. Trimble, et al.

About VGX-3100

Inovio's VGX-3100 is an immunotherapy containing two DNA plasmids targeting the E6 and E7 oncogenes of HPV types 16 and 18. These oncogenes are responsible for transforming HPV-infected cells into pre-cancerous and cancerous cells. The treatment is administered to patients by injection into muscle (typically in the arm), followed by electroporation using Inovio's CELLECTRA® device. VGX-3100 has been shown to induce a robust immune response against the E6 and E7 oncogenes associated with HPV types 16 and 18.

About HPV and Cervical Dysplasia

Human papillomavirus (HPV) is the most common sexually transmitted disease. At any given time, approximately 11% percent of the world population is infected with HPV. Roughly 75% or less of HPV 16/18 infections are cleared by naturally occurring immune responses in women of all ages.

Persistent HPV infection can lead to dysplasia, or premalignant changes, in cervical cells. HPV types 16 and 18 cause 70% of cervical dysplasia and cervical cancer cases. Each year in the United States, 1.4 million women are diagnosed with CIN1 and 300,000-400,000 women are diagnosed with CIN2/3. All cervical cancers arise from untreated CIN2/3.

About Inovio Pharmaceuticals, Inc.

Inovio is taking immunotherapy to the next level in the fight against cancer and infectious diseases. We are the only immunotherapy company that is generating T cells in vivo in high quantity that are fully functional and whose killing capacity correlates with relevant clinical outcomes with a favorable safety profile. With an expanding portfolio of immune therapies, the company is advancing a growing preclinical and clinical stage product pipeline. Partners and collaborators include MedImmune, Roche, University of Pennsylvania, DARPA, GeneOne Life Science, Drexel University, NIH, HIV Vaccines Trial Network, National Cancer Institute, U.S. Military HIV Research Program, and University of Manitoba. For more information, visit www.inovio.com.

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 and our capital resources. 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 (including, but not limited to, the fact that pre-clinical and clinical results referenced in this release may not be indicative of results achievable in other trials or for other indications, that the studies or trials may not be successful or achieve the results desired, including safety and efficacy for VGX-3100 and INO-3112, that pre-clinical studies and clinical trials may not commence or be completed in the time periods anticipated, that results from one study may not necessarily be reflected or supported by the results of other similar studies and that results from an animal study may not be indicative of results achievable in human studies), 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 broad pipeline of SynCon® active immune therapy and vaccine products, our ability to advance our portfolio of immune-oncology products independently, 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 the company or its collaborators, including alternatives that may be more efficacious or cost-effective than any therapy or treatment that the company and its collaborators hope to develop, our ability to enter into partnerships in conjunction with our research and development programs, evaluation of potential opportunities, issues involving product liability, issues involving patents and whether they or licenses to them will provide the company 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 the company can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of the company's 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, 2014, our Form 10-Q for the quarter ended September 30, 2015, and other regulatory filings from time to time. There can be no assurance that any product in Inovio's pipeline will be successfully developed or manufactured, that final results of clinical studies 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.

CONTACTS:

Investors: Bernie Hertel, Inovio Pharmaceuticals, 858-410-3101, bhertel@inovio.com

Media: Jeff Richardson, Inovio Pharmaceuticals, 267-440-4211, jrichardson@inovio.com

Source: Inovio Pharmaceuticals