

# **Inovio Announces FDA Request for Additional Information For Phase III Program; Trial Initiation Delayed**

**Inovio Pharmaceuticals, Inc. {NASDAQ: INO}** has announced that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on its proposed phase III clinical program for VGX-3100.

A clinical hold is a notification issued by the FDA to a trial sponsor to delay a proposed clinical trial or suspend an ongoing clinical trial.

## **Inovio Announces FDA Request for Additional Information For Phase III Program; Trial Initiation Delayed**

PLYMOUTH MEETING, Pa. – October 24, 2016 – **Inovio Pharmaceuticals, Inc. {NASDAQ: INO}** today announced that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on its proposed phase III clinical program for VGX-3100.

*A clinical hold is a notification issued by the FDA to a trial sponsor to delay a proposed clinical trial or suspend an ongoing clinical trial. This study has not yet been initiated and has not enrolled or dosed subjects. Additionally, the hold does not pertain to any of Inovio's other ongoing clinical studies.*

Inovio anticipates receiving a formal letter with complete information from the FDA within 30 days.

In its initial communication, the FDA has requested additional data to support the shelf-life of the newly designed and manufactured disposable parts of the CELLECTRA® 5PSP immunotherapy delivery device. Inovio is working diligently with the FDA to address its concerns and anticipates that the requested data will be available before the end of this year.

Inovio estimates that the start of the phase III clinical program will be delayed until the first half of 2017 pending resolution of the FDA's requests.

#### **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 has reported 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, The Wistar Institute, University of Pennsylvania, DARPA, GeneOne Life Science, Plumblin Life Sciences, Drexel University, NIH, HIV Vaccines Trial Network, National Cancer Institute, U.S. Military HIV Research Program, 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. 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 our ability to obtain a release of the clinical hold from the FDA, 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 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 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, 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, 2015, our Form 10-Q for the quarter ended June 30, 2016, 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.