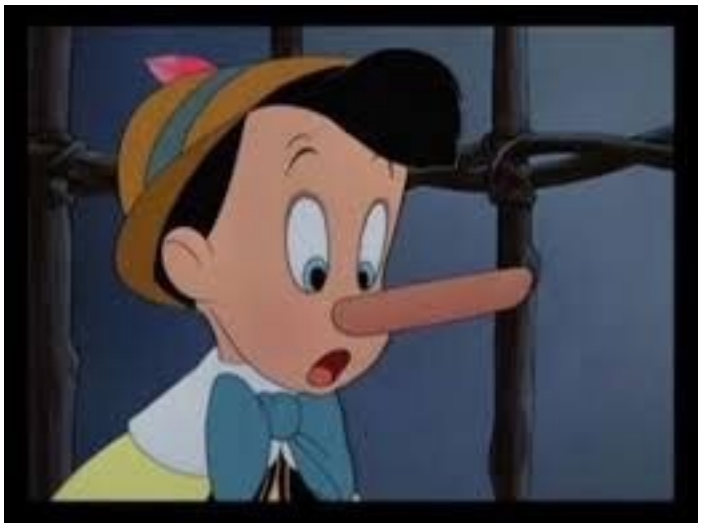
Citron Comments on Inovio (INO) "Partial Clinical Hold"

Price Target Lowered to $2



Yesterday, Inovio announced a "partial clinical hold" from the FDA for its COVID-19 vaccine candidate INO-4800.

http://ir.inovio.com/news-releases/news-releases-details/2020/INOVIO-Reports-FDA-Partial-Clinical-Hold-for-Planned-Phase-2--3-Trial-of-COVID-19-Vaccine-Candidate-INO-4800/default.aspx

Below we explain why this announcement has caused Inovio to become Pinocchio.

The Normal Clinical Trials Process

Below is the timeline for a normal clinical trials process:

- A sponsor submits their investigational new drug application to the FDA
- The FDA has 30 days to respond
- If the FDA does not respond, the sponsor is free to proceed
- Alternatively, the FDA can respond by placing the proposed trial on a clinical hold

In the case of Inovio's planned phase 2/3 clinical trial, the obvious question is:

"Why did the FDA order a clinical hold?"

Inovio mentions in their press release that:

- *"The U.S. Food and Drug Administration (FDA) has notified the company it has additional questions about the company's planned Phase 2/3 trial of its COVID-19 vaccine candidate INO-4800, including its CELLECTRA® 2000 delivery device to be used in the trial"*

We do not think this is the full story.

Inovio = Pinocchio

You can see below that there are multiple studies using the CELLECTRA 2000 device that are NOT on clinical hold by the FDA.

https://clinicaltrials.gov/ct2/results?term=CELLECTRA+2000&Search=Apply&recrs=a&age_v=&gndr=&type=&rslt=

Status	Study Title	Conditions	Interventions
Recruiting	INO-3107 With Electroporation (EP) in Participants With HPV-6- and/or HPV-11-Associated Recurrent Respiratory Papillomatosis (RRP)	• Respiratory Papillomatosis	• Drug: INO-3107 • Device: **CELLECTRA™ 2000**
Recruiting	Safety, Tolerability and Immunogenicity of INO-4800 Followed by Electroporation in Healthy Volunteers for COVID19	• Coronavirus Infection • SARS-CoV 2	• Biological: INO-4800 • Device: **CELLECTRA® 2000** • Other: Saline-sodium citrate (SSC) buffer
Recruiting	Neoantigen-based Personalized DNA Vaccine in Patients With Newly Diagnosed, Unmethylated Glioblastoma	• Glioblastoma	• Biological: Personalized neoantigen DNA vaccine supplied by Geneos Therapeutics • Device: **CELLECTRA®2000** EP Device supplied by Geneos Therapeutics • Drug: Plasmid encoded IL-12
Recruiting	Therapeutic Vaccination in Treated HIV Disease	• HIV-1-infection	• Biological: PENNVAX-GP • Biological: INO-6145 • Biological: INO-9012 • Device: **CELLECTRA® 2000**

If the FDA's issues were solely related to the CELLECTRA 2000 device, they would have placed multiple studies using that device on clinical hold. That did not happen. So, what is the explanation?

FDA's Guidance for Clinical Holds

As noted on the FDA's website, there are a large number of reasons why the FDA can institute a clinical hold.

https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-procedures-clinical-hold

Some examples of reasons for clinical hold are shown below:

Product Quality:

- Product has an impurity profile indicative of a potential health hazard or an impurity profile insufficiently defined to assess health hazard
- Product cannot remain chemically stable throughout the testing program

Pharmacology and Toxicology:

- Data from animal studies are not sufficient to support the anticipated exposure (dose, route of administration, and duration) for the proposed clinical trial
- Poor quality non-GLP toxicology studies with difficult to interpret results and a safety signal that has not been sufficiently studied are proposed as pivotal toxicology studies to support use of the product in humans

Clinical:

- Previously observed toxicities of the product are not addressed by the proposed safety assessments in a clinical protocol
- For a product with a high potential for an unpredictable acute reaction, all subjects are dosed at the same time without consideration to staggered administration.

Explanation for the FDA's Clinical Hold on Inovio Trials

We believe Inovio's chemistry manufacturing and controls are unacceptable to the FDA and this is why a clinical hold was instituted. Why do we think this?

Look no further than the "About INOVIO's Global Coalition Advancing INO-4800" section of Inovio's latest two press releases to see a MAJOR DISCREPANCY in the language being used.

Inovio press release 9/8/20

- "INOVIO is also assessing **preclinical** efficacy of INO-4800 in several animal challenge models with Public Health England (PHE) and Commonwealth Scientific and Industrial Research Organization (CSIRO) in Australia"

Inovio press release 9/28/20

- "INOVIO is also assessing **nonclinical** efficacy of INO-4800 in several animal challenge models with Public Health England (PHE) and Commonwealth Scientific and Industrial Research Organization (CSIRO) in Australia"

http://ir.inovio.com/news-releases/news-releases-details/2020/INOVIO-Adds-Thermo-Fisher-Scientific-To-Global-Manufacturing-Consortium/default.aspx
http://ir.inovio.com/news-releases/news-releases-details/2020/INOVIO-Reports-FDA-Partial-Clinical-Hold-for-Planned-Phase-2--3-Trial-of-COVID-19-Vaccine-Candidate-INO-4800/default.aspx

The implications range from 1) Inovio has to address some non-clinical issues such as stability or packaging to 2) the FDA is concerned about toxicology.

We suspect this is related to the fact that their previous drug substance manufacturer VGXI who Inovio sued is no longer making the drug for them and that switching manufacturers mid-development prompted the FDA to reassess to make sure the drug substance they will manufacture is the same as that manufactured by VGXI.

Conclusion

As a reminder, Inovio has delivered precisely ZERO FDA approved products in its multi-decade existence. Inovio was already WAY behind the competition when it comes to COVID-19 vaccine development while this partial clinical hold sets them back even further.

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