

# Inovio Receives Advanced Therapy Medicinal Product Certificate from European Medicines Agency for Quality and Non-Clinical Data for Lead Candidate INO-3107

7/25/2024

Data reviewed complies with standards that would be used to evaluate an EU Marketing Authorization Application

PLYMOUTH MEETING, Pa., July 25, 2024 /PRNewswire/ -- INOVIO (NASDAQ: INO), a biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from HPV-related diseases, cancer, and infectious diseases, today announced that the European Medicines Agency's Committee for Advanced Therapies (CAT) has certified the quality and non-clinical data for INO-3107, INOVIO's lead candidate for the treatment of Recurrent Respiratory Papillomatosis (RRP). The certification confirms that INOVIO's chemistry, manufacturing and controls (CMC) data and nonclinical results available to date comply with the scientific and technical standards that would be used for evaluating a European Marketing Authorization Application.

"This latest regulatory achievement further validates our efforts to bring INO-3107 to RRP patients around the world and shows that our cross functional development team is meeting the highest of standards in pursuit of that goal," said Cheryl Elder, INOVIO's Senior Vice President of Regulatory Affairs. "We're pleased to receive confirmation that our development efforts in Europe continue to make progress."

The CAT provides assessment and certification of advanced therapy medicinal products (ATMPs) under development by micro-, small- and medium-sized enterprises (SMEs), providing an important opportunity to identify any potential development issues prior to the submission of a Marketing Authorization Application.

## About INO-3107

INO-3107 is designed to elicit an antigen-specific T cell response against both HPV-6 and HPV-11 proteins. These targeted T cells are designed to seek out and kill HPV-6 and HPV-11 infected cells, with the aim of potentially

preventing or slowing the growth of new papillomas. In a Phase 1/2 clinical trial conducted with INO-3107, 81.3% (26/32) of patients had a decrease in surgical interventions in the year after INO-3107 administration compared to the prior year, including 28.1% (9/32) that required no surgical intervention during or after the dosing window. Patients in the trial had a median range of 4 surgeries (2-8) in the year prior to dosing. After dosing, there was a median decrease of 3 surgical interventions (95% confidence interval -3, -2). At the outset of the trial (Day 0), patients had a clinically warranted procedure to have RRP tissue surgically removed, but any surgery performed after Day 0 during the dosing window was counted against the efficacy endpoint. Treatment with INO-3107 generated a strong immune response in the trial, inducing activated CD4 T cells and activated CD8 T cells with lytic potential. T-cell responses were also observed at Week 52, indicating a persistent cellular memory response. INO-3107 was well tolerated by participants in the trial, resulting in mostly low-grade (Grade 1) treatment-emergent adverse effects such as injection site pain and fatigue. Like other DNA medicines, INO-3107 has demonstrated the ability to generate antigen-specific T cells that is not affected by anti-vector immunity impacting immunogenicity, either before administration or after the first dose unlike other T-cell generating platforms such as viral vectors. This feature of DNA medicines is expected to allow INO-3107 to maintain T cell response and overall efficacy, which would make it an important therapeutic option for a majority of RRP patients.

The FDA granted INO-3107 Orphan Drug designation and Breakthrough Therapy designation, and advised INOVIO that it could submit its BLA under the accelerated approval program using data from its already completed Phase 1/2 trial. The European Commission granted INO-3107 Orphan Drug designation and assigned INOVIO's delivery device CELLECTRA® a CE marking, a regulatory standard that certifies that a product has met European Union's safety, health, and environmental standards. The United Kingdom awarded INO-3107 the Innovation Passport. This designation serves as the entry point to the Innovative Licensing and Access Pathway (ILAP), which aims to accelerate time to market and facilitate patient access to medicines.

## About RRP

RRP is a debilitating and rare disease caused primarily by HPV-6 and/or HPV-11. RRP is characterized by the development of small, wart-like growths, or papillomas, in the respiratory tract. While papillomas are generally benign, they can cause severe, life-threatening airway obstruction and respiratory complications. RRP can also significantly affect quality of life for patients by affecting the voice box, limiting the ability to speak effectively. Surgery to remove papillomas is the standard of care for RRP; however, the papillomas often grow back. INOVIO's market research to date with patients and healthcare professionals indicates that a reduction of even one surgery matters, because every surgery poses a significant risk of causing permanent damage to the vocal cords. The most widely cited U.S. epidemiology data published in 1995 estimated that there were 14,000 active cases and about 1.8 per 100,000 new cases in adults each year.

## About INOVIO's DNA Medicines Platform

INOVIO's DNA medicines platform has two innovative components: precisely designed DNA plasmids, delivered by INOVIO's proprietary investigational medical device, CELLECTRA®. INOVIO uses proprietary technology to design its DNA plasmids, which are small circular DNA molecules that work like software the body's cells can download to produce specific proteins to target and fight disease. INOVIO's proprietary CELLECTRA® delivery devices are designed to optimally deliver its DNA medicines to the body's cells without requiring chemical adjuvants or lipid nanoparticles and without the risk of the anti-vector response historically seen with viral vector platforms.

## About INOVIO

INOVIO is a biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from HPV-related diseases, cancer, and infectious diseases. INOVIO's technology optimizes the design and delivery of innovative DNA medicines that teach the body to manufacture its own disease-fighting tools. For more information, visit [www.inovio.com](http://www.inovio.com).

## Forward-Looking Statements

This press release contains certain forward-looking statements relating to our business, including our plans to develop and commercialize DNA medicines and expectations regarding our research and development programs, including timelines and prospects for regulatory approval, expectations regarding INO-3107's ability to maintain T cell response and overall efficacy, as well as benefits for patients. 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, 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 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, 2023, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, 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 the 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.

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