

INOVIO Plans to Submit a BLA for INO-3107 as a Potential Treatment for RRP in Second Half of 2024 Under Accelerated Approval Program

1/3/2024

- Company will request Rolling Submission and Priority Review of its Biological License Application (BLA) by U.S. Food and Drug Administration (FDA) to expedite review process
- Accelerating commercialization efforts to be prepared to launch INO-3107 in 2025

PLYMOUTH MEETING, Pa., Jan. 3, 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 plans to submit a BLA for INO-3107 as a potential treatment for Recurrent Respiratory Papillomatosis (RRP) in the second half of 2024. This announcement follows an Initial Comprehensive Multidisciplinary Breakthrough Therapy (Type B) Meeting with the FDA on critical aspects of the data package required to submit a BLA under the agency's accelerated approval program.

"Based on productive discussions with the FDA, we believe we now have established a path to submitting a BLA for INO-3107 under the accelerated approval program," said Dr. Jacqueline Shea, INOVIO's President & Chief Executive Officer. "Our plan is to complete the submission of our BLA in the second half of 2024 and request a Priority Review. We also plan to initiate a confirmatory trial prior to submission of our BLA. Concurrently, we will continue advancing our commercial plans, with the goal of being ready to launch INO-3107 in 2025."

A Priority Review, if granted, could shorten the FDA's review of the BLA to approximately six months from the time of the submission being accepted, as compared to a standard review timeline of approximately 10 months. If approved, INO-3107 would be the first DNA medicine made available to RRP patients in the United States and INOVIO's first approved product. The FDA previously 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 has also granted INO-3107 Orphan Drug designation. INOVIO's delivery device, CELLECTRA®, received CE marking, a regulatory standard that

certifies that a product has met European Union's safety, health, and environmental standards.

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 because the underlying HPV infection has not been eradicated. 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 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 study (Day 0), patients could 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.

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 CELLECTRA® delivery devices help ensure its DNA medicines enter the body's cells for optimal effect, without chemical adjuvants or nanoparticles and without the risk of the anti-vector response seen in 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.

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to INOVIO's business, including its plans to develop and commercialize DNA medicines and its expectations regarding its research and development programs, including plans to submit a BLA for priority review and to initiate a confirmatory trial for INO-3107, and expectations with respect to the commercialization of INO-3107 if it is approved by regulatory authorities. 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, INOVIO's ability to support its pipeline of DNA medicine products, the ability of INOVIO's collaborators to attain development and commercial milestones for products INOVIO licenses and product sales that will enable INOVIO to receive future payments and royalties, the adequacy of INOVIO's capital resources, the availability or potential availability of alternative therapies or treatments for the conditions targeted by INOVIO or its collaborators, including alternatives that may be more efficacious or cost effective than any therapy or treatment that INOVIO and its collaborators hope to develop, issues involving product liability, issues involving patents and whether they or licenses to them will provide INOVIO 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 INOVIO can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of INOVIO'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 INOVIO's Annual Report on Form 10-K for the year ended December 31, 2022, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, and other filings INOVIO makes from time to time with the Securities and Exchange Commission. There can be no assurance that INO-3107 or any other product candidate in INOVIO's 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 INOVIO undertakes no obligation to update or revise these statements, except as may be required by law.

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