NEWS RELEASE

INOVIO Highlights Anticipated 2025 Milestones and 2024 Key Accomplishments

2025-01-09

PLYMOUTH MEETING, Pa., Jan. 9, 2025 /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 highlighted anticipated milestones for 2025 and key accomplishments from 2024 in advance of upcoming investor meetings.

"Based on the progress achieved in 2024, we anticipate 2025 to be a transformational year for INOVIO as we move closer to our goal of becoming a commercial-stage company providing a breakthrough therapy for patients suffering from a devastating rare disease and delivering on the promise of DNA medicines," said Dr. Jacqueline Shea, INOVIO's President and Chief Executive Officer. "Our top priorities for the coming year are the submission of our biologics license application (BLA) for INO-3107 and preparing to expedite the launch of the product commercially, should it be approved. We also look forward to making progress with our pipeline through collaborations and other potential strategic opportunities."

INO-3107

Anticipated Milestones for 2025

- Submit BLA to the U.S. Food and Drug Administration (FDA) by mid-2025 and request priority review. INO-3107 could be the preferred non-surgical therapeutic option for recurrent respiratory papillomatosis (RRP) and would be the first DNA medicine approved for any indication in the United States, should it be approved.
    - Resolution of previously announced single-use array manufacturing issue expected by February 2025. Next steps following resolution include completion of retesting process for the CELLECTRA® device and finalization of the device sections of the Chemistry, Manufacturing and Controls (CMC) module, which will be used to update the active Investigational New Drug (IND) Application for the confirmatory trial as well as the BLA submission.

- Initiate confirmatory trial.
    - Trial will be conducted at approximately 20 leading U.S. academic centers, enrolling approximately 100 patients randomized to receive either INO-3107 or placebo on a 2:1 basis. With eligible patients having a history of two or more surgeries per year to treat their RRP, this trial is intended to evaluate a population that is highly representative of the broad spectrum of RRP disease.
    - INOVIO believes that the design of the confirmatory trial could also support expansion into global markets based on feedback received to date from European and UK regulators.
- Submit a redosing study protocol to the FDA.
    - Recently announced durability data support rationale for redosing patients with goal to maintain or improve clinical benefit.
- Present and publish recently announced durability data and immunology data, as well as the full efficacy and tolerability data from completed Phase 1/2 clinical trial, in a peer-reviewed scientific journal.

Key 2024 Accomplishments

- Reported data from a retrospective trial showing that half of RRP patients treated with INO-3107 achieved a complete response (CR) and required no surgery when evaluated at the end of year two and into year three after the initial Phase 1/2 trial, increasing from the initial CR rate of 28% at the end of the first year.
    - The retrospective analysis showed that of those patients who had an initial CR, 88% maintained their CR by end of the second year and 63% into the third year.
    - 95% of patients maintained or enhanced their original Overall Response Rate ("ORR," defined as those patients who achieved either a CR or a partial response) after two years, while 86% of patients maintained or enhanced their ORR into year three.
- Presented new immunology data demonstrating the ability of INO-3107 to induce antigen-specific T cell responses against HPV-6 and HPV-11 and drive recruitment of those T cells into airway tissues and papilloma of RRP patients, which could potentially slow or eliminate papilloma regrowth.
- Presented the full safety and efficacy data set for the Phase 1/2 trial in which administration of INO-3107 was shown to be well tolerated and resulted in clinical benefit.
    - No treatment-related serious adverse events among patients in the trial, and all treatment-related adverse events (AEs) were Grade 1 or Grade 2. The most commonly reported AEs were injection site pain (31%) and fatigue (9%). There were no patients who discontinued treatment during the trial.
    - Of the 32 patients in the trial, 26 patients, or 81%, experienced a decrease in the number of surgical interventions in the year after treatment when compared to the year before treatment.
- The European Medicines Agency's Committee for Advanced Therapies (CAT) certified the quality and non-clinical data for INO-3107, confirming that CMC data and nonclinical results available to date comply with the

scientific and technical standards to be used in evaluating a potential European Marketing Authorization Application.
- INO-3107 was designated an innovative medicine as part of the U.K.'s Innovative Licensing and Access Pathway (ILAP).
- Progressed commercial readiness plans to be launch ready by the end of 2025, including: refining go-to-market strategy focused on patient and physician needs; driving key strategic decisions on pricing and access, product distribution, targeting and segmentation, and product positioning; and developing plans for the build out of the commercial organization.

INO-3112

Anticipated Milestones for 2025 and Key 2024 Accomplishments

- Gain alignment on planned Phase 3 trial design with European Union regulators
    - Trial to be conducted in North America and Europe through a clinical collaboration and supply agreement signed in 2024 with Coherus BioSciences, Inc., evaluating the combination of INO-3112 and LOQTORZI® (toripalimab-tpzi) in patients with locoregionally advanced, high-risk, HPV16/18-positive oropharyngeal squamous cell carcinoma (OPSCC). LOQTORZI is a PD-1 inhibitor approved by the FDA and European Commission for the treatment of recurrent locally advanced/metastatic nasopharyngeal carcinoma (R/P NPC). The European Commission also approved LOQTORZI for the treatment of unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC).
    - Gained alignment with FDA on the planned Phase 3 trial design in 2024 and received initial feedback from European regulatory authorities on proposed trial design.

Emerging Pipeline

Anticipated Milestones for 2025 and Key 2024 Accomplishments

- INO-4201: potential booster to ERVEBO®
    - Finalize Phase 2 trial protocols and seek funding to support trial activities.
    - Submit data from completed Phase 1b trial to a peer-reviewed publication, including FANG assay data indicating that boosting with INO-4201 elicits neutralizing antibody response comparable to that achieved by ERVEBO, an approved primary series vaccination against Ebola.
- DNA encoded monoclonal antibody (DMAb) targeting SARS-CoV-2
    - Report first clinical data from ongoing Phase 1 trial in first quarter of 2025.
    - The trial, now in its third year, is led by the Wistar Institute in collaboration with AstraZeneca, the University of Pennsylvania, and Indiana University and is being funded by DARPA.

- INO-5401
  - Continue to dose patients in the GBM-001 Phase 1 trial in newly diagnosed glioblastoma that combines INO-5401 with Regeneron's PD-1 checkpoint inhibitor Libtayo®. Next development step is to conduct a controlled Phase 2 trial.
  - The Basser Center at the University of Pennsylvania is evaluating the tolerability and immunogenicity of INO-5401 in a Phase 1 study exploring the potential to prevent cancer in people with BRCA1 or BRCA2 mutations.
- INOVIO's partner, ApolloBio, continues recruitment into its Phase 3 trial evaluating INO-3100 as a potential treatment for HPV 16/18 positive cervical dysplasia in China.

General Corporate

- Strengthened balance sheet with total net proceeds of more than $60 million from two offerings of equity securities in April and December 2024. At September 30, 2024, INOVIO had $84.4 million in cash, cash equivalents and short-term investments, which does not reflect the approximately $27.6 million received from the December 2024 offering.
- Announced appointment of Steven Egge as Chief Commercial Officer in July 2024. Mr. Egge has broad commercial and therapeutic area experience, including in HPV-related diseases and cancers, vaccines and rare diseases, and has overseen or contributed to more than a dozen commercial product launches throughout his career.

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**.

Forward-Looking Statements

This press release contains certain forward-looking statements relating to our business, including the planned

initiation and conduct of pre-clinical studies and clinical trials and the availability and timing of data from those studies and trials, the resolution of manufacturing issues, the planned submission of a BLA in mid-2025, and the potential commercial launch of INO-3107 if regulatory approval is obtained. 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 September 30, 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.

Contacts

Media: Jennie Willson (267) 429-8567 **communications@inovio.com**
Investors: Peter Vozzo, ICR Healthcare, 443-213-0505 **investor.relations@inovio.com**

View original content to download multimedia:**https://www.prnewswire.com/news-releases/inovio-highlights-anticipated-2025-milestones-and-2024-key-accomplishments-302346813.html**

SOURCE INOVIO Pharmaceuticals, Inc.