



INOVIO and Coherus Announce Clinical Collaboration to Advance Development of INO-3112 in Combination with LOQTORZI™ (toripalimab-tpzi)

- Combination therapy to be evaluated in a Phase 3 trial in patients with locoregionally advanced, high-risk, HPV16/18-positive head and neck cancer

PLYMOUTH MEETING, Pa. and REDWOOD CITY, Calif., Jan. 4, 2024 /PRNewswire/ -- INOVIO (NASDAQ:INO), a biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from HPV-associated diseases, cancer and infectious diseases, today announced a clinical collaboration and supply agreement with Coherus BioSciences, Inc. (Coherus, NASDAQ: CHRS) to evaluate the combination of INO-3112 and LOQTORZI™ (toripalimab-tpzi) as a potential treatment for patients with locoregionally advanced, high-risk, HPV16/18 positive oropharyngeal squamous cell carcinoma (OPSCC), a type of head and neck cancer commonly known as throat cancer.



Under the terms of the supply agreement, Coherus will provide LOQTORZI™ (toripalimab-tpzi), for a Phase 3 clinical trial to be conducted by INOVIO, pending alignment with the U.S. Food and Drug Administration (FDA) on study design. LOQTORZI™ is a PD-1 inhibitor recently approved by the FDA for the treatment of recurrent locally advanced/metastatic nasopharyngeal carcinoma (R/P NPC).

"Existing trial data highlights the strong rationale for and potential benefit of combining INO-3112 with a PD-1 inhibitor to generate tumor-specific T cells in HPV-related head and neck cancer," said Dr. Glenn Hanna, Director of the Center for Cancer Therapeutic Innovation (early drug development program) at Dana Farber Cancer Institute, Assistant Professor of Medicine at Harvard Medical School and principal investigator for the planned trial. "I look forward to advancing this research for patients by harnessing their immune system to fight against this life-altering, virally mediated cancer."

"We are very pleased to be collaborating with Coherus on this novel combination therapy and are excited about the opportunity to build on encouraging data from our previous trials involving INO-3112 in HPV-related head and neck cancer," said INOVIO's President and Chief Executive Officer, Dr. Jacqueline Shea. "There is unique potential in combining our DNA medicines platform, which a growing body of research indicates is adept at fighting HPV-related diseases, with a proven PD-1 inhibitor to improve clinical outcomes for patients."

"We are delighted to be partnering with INOVIO on the development of the toripalimab/INO-3112 combination in HPV-related OPSCC, a tumor type that is synergistic to the current toripalimab indication in R/P NPC," said Rosh Dias, M.D., Chief Medical Officer at Coherus. "With its differentiated mechanism of action, toripalimab in combination with the INO-3112 vaccine may hold promise for these patients in earlier-stage disease, where treatment options are more limited. This partnership fits in well with our strategic vision to investigate toripalimab across additional tumor types as the PD-1 backbone in combination with novel agents of multiple modalities with the goal of improving patient benefit."

About Oropharyngeal Squamous Cell Carcinoma

Oropharyngeal squamous cell carcinoma, commonly known as throat cancer, is a type of head and neck cancer that occurs in the base of the tongue, tonsils and/or soft palate. OPSCC is typically causally related to high-risk subtypes of human papillomavirus (HPV), but some cases are carcinogen-driven due to tobacco and/or alcohol use. HPV-positive OPSCC is rapidly increasing in incidence among patients in high-income countries and has surpassed cervical cancer as the most common HPV-related cancer diagnosed in the United States, with nearly 20,000 new cases each year. HPV is thought to cause 70%-80% of all oropharyngeal cancers diagnosed in the United States.

About INO-3112

INO-3112 is a DNA medicine candidate targeting HPV 16/18 combined with a DNA plasmid for IL-12 as an immune activator. INOVIO is investigating the potential benefit of the antigen-specific T cell generation and tumor infiltration abilities of INO-3112 in HPV-related cancers, especially when used in novel combinations. Results from a Phase 1/2a trial of INO-3112 alone in 22 HPV-positive head and neck squamous cell carcinoma (HNSCC) patients, published in *Clinical Cancer Research* in 2019, included the observation of T cell responses and infiltration of CD8+ T cells into the head and neck tumors. In early 2023, updated results were published in *Clinical Cancer Research* from a Phase 1b/2a trial of INO-3112 in combination with AstraZeneca's PD-L1 checkpoint inhibitor, durvalumab, showing an ORR of 27.6% (4 CR, 4 PR) in 29 evaluable patients and increased peripheral HPV-specific T cells and tumoral CD8+ T cells.

About LOQTORZI™ (toripalimab-tpzi)

LOQTORZI is a next generation anti-PD-1 monoclonal antibody that blocks PD-L1 binding to the PD-1 receptor at a unique site with high affinity and activates anti-tumor immunity demonstrating improvement in the overall survival of cancer patients in several tumor types. LOQTORZI was recently approved by the FDA for the treatment of recurrent locally advanced/metastatic NPC. For more information about LOQTORZI, including important safety information, please visit www.loqtorzi.com.

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.

About Coherus

Coherus is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Coherus is developing an innovative immuno-oncology pipeline that will be synergistic with its proven commercial

capabilities in oncology.

Coherus' immuno-oncology pipeline includes multiple antibody immunotherapy candidates focused on enhancing the innate and adaptive immune responses to enable a robust immunologic response and enhance outcomes for patients with cancer.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®, YUSIMRY™ (adalimumab-aqvh), a biosimilar of Humira® and LOQTORZI (toripalimab-tpzi), a novel next generation PD-1 inhibitor. For more information, visit www.coherus.com.

INOVIO 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 advance development of INO-3112 in a Phase 3 clinical trial in combination with LOQTORZI (toripalimab-tpzi). 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-3112 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.

Coherus Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 including, but not limited to, statements regarding Coherus' ability to achieve synergies between its I-O pipeline and its commercial capabilities; Coherus' projections about synergies for LOQTORZI between NPC and HPV-associated HNSC; and Coherus' expectations that it will be able to benefit patients by investigating LOQTORZI in combination with multiple novel agents. Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus' actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, risks and uncertainties inherent in the clinical drug development process; risks related to our existing and potential collaboration partners; risks of the drug development position of Coherus' competitors; the risks and uncertainties of the collaboration between Coherus and INOVIO; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review, international aspects of Coherus' business; the risk of FDA review issues; the risk that Coherus is unable to complete commercial transactions; and the risks and uncertainties of possible litigation. All forward-looking statements contained in this press release speak only as of the date of this press release. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the significant risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, see Coherus' Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed with the Securities and Exchange Commission on November 6, 2023, including the section therein captioned "Risk Factors" and in other documents that Coherus files with the Securities and Exchange Commission.

INOVIO Contacts

Media: Jennie Willson, (267) 429-8567, jennie.willson@inovio.com
Investors: Thomas Hong, (267) 440-4298, thomas.hong@inovio.com

Coherus Contact

Investors & Media:
Jami Taylor, Head of Investor Relations for Coherus
IR@coherus.com



View original content to download multimedia: <https://www.prnewswire.com/news-releases/inovio-and-coherus-announce-clinical-collaboration-to-advance-development-of-ino-3112-in-combination-with-loqtorzi-toripalimab-tpzi-302025891.html>

SOURCE INOVIO Pharmaceuticals, Inc.; Coherus BioSciences, Inc.