

INOVIO Announces Orphan Drug Designation for INO-3107 for the Treatment of Recurrent Respiratory Papillomatosis from the European Commission

5/23/2023

PLYMOUTH MEETING, Pa., May 23, 2023 /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 Commission (EC) has granted orphan drug designation for INO-3107, the company's product candidate for the treatment of Recurrent Respiratory Papillomatosis (RRP). INO-3107 is an investigational DNA medicine candidate designed to elicit a targeted T cell response against HPV-6 and HPV-11, the HPV types that cause RRP and other HPV-related diseases.

INOVIO previously announced that the European Committee for Orphan Medicinal Products (COMP) had provided a positive opinion on INOVIO's application for orphan drug designation in the European Union (EU) for INO-3107. The adoption of this decision by the EC formalizes INO-3107 as a designated orphan drug in the EU. INO-3107 received orphan drug designation from the U.S. Food and Drug Administration (FDA) in July 2020, making it the first RRP product candidate to receive designations from both U.S. and EU regulatory bodies.

"By granting orphan drug designation, U.S. and EU regulators are acknowledging the high unmet medical need of those suffering from this debilitating disease," said INOVIO's Senior Vice President of Regulatory Affairs, Dr. Cheryl Elder. "This is yet another important step forward for our development process and for the RRP patients around the world who could benefit from a potentially game-changing therapy."

Orphan drug designation is granted for the treatment, prevention, or diagnosis of diseases that are life-threatening or chronically debilitating and affect no more than five in 10,000 people across the European Union (EU). Medicines that are granted orphan drug designation by the EC qualify for financial and regulatory incentives including protocol assistance at reduced charges, access to centralized marketing authorization, and up to 10 years of market exclusivity in the EU after product approval.

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.

About INO-3107

INO-3107 is INOVIO's clinical-stage DNA medicine product candidate being developed as a potential treatment for RRP. INO-3107 is designed to elicit a targeted T cell response against HPV-6 and HPV-11, the HPV types responsible for causing RRP among other HPV-related diseases. These targeted T cells are designed to seek out and kill infected cells, with the aim of potentially preventing or slowing the growth of new papillomas. INO-3107 **received** orphan drug designation from the U.S. Food and Drug Administration (FDA) in July 2020. For more information about INOVIO's HPV franchise, please visit <https://ir.inovio.com/events-and-presentations/default.aspx>

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 DNA medicines in development are delivered using its investigational proprietary smart device, CELLECTRA®, to produce immune responses against targeted pathogens and cancers. For more information, visit www.inovio.com.

Contacts

Media: Jennie Willson (267) 429-8567 jennie.willson@inovio.com

Investors: Thomas Hong (267) 440-4298 thomas.hong@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 our expectations regarding our research and development programs, including the planned initiation and conduct of clinical trials and the availability and timing of data from those trials. 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, 2022, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, 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.

View original content:<https://www.prnewswire.com/news-releases/inovio-announces-orphan-drug-designation-for-ino-3107-for-the-treatment-of-recurrent-respiratory-papillomatosis-from-the-european-commission-301832688.html>

SOURCE INOVIO Pharmaceuticals, Inc.