



NEWS RELEASE

INOVIO Announces FDA Accelerated Approval of VOCERYQ™, an Immunotherapy to Reduce the Frequency of Surgery in Adults with Recurrent Respiratory Papillomatosis (RRP)

2026-10-30

- INOVIO delivers a new nonsurgical treatment option with a broad indication for adults living with RRP, a rare and debilitating disease that often requires surgery
- VOCERYQ™ is a plasmid DNA-based immunotherapy that targets the root cause of RRP: HPV-6 and HPV-11
- INOVIO expects to make VOCERYQ available to order and ship in approximately 60 days, with full commercial launch in the first quarter of 2027
- VOCERYQ represents the first U.S. FDA approved DNA medicine, validating INOVIO's novel platform technology
- INOVIO will host a conference call Monday, November 2, 2026 at 8:00 AM ET

PLYMOUTH MEETING, Pa., Oct. 30, 2026 /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 U.S. Food and Drug Administration (FDA) has granted accelerated approval for VOCERYQ (doruxapapogene ralaplasmid and lalikinogene sifuplasmid-gxfd), previously referred to as INO-3107, to reduce the frequency of surgery in adults with RRP. This indication is approved under the accelerated approval program based on demonstrated complete response defined as no requirement for surgical intervention in the 12 months after treatment in the efficacy population. Continued approval for this indication may be contingent on verification and description of clinical benefit in a confirmatory study(ies).

"With the approval of VOCERYQ, we believe our DNA medicine platform has the potential to transform the treatment paradigm for RRP by offering a patient-centric treatment option. VOCERYQ is designed to deliver what we understand matters most to patients, which is the reduction of the surgical burden caused by RRP," said Dr. Jacqueline Shea, INOVIO's President and Chief Executive Officer. "INOVIO is grateful to the patients, study investigators, and the RRP Foundation, who helped make this achievement possible, and also to the FDA, who recognized the significant unmet need in this patient community. We would like to thank our dedicated INOVIO team and their ongoing commitment to patients. We look forward to delivering VOCERYQ to the RRP community and believe it has the potential to become a new standard of care for this devastating disease."

The approval is supported by data from INOVIO's RRP-001 study which evaluated VOCERYQ in 32 adult patients with RRP who had two or more surgeries in the year prior to treatment. During the VOCERYQ dosing window, no additional papilloma surgical excisions were required in the protocol. Of the 32 patients, 26 patients required 3 or more surgeries for papilloma excision in the 12 months prior to treatment and were included in the efficacy evaluation (median number of surgical excisions in the 12 months prior to the first dose in the efficacy population was 4.5 (range: 3 to 8)). Seven out of the 26 patients (27% [95% CI: 12; 48%]) demonstrated a complete response, defined as requiring no surgical excision of papillomas, after 12 months of follow up, which is not expected as part of the natural history of the disease when untreated. The complete clinical data for VOCERYQ were published in **Nature Communications** and in **The Laryngoscope**, the leading journal for the specialists who treat RRP.

"This new FDA-approved therapy brings us an important step closer to ensuring every RRP patient has access to a non-surgical treatment option that works for them. In reaching this milestone, we have shown that patient voices matter in the drug development process," said Kim McClellan, President of the RRP Foundation. "Patients have often had to endure repeated surgeries to control their RRP disease, but now thanks to the INOVIO team and the patients and investigators involved in the clinical development program for VOCERYQ, a new option is available that has the potential to further transform the treatment landscape for RRP patients. We look forward to continuing to work with clinicians, regulators and our partners in the healthcare industry to further improve the quality of life for those living with RRP."

Dr. Simon Best, Associate Professor of Otolaryngology at Johns Hopkins University and a lead investigator for INOVIO's RRP-001 study, said, "The approval of VOCERYQ is an important step in improving the quality of life for RRP patients as every surgery carries the risk of laryngeal injury. I believe it is in the best interest of RRP patients that the standard of care quickly transition away from surgical interventions to immunotherapy after RRP is diagnosed."

VOCERYQ was found to be well tolerated, with the most common adverse reactions (incidence $\geq 5\%$) including injection site reactions, headache, fatigue, hypertension, nausea and dizziness. Most treatment-related adverse reactions were grade 1 and 2 and transient. There were no grade 4 or 5 common adverse events. All 32 patients completed the study. See additional Important Safety Information below.

To verify the clinical benefit of VOCERYQ, a confirmatory study is expected to be conducted. The FDA requires INOVIO to submit a draft protocol for the study by the end of 2026 with the expectation of aligning on a final protocol by mid-2027.

VOCERYQ was approved in combination with CELLECTRA® 5PSP, INOVIO's proprietary DNA medicine delivery device. INOVIO expects to make VOCERYQ available to order and ship in approximately 60 days and anticipates full field deployment during the first quarter of 2027. INOVIO has engaged Syneos Health to support the recruitment and deployment of our medical and commercial field teams.

Conference Call

INOVIO will host a conference call on Monday, November 2 at 8:00 AM ET to provide additional details regarding the approval, including key aspects of the label and commercialization. You can watch the webcast at <https://app.webinar.net/6LNlx7kxyqd>.

Event details can be found on INOVIO's website in the Events & Presentations section at <https://ir.inovio.com/events-and-presentations/default.aspx>.

Conference Call Dial-In Number

Local/International (toll): 1-646-357-8785

North American Toll Free: 1-800-836-8184

About RRP

RRP is a rare, debilitating 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 current 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 and comes with potential costs to the patient, including adverse impacts to both quality of life and finances. Based on ongoing analysis of claims data, INOVIO believes there is a prevalent population of at least 25,000 patients with RRP in the United States, with additional patients diagnosed each year.

About VOCERYQ™

VOCERYQ™ is a plasmid DNA-based immunotherapy designed to reduce the frequency of surgery for adults with RRP. VOCERYQ targets the root cause of RRP by generating an immune response using DNA plasmids that encode for HPV-6 and HPV-11 antigens. VOCERYQ is administered using the CELLECTRA® delivery device. Following a standard-of-care surgical debulking of visible papilloma prior to the initial administration of VOCERYQ, no additional surgical intervention is required as part of the 9-week dosing regimen.

The FDA previously granted VOCERYQ both **Orphan Drug** and **Breakthrough Therapy** designations, and the European Commission granted INO-3107 **Orphan Drug designation**.

Learn more at www.voceryq.com.

INDICATION

VOCERYQ is indicated to reduce the frequency of surgical papilloma excisions in adults with recurrent respiratory papillomatosis.

This indication is approved under accelerated approval based on reduction in the frequency of surgical papilloma excisions. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory study(ies).

IMPORTANT SAFETY INFORMATION

Warnings & Precautions: Injection site reactions have occurred with VOCERYQ injection. Monitor patients for local site reactions for at least 30 minutes after treatment and manage accordingly.

Electroporation Related Adverse Reactions: Procedure-related effects including muscle contractions, transient bleeding, and vasovagal reactions may occur. Avoid use in patients with ipsilateral ICDs/pacemakers, metal implants or skin abnormalities at treatment site.

Adverse Reactions: Most common adverse reactions (incidence >5%) are injection site reactions, headache, fatigue, hypertension, nausea and dizziness.

Please go to **www.voceryq.com** for full Prescribing Information, including Patient Information.

About INOVIO's DNA Medicines Platform

INOVIO's DNA medicines platform has two innovative components: precisely designed DNA plasmids, delivered by INOVIO's proprietary medical device, CELLECTRA. INOVIO uses proprietary technology to design its DNA plasmids, which are small circular DNA molecules that enable the body's cells 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 innovative 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 DNA medicines that enable the body to manufacture its own disease-fighting tools. For more information, visit **www.inovio.com** and follow us on **LinkedIn** and **X** (formerly known as Twitter).

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to our business, including the timing and success of preclinical studies and clinical studies; the ability to obtain and maintain regulatory approval of our product candidates, including that continued approval for VOCERYQ may be contingent on verification of clinical benefit in a confirmatory study, and the timing of submission of a draft and final protocol for such confirmatory study; the potential benefits of VOCERYQ, including our belief that VOCERYQ has a positively differentiated product profile and the potential to become the preferred product by patients and their physicians, and the anticipated impact of VOCERYQ on treatment practices and outcomes for patients with RRP; the scope, progress and expansion of developing and commercializing our product candidates, including the anticipated commercial launch and field deployment timeline for VOCERYQ and our engagement of Syneos Health to support such commercialization efforts; our estimate of the prevalent population of patients with RRP in the United States; and our anticipated growth strategies. 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 studies, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 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 studies 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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