ImmunityBio Announces First Patients in Europe Treated with ANKTIVA® Plus BCG for BCG-unresponsive Non-Muscle Invasive Bladder Cancer with Carcinoma in Situ

November 4, 2026

- First patients treated in Germany and Austria, with commercial support from Accord Healthcare
- Treatment milestone follows European Commission's February 2026 conditional marketing authorization of ANKTIVA in combination with Bacillus Calmette-Guérin (BCG)
- Uniphar provides order-to-cash, supply chain, distribution, importation and commercial support services to facilitate ANKTIVA availability across multiple international markets
- ImmunityBio and its partners are working to expand access to ANKTIVA for eligible patients across Europe

CULVER CITY, Calif. & DUBLIN--(BUSINESS WIRE)--Nov. 4, 2026-- ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced that the first patients in Europe received treatment with ANKTIVA® (nogapendekin alfa inbakicept) in combination with Bacillus Calmette-Guérin (BCG) for BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. The treatments were administered in Germany and Austria, marking an important step in expanding patient access to ANKTIVA across Europe.

The treatment milestone follows the European Commission's conditional marketing authorization of ANKTIVA in February 2026 for the treatment of adult patients with BCG-unresponsive NMIBC with carcinoma in situ (CIS), with or without papillary tumors. The conditional marketing authorization includes all 27 European Union (EU) member states plus Iceland, Norway and Liechtenstein.

"Our patients should benefit from medical innovations at the earliest possible stage and receive treatment tailored to their specific disease. Through our Bladder Cancer Program, we bring together specialized clinical care and scientific expertise to achieve this goal," said Priv. Doz. Dr. Maximilian Pallauf, FEBU, Director of the Bladder Cancer Program, and Univ. Prof. Dr. Lukas Lusuardi, FEBU, Head of the Department of Urology and Andrology at Salzburg University Hospital of the Salzburg Regional Hospitals (SALK). "Being the first center in Europe to administer ANKTIVA for the treatment of BCG-unresponsive non-muscle-invasive bladder cancer highlights our pioneering role in translating novel therapeutic approaches into routine clinical practice."

Accord Healthcare, a leading European pharmaceutical company and major player in oncology and urology, is providing commercial expertise and market access support, while Dublin-based Uniphar is providing supply chain and distribution services to facilitate ANKTIVA availability across European markets.

"Treating the first patients in Europe represents an important step in expanding access to ANKTIVA across the region," said Richard Adcock, President and Chief Executive Officer of ImmunityBio. "Our collaborations with Accord and Uniphar bring together commercial expertise, local market knowledge, and distribution capabilities to help make ANKTIVA available to more eligible patients."

"We are delighted to see the first patients in Europe receive ANKTIVA, marking an important step for those seeking additional treatment options," said Paul Tredwell, Global Chief Executive Officer of Accord Healthcare. "Our partnership with ImmunityBio combines scientific innovation with the commercial infrastructure and local expertise needed to expand patient access across Europe."

"This partnership reinforces Uniphar's role as a trusted international partner for biotechnology companies bringing highly specialized therapies to patients across complex markets," said Brian O'Shaughnessy, Chief Commercial Officer at Uniphar. "By combining our regulatory, quality, supply chain, distribution, and order-to-cash capabilities, we can support ImmunityBio with a scalable platform that enables launch readiness and ongoing commercial supply for ANKTIVA."

Unmet Medical Need in Europe

Bladder cancer represents a significant public health burden in the European Union, ranking as the fifth most common cancer overall and the seventh most frequently diagnosed cancer among men.[1,2] The European Association of Urology and the World Bladder Cancer Patient Coalition estimate that more than 200,000 new cases of bladder cancer were diagnosed in 2025.[3] Approximately 75% of these cases are NMIBC, the most common form of the disease, which is confined to the bladder lining and has not invaded the underlying muscle layer. For patients whose NMIBC does not respond to BCG therapy, there were no authorized treatment options in the European Union prior to this authorization. The primary alternative has been radical cystectomy, which carries significant morbidity, affects quality of life, and is not suitable for all patients.

About the ImmunityBio, Accord Healthcare, and Uniphar Partnerships

The partnership between ImmunityBio and Accord Healthcare, announced in February 2026, brings together ImmunityBio's expertise in developing innovative immunotherapies with Accord's established European commercial infrastructure, oncology and urology experience, and market access capabilities. Under the partnership, Accord is supporting the commercialization of ANKTIVA across European markets, working with ImmunityBio to help healthcare professionals and eligible patients access the treatment. ImmunityBio retains all global rights to ANKTIVA.

Dublin-based Uniphar serves as ImmunityBio's supply-chain partner, providing an integrated platform encompassing order-to-cash services, storage, distribution, importation, and quality oversight. Leveraging its expertise in specialty pharmaceutical logistics, Uniphar is supporting the launch and

ongoing supply of ANKTIVA across multiple European and Middle Eastern markets. For more information, email immunitybio@uniphar.com.

About ANKTIVA® (nogapendekin alfa inbakicept)

The interleukin-15 (IL-15) cytokine plays a crucial role in the immune system by affecting the development, maintenance, and function of key immune cells, NK and CD8+ killer T cells, that are involved in killing cancer cells. By activating NK cells, ANKTIVA overcomes the tumor escape phase of clones resistant to T cells and restores memory T cell activity with resultant prolonged duration of complete response. ANKTIVA is a first-in-class IL-15 receptor agonist IgG1 fusion complex, consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15 receptor alpha, which binds with high affinity to IL-15 receptors on NK, CD4+, and CD8+ T cells. This fusion complex of ANKTIVA mimics the natural biological properties of the membrane-bound IL-15 receptor alpha, delivering IL-15 independent of dendritic cells and driving the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones.

About Conditional Marketing Authorization

A conditional marketing authorization is an EU regulatory mechanism designed to facilitate early access to medicines that address an unmet medical need. This pathway allows the European Commission to grant marketing authorization when the benefit of a medicine's immediate availability to patients outweighs the risk inherent in the fact that additional data are still required. The European Commission's implementing decision for ANKTIVA (EU marketing authorization number: EU/1/25/2002/001; EMA product number: EMEA/H/C/006622/0000), referenced as C(2026)1197 and dated Brussels, February 16, 2026, was issued by the Director-General for Health and Food Safety under Regulation (EC) No. 726/2004 of the European Parliament and of the Council. As a condition of the authorization, ImmunityBio is required to submit long-term follow-up results from ongoing studies to confirm the efficacy and safety of ANKTIVA. The conditional marketing authorization is subject to annual renewal.

IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA in combination with Bacillus Calmette-Guérin (BCG) is indicated for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours.

WARNINGS AND PRECAUTIONS: The possibility of severe systemic BCG-infections with the necessity of anti-tuberculosis therapy should be considered before initiating the BCG-therapy.

Delaying cystectomy in patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumours, treated with ANKTIVA therapy in combination with BCG could lead to development of muscle invasive or metastatic bladder cancer.

If patients with CIS that are medically eligible for cystectomy have not achieved a CR (absence of disease or low-grade Ta) to treatment after an induction course of ANKTIVA in combination with BCG at the 12-weeks assessment, cystectomy should be reconsidered as an alternative to re-induction. The risk of developing muscle-invasive or metastatic bladder cancer increases the longer cystectomy is delayed in the presence of persisting CIS.

DOSAGE AND ADMINISTRATION: For intravesical use only. ANKTIVA should NOT be administered by subcutaneous or intravenous or intramuscular use.

From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

ANKTIVA is administered intravesically as a mixture with BCG.

USE IN SPECIFIC POPULATIONS: Pregnancy: Treatment is not recommended during pregnancy and in women of childbearing potential not using effective contraception.

Please see the Summary of Product Characteristics for ANKTIVA® available on the European Medicines Agency website at www.ema.europa.eu.

About ImmunityBio

ImmunityBio, Inc. is a biotechnology company focused on innovating, developing, and commercializing next-generation immunotherapies designed to activate the patient's immune system and deliver durable protection against cancer and infectious diseases. Our approach harnesses both the adaptive and innate immune systems with the goal of restoring immune function and generating lasting immunological memory in patients. At the core of our strategy is the Cancer BioShield ™ platform, which is designed to stimulate critical lymphocytes, including natural killer (NK) cells, cytotoxic T cells, and memory T cells via our proprietary IL-15 receptor agonist, ANKTIVA® (nogapendekin alfa inbakicept). Our Cancer BioShield platform is anchored by this antibody-cytokine fusion protein and is complemented by a portfolio that includes adenovirus-vectored vaccines, allogeneic (off-the-shelf) and autologous NK-cell therapies, and additional immunomodulators intended to promote immunogenic cell death and support durable immune responses while potentially reducing reliance on high-dose chemo-radiation therapy. For more information, visit ImmunityBio.com and connect with us on X (Twitter), Facebook, LinkedIn, and Instagram.

About Accord Healthcare

Accord Healthcare is one of the fastest-growing generic and biosimilar pharmaceutical companies in the UK and Europe. Through its focus on quality, accessibility, and sustainability, Accord works with healthcare professionals and health systems to improve patient outcomes and deliver value across therapeutic areas including oncology, bone health, autoimmune disease and ophthalmology.

Further information: www.accord-healthcare.com

About Uniphar

Uniphar is a trusted global partner to pharmaceutical, medtech and biotech companies, connecting medicines and technologies with patients worldwide. With over 57 years of experience and more than 200 multinational clients, Uniphar combines deep expertise and global infrastructure to support the full product lifecycle, from early-stage research through commercialization and beyond. Its integrated services span clinical development,

regulatory strategy, medical affairs, market access, patient engagement, commercialization, distribution, and global sourcing. Operating across 160 countries with a global team of more than 3,600 employees, Uniphar bridges manufacturers, healthcare providers, and patients to accelerate access to innovative therapies, improve patient outcomes and deliver value across the healthcare ecosystem.

References:

1. European Association of Urology. EAU Guidelines on Muscle-invasive and Metastatic Bladder Cancer. Limited Update March 2025.
2. European Association of Urology. Bladder Cancer: The Forgotten Cancer. Sep 2022.
3. World Bladder Cancer Patient Coalition, EAU. Tackling Bladder Cancer in Europe. February 2025. https://worldbladdercancer.org/wp-content/uploads/2025/03/WBCPC-EAU-Bladder-Cancer-MEP-A4-2025-Digital59.pdf Accessed October 2026.

ImmunityBio Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. All statements contained in this press release other than statements of historical fact, including, without limitation, statements regarding the Company's plans and timing for expanding patient access to and the availability of ANKTIVA (nogapendekin alfa inbakicept) across Europe and other international markets, the Company's commercialization and supply-chain partnerships with Accord Healthcare and Uniphar and their expected roles and benefits, are forward-looking statements.

Forward-looking statements include, without limitation, statements regarding the Company's expectations, beliefs, plans, objectives, strategies, prospects, and future performance relating to: the commercial launch, supply and continued availability of ANKTIVA in the European Union and other markets covered by the conditional marketing authorization; the ability of the Company, Accord Healthcare, and Uniphar to perform their respective commercialization, market access, supply chain and distribution roles and to expand patient access across Europe and other international markets; the Company's ability to maintain and obtain renewal of the conditional marketing authorization, including the submission of long-term follow-up results from ongoing studies; and the potential for ANKTIVA to address unmet medical needs of patients with BCG-unresponsive NMIBC with CIS.

These forward-looking statements are based on the Company's current expectations, estimates, forecasts, assumptions, and beliefs as of the date of this press release and involve known and unknown risks, uncertainties, assumptions, and other factors, many of which are outside the Company's control, that could cause actual results, developments, performance, or achievements to differ materially from those expressed, implied, or anticipated by such statements. Such risks and uncertainties include, among others: risks related to the Company's ability to successfully commercialize ANKTIVA in Europe and the timing and extent of patient access across the markets covered by the conditional marketing authorization; the Company's reliance on third-parties, including Accord Healthcare and Uniphar for commercialization, market access, supply chain and distribution support; risks relating to the conditional nature of the marketing authorization, including the requirement to submit long-term follow-up data and the annual renewal requirement; pricing, reimbursement and market acceptance; manufacturing and supply risks; competition from existing or future therapies; the timing, outcome and unpredictability of regulatory review by the European Commission, the European Medicines Agency, and other regulatory authorities; risks and uncertainties associated with evolving most favored nations pricing policies in the U.S. and their potential impact on EU pricing and reimbursement, product launch timing, market access, and future revenues both in the EU and the U.S.; and the possibility that additional safety, efficacy, or other product-related information, including adverse events or previously unidentified risks, may emerge from ongoing or post-authorization studies or commercial use.

More details about these and other risks that may impact ImmunityBio's business are described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the SEC) on February 23, 2026, the Company's Quarterly Report on Form 10-Q filed with the SEC on August 4, 2026, and in subsequent filings made by ImmunityBio with the SEC, which are available on the SEC's website at www.sec.gov. ImmunityBio cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. ImmunityBio does not undertake any duty to update any forward-looking statement or other information in this press release, except to the extent required by law.

View source version on businesswire.com: https://www.businesswire.com/news/home/20261104114389/en/

ImmunityBio and Accord Healthcare Contacts:

Investors
Hemanth Ramaprakash, PhD, MBA
ImmunityBio, Inc.
+1 858-746-9289

Media
Sarah Singleton
ImmunityBio, Inc.
+1 415-290-8045
Sarah.Singleton@ImmunityBio.com

Media Uniphar
Heather.Hopkin@teamtala.com and Beth.Oshea@teamtala.com
Enquires Immunitybio@Uniphar.com

Nick Johnson
Accord Healthcare
+44 7435 220822
nick_johnson@accord-healthcare.com

Source: ImmunityBio, Inc.