



ImmunityBio Signs Exclusive U.S. Agreement with Japan BCG Laboratory for the Tokyo Strain of BCG to Enhance BCG Supply in the United States

May 16, 2026

- Positive Phase III readout of National Cancer Institute sponsored SWOG S1602 randomized clinical trial demonstrating non-inferior efficacy of the Tokyo strain of BCG (Tokyo-172 BCG) versus TICE BCG in BCG-naïve high-grade non-muscle invasive bladder cancer
- ImmunityBio to serve as sole U.S. Biologics License Application applicant for the Tokyo strain of BCG and plans to engage with U.S. Food and Drug Administration (FDA) on regulatory pathway to address the over decade long unresolved BCG shortage in the United States
- Agreement positions ImmunityBio with second potential BCG source to help address U.S. supply needs
- Through ImmunityBio's ongoing partnership with Serum Institute of India, recombinant BCG (rBCG) remains available to eligible patients under ImmunityBio's FDA Expanded Access Program
- Details of the Japan BCG Laboratory agreement will be shared during Dr. Patrick Soon-Shiong's presentation at the American Urological Association Annual Meeting (AUA 2026) in Washington, DC, on May 16, 2026 at 1:30 p.m. EDT. A link to the livestream is included below.

WASHINGTON--(BUSINESS WIRE)--May 16, 2026-- ImmunityBio, Inc. ([NASDAQ: IBRX](#)), a commercial-stage immunotherapy company, today announced an exclusive U.S. Development and Supply Agreement with Japan BCG Laboratory ("JBL"), the Tokyo-based developer and manufacturer of the Tokyo strain of BCG (Tokyo-172 BCG). The agreement provides ImmunityBio exclusive U.S. rights to develop, import, and commercialize intravesical Tokyo-172 BCG.

JBL's Tokyo strain of BCG is supported by the February 2026 positive Phase III readout of SWOG S1602, a randomized Phase III study sponsored by the National Cancer Institute (NCI), which demonstrated non-inferiority of the Tokyo strain of BCG to TICE BCG in BCG-naïve high-grade non-muscle invasive bladder cancer (NMIBC). The pre-specified non-inferiority margin was a hazard ratio of 1.34 (hazard ratio 0.82; 95.8% CI 0.63–1.08). The Tokyo strain of BCG is investigational in the United States and has not been approved by the FDA.

Dr. Patrick Soon-Shiong will discuss the JBL agreement and provide updates on ImmunityBio's efforts to expand BCG access and advance research in the BCG-naïve setting during his presentation, "The Role of IL-15 in the Urological Setting," at the American Urological Association Annual Meeting on May 16, 2026 at 1:30 EDT. The presentation will also highlight the role of IL-15 in urological oncology, including mechanisms driving T cell and natural killer (NK) cell activation, current clinical evidence, and emerging combination approaches in bladder and prostate cancer. A livestream of the presentation will be available through the [2026 AUA Annual Meeting website](#).

"For more than 70 years, Japan BCG Laboratory has been dedicated to the development and manufacture of high-quality BCG products," said Seiichi Inoue, President of Japan BCG Laboratory. "We are pleased to partner with ImmunityBio to bring the Tokyo strain of BCG to patients in the United States, and we look forward to supporting ImmunityBio in its engagement with the FDA."

ImmunityBio plans to engage with the FDA to pursue U.S. approval of the Tokyo strain of BCG and will lead all regulatory submissions, clinical development, and commercialization in the United States as the sole BLA applicant. Upon any approval, ImmunityBio will be the sole Marketing Authorization Holder. The Tokyo strain of BCG has been used in Japan for almost 30 years for the treatment of high-risk NMIBC.

SWOG S1602 (NCT03091660) is a Phase III randomized controlled trial that enrolled 1,000 patients (984 eligible) between February 2017 and December 2020 with BCG-naïve high-grade NMIBC, randomized 1:1:1 to intravesical TICE BCG (n=330), intravesical Tokyo-172 BCG (n=327), or intradermal priming, followed by intravesical Tokyo-172 BCG (n=327). The pre-specified non-inferiority margin for the primary endpoint of high-grade recurrence-free survival (HGRFS) was a hazard ratio of 1.34.

At a median follow-up of 4.6 years, results presented at the February 2026 ASCO Genitourinary Cancers Symposium (Svatek RS, et al. J Clin Oncol. 2026;44[7 suppl]:LBA629) demonstrated non-inferiority of intravesical Tokyo strain of BCG versus intravesical TICE BCG on the primary endpoint of HGRFS (HR 0.82; 95.8% CI 0.63–1.08), with the upper confidence bound well below the pre-specified non-inferiority margin of HR 1.34. Complete response (CR) in carcinoma in situ (CIS) at 6 months was 66.4% (Tokyo) versus 70.2% (TICE). Progression-free survival was similar across arms. The estimated 5-year HGRFS was 64% in the Tokyo arm, 58% in the TICE arm.

ImmunityBio is in discussions with the SWOG Cancer Research Network, the NCI, and Fred Hutchinson Cancer Research Center to establish a Data Use Agreement that would allow incorporation of the S1602 data into the company's planned BLA submission.

"SWOG and the National Cancer Institute have our deep respect for designing and completing SWOG S1602, a randomized controlled trial of approximately one thousand patients in BCG-naïve high-grade NMIBC that took nearly a decade to read out," said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. "S1602 is the kind of rigorous, publicly funded science that should inform FDA decision-making. Its non-inferiority finding for the Tokyo strain of BCG, alongside our rBCG partnership with Serum Institute and the FDA-approved use of ANKTIVA® with BCG in BCG-unresponsive disease, points to a future where U.S. patients with bladder cancer will have the supply and the treatment options they need."

With the JBL agreement, ImmunityBio now has a second potential BCG source for the United States. The Company's ongoing partnership with Serum Institute of India, one of the world's largest vaccine manufacturers, supports the supply of recombinant BCG (rBCG), an investigational product. ImmunityBio will continue its FDA Expanded Access Program (EAP) for rBCG, so eligible patients can receive treatment while the regulatory path for the Tokyo strain of BCG moves forward. Taken together, the two partnerships aim to give U.S. urologists and their patients a more reliable BCG supply.

"U.S. urologists and their patients have lived with a chronic BCG shortage for more than a decade," said Richard Adcock, President and Chief Executive Officer of ImmunityBio. "This agreement with Japan BCG Laboratory for the Tokyo strain of BCG gives ImmunityBio a second potential BCG source for the United States. We plan to work with the FDA on the regulatory path for the Tokyo strain of BCG. In the meantime, through our ongoing partnership with the Serum Institute of India, rBCG remains available to eligible patients through our FDA Expanded Access Program."

ANKTIVA is approved by the FDA in combination with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with carcinoma in-situ (CIS), with or without papillary tumors. ImmunityBio expects to provide further updates on the U.S. regulatory pathway for the Tokyo strain of BCG, including the timing of pre-FDA interactions and any anticipated BLA submission, in future communications.

Important Safety Information

U.S. IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA® is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

WARNINGS AND PRECAUTIONS: Risk of Metastatic Bladder Cancer with Delayed Cystectomy. Delaying cystectomy can lead to the development of muscle-invasive or metastatic bladder cancer, which can be lethal. If patients with CIS do not have a complete response to treatment after a second induction course of ANKTIVA® with BCG, reconsider cystectomy.

DOSAGE AND ADMINISTRATION: For Intravesical Use Only. Do not administer by subcutaneous or intravenous routes. Please see the complete Indication and Important Safety Information and Prescribing Information for ANKTIVA® at [Anktiva.com](https://anktiva.com).

Investigational Use Notice: The Tokyo strain of BCG (manufactured by Japan BCG Laboratory) and recombinant BCG or rBCG (manufactured by Serum Institute of India under ongoing partnership with ImmunityBio) are investigational in the United States and have not been approved by the FDA. The safety and effectiveness of these investigational products have not been established. Availability of rBCG is limited to ImmunityBio's FDA Expanded Access Program for eligible patients. To enroll in the Expanded Access Program for recombinant BCG, please visit <https://immunitybio.com/rbcg/>

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 superagonist. Our Cancer BioShield platform is anchored by this antibody-cytokine fusion protein and is complemented by an investigational 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](https://immunitybio.com) and connect with us on X (Twitter), Facebook, LinkedIn, and Instagram.

About Japan BCG Laboratory

Japan BCG Laboratory, headquartered in Tokyo, Japan, is a developer and manufacturer of Bacillus Calmette-Guérin (BCG) products, including intravesical BCG for bladder cancer and BCG vaccines for tuberculosis prevention. JBL has supplied BCG for more than 70 years.

About ImmunityBio's Partnership with Serum Institute of India

Serum Institute of India is one of the world's largest vaccine manufacturers and is ImmunityBio's manufacturing partner for recombinant BCG (rBCG). The ongoing partnership supports the continued availability of rBCG under ImmunityBio's FDA Expanded Access Program for eligible patients in the United States.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, statements regarding the Development and Supply Agreement with Japan BCG Laboratory; the development, regulatory pathway, manufacturing, supply, and potential U.S. commercialization of the Tokyo strain of BCG; ImmunityBio's plans to engage with the U.S. Food and Drug Administration to pursue U.S. approval of the Tokyo strain of BCG; the SWOG S1602 trial, including the interpretation and use of S1602 data in the planned BLA, and the Company's ability to enter into a Data Use Agreement with SWOG, the National Cancer Institute, and Fred Hutchinson Cancer Research Center; the continuation, scope, and impact of ImmunityBio's Expanded Access Program for recombinant BCG (rBCG) and its role in helping address the U.S. BCG shortage; the potential complementary use of the Tokyo strain of BCG with ANKTIVA®; and statements regarding ImmunityBio's pipeline and strategy.

These forward-looking statements are based on ImmunityBio's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: the FDA's review and acceptance of any future BLA submission for the Tokyo strain of BCG; ImmunityBio's ability to secure a Data Use Agreement with SWOG, the NCI, and Fred Hutchinson Cancer Research Center on acceptable terms; manufacturing, supply, and import logistics for the Tokyo strain of BCG and rBCG; the continued availability of rBCG under the Expanded Access Program; clinical, regulatory, and commercial risks associated with ANKTIVA® and the Company's broader pipeline; competition; intellectual property; macroeconomic and geopolitical conditions; and the additional risks and uncertainties identified in ImmunityBio's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q,

available at www.sec.gov. The forward-looking statements in this press release speak only as of the date hereof, and ImmunityBio undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

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