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ImmunityBio signs exclusive US agreement with Japan BCG Laboratory

May 18, 2026 | News

ImmunityBio to serve as sole US Biologics License Application (BLA) applicant for the Tokyo strain of BCG



ImmunityBio, Inc., a commercial-stage immunotherapy company, has announced an exclusive US 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 US rights to develop, import, and commercialise intravesical Tokyo-172 BCG.

JBL's Tokyo strain of BCG is supported by the February 2026 positive Phase III readout of SWOG S1602, a randomised 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.

ImmunityBio plans to engage with the FDA to pursue US approval of the Tokyo strain of BCG and will lead all regulatory submissions, clinical development, and commercialisation in the United States as the sole BLA applicant.

Upon any approval, ImmunityBio will be the sole Marketing Authorisation Holder. The Tokyo strain of BCG has been used in Japan for almost 30 years for the treatment of high-risk NMIBC.

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.