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Serum Institute of India partners with ImmunityBio for global supply of BCG across all cancer types

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Supply of BCG is expected to be available once the protocol for the trial has been authorised by the US FDA



US-based ImmunityBio, Inc. has signed an exclusive global arrangement with the Serum Institute of India (SII), to supply ImmunityBio with Bacillus Calmette-Guerin (BCG). The agreement covers the manufacturing of standard BCG (sBCG) that is currently approved for use outside the US, as well as a next-generation recombinant BCG (iBCG) undergoing testing, intended for use in combination with ImmunityBio's ANKTIVA for currently approved and potential future indications, subject to regulatory approvals.

The arrangement will result in additional supplies of the current standard sBCG immediately for trials. At the same time, the two companies will work to accelerate the ongoing Phase 2 clinical trials of iBCG currently being conducted in Europe which has so far demonstrated safety advantageous over standard BCG as well as enhanced immunogenicity in driving both CD8+ and CD4 T cells.

The collaboration between SII and ImmunityBio comes on the heels of the FDA's approval of ANKTIVA for the treatment of non-muscle invasive bladder cancer with carcinoma in situ (CIS). Increasing the available supply of BCG is intended to address shortages for the combination therapy with ANKTIVA.

Originally used as a tuberculosis vaccine, BCG administered via intravesical instillation (delivery to the bladder via a catheter) has been the standard of care for patients with non-muscle invasive bladder cancer since 1977. BCG is a benign bacterium that induces an immune response in the bladder in proximity to the cancer cells, leading to clearance of the cancer in many patients.