

June 2025

UPDATE: TICE® BCG (BCG LIVE for intravesical use)

Dear BCAN:

I am writing on behalf of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., to provide you with an update regarding TICE® BCG (BCG LIVE for intravesical use; “TICE BCG”).

Background:

In 2012, Merck unexpectedly became the sole supplier of BCG in many countries around the world and the sole manufacturer in the US. To address the medical need for TICE BCG, Merck increased production to our maximum manufacturing capacity and, as a result, we were able to double the supply of TICE BCG to the US and other markets.

However, the increasing global demand for TICE BCG has exceeded our manufacturing capabilities. In 2020, we announced our decision to build a new manufacturing facility and commit to the reliable and sustainable production of TICE BCG to fulfill the demand.

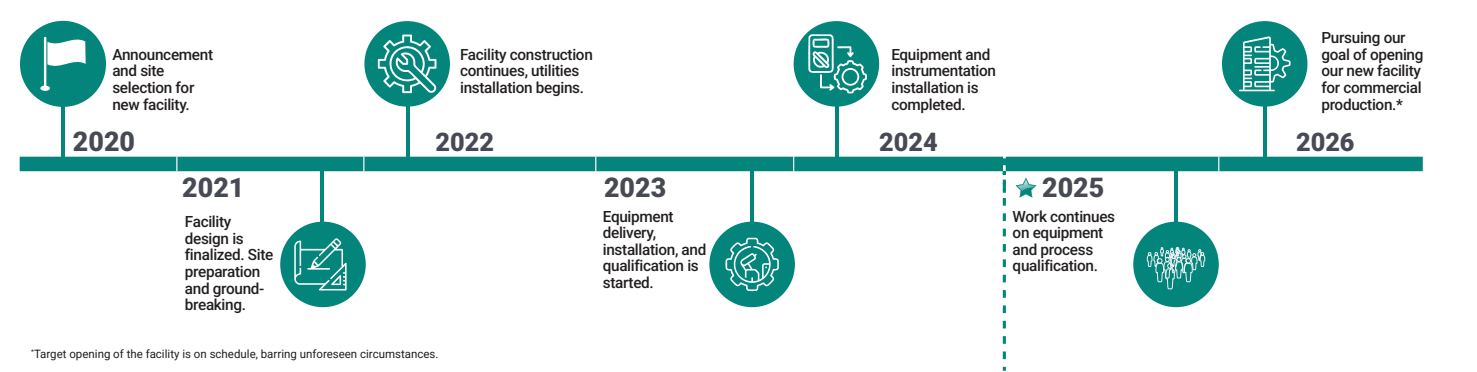
As our company works on completing our new manufacturing facility, we would like to acknowledge the challenges you may have experienced when the supply of TICE BCG has been insufficient to meet market needs. We are sincerely grateful for the patience and efforts of the healthcare practitioners who navigated the supply limitations for their patients. We share your goal of ensuring that patients have access to the medicines they need.

Update on manufacturing for TICE BCG:

We believe that, barring any unforeseen circumstances, we are on track to complete the project on time and expect our plant to open by late 2026, following regulatory review and approval. Once operational, our facility is expected to triple our TICE BCG manufacturing capacity, which we anticipate will meet the needs of physicians and patients for the foreseeable future.

The expansion of the production capacity for TICE BCG represents an investment that reaffirms our long-standing commitment to deliver treatment for patients.

Since our initial announcement in October 2020, we have reached a number of milestones in the development of our facility.



Recent pictures of Merck’s new TICE BCG manufacturing facility:



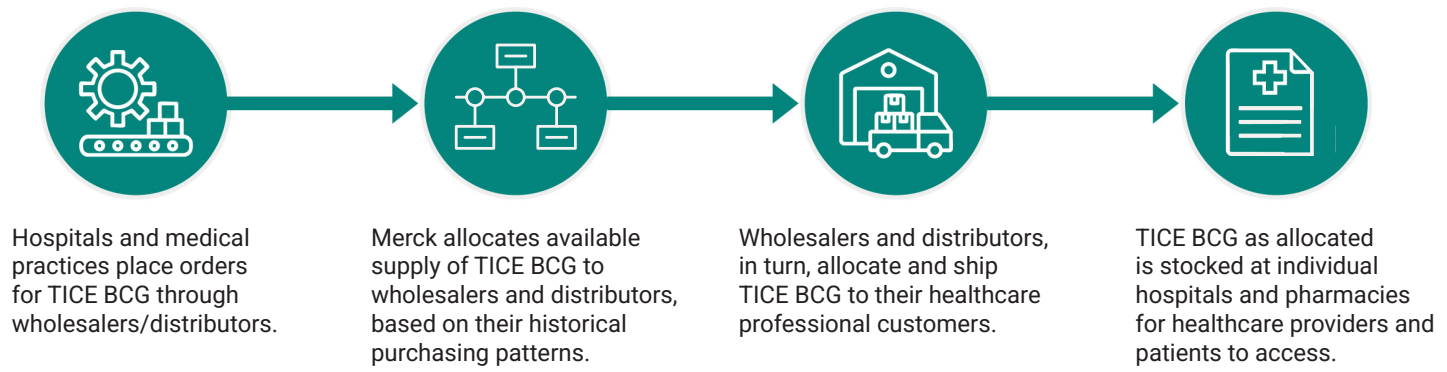
Closed restricted-access barrier system used for aseptic processing of TICE BCG.



Warehouse used to maintain inventory of materials used for TICE BCG production.

Supply allocation of TICE BCG:

As a reminder, Merck continues to allocate available supply of TICE BCG to wholesalers and distributors, based on their historical purchasing patterns. In turn, wholesalers and distributors allocate their inventory of TICE BCG to their healthcare professional customers based on available supply and the historical purchasing patterns of those customers. Merck does not directly determine the amount of supply to individual hospitals, hospital pharmacies, or medical practices.



Merck’s commitment:

Supply continuity and sustainability of our medicines and vaccines have been, and remain, two of our highest priorities. We are proud that we have been able to maintain a consistent supply of TICE BCG since 2012, when we became the sole supplier of BCG in the US. Merck continues to do everything we can to complete this new manufacturing project as expediently as possible.

If you have additional questions, you may refer to the TICE BCG frequently asked questions on Merck.com (<https://www.merck.com/stories/facing-a-global-shortage-merck-commits-to-meeting-patient-demand>), or contact the Merck National Service Center at 800-NSC-MERCK (800-672-6372).

Regards,

Jannie Rothman
President, Merck Human Health
Manufacturing Division

[Signature]
Senior Vice President,
Global Vaccine Operations



Aerial photo of our new manufacturing facility.