



October 2020

## **UPDATED NOTIFICATION OF SUPPLY ALLOCATION: TICE® BCG BCG LIVE (for intravesical use)**

This is an update regarding the supply of TICE® BCG BCG LIVE (for intravesical use) ("TICE BCG"), from Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

As explained in our January 2019 notice, Merck has been experiencing a supply shortage for TICE BCG due to increasing global demand. Though Merck has increased production of TICE BCG in recent years, despite our best efforts, the demand for this medicine now outpaces our maximum supply.

### **Manufacturing Update of TICE BCG:**

Merck has announced it will construct a new manufacturing facility to significantly expand its production capacity of TICE BCG. This investment reaffirms Merck's longstanding commitment to producing this medicine. Since Merck unexpectedly became the sole manufacturer of BCG in many countries around the world in 2012, increasing global demand has outpaced our current maximum manufacturing capabilities. Once this new facility is fully operational, we expect to triple our current manufacturing capacity of TICE BCG. We anticipate that this will meet the needs of patients and their physicians for the foreseeable future.

While this commitment is an important step in making sure that adequate supply of TICE BCG is available, completing construction of a new manufacturing facility may take approximately 5 to 6 years. Once construction is complete, and following regulatory reviews and approvals, supplies of TICE BCG will gradually increase over time.

### **Supply Allocation of TICE BCG:**

Merck will continue to use an allocation model to address the imbalance between supply and demand and to minimize disruption to patient care. The allocation model for TICE BCG in the United States is to help ensure proportional distribution of available supply.

As a reminder, Merck continues to allocate available supply of TICE BCG to wholesalers and distributors based on their historical purchasing patterns. Beginning November 2020, Merck will transition from a weekly allocation to a monthly allocation program. No other changes will be made to the allocation program. Merck will continue to direct wholesalers and distributors, in turn, to allocate and ship TICE BCG to their healthcare professional customers based on available supply and the historical purchasing patterns of their healthcare professional customers. The same allocation procedure will continue to apply to both 340B covered entities and non-340B covered entities. Questions about the quantity or timing of supply available for a healthcare professional practice should be directed to the practice's wholesaler or distributor for more information.

### **Merck's Commitment:**

The continuity of supply of our medicines and vaccines has been, and remains, one of our highest priorities. We regret any inconvenience these supply constraints may cause covered entities and their patients. Our company will do everything we can to complete this new manufacturing project in as timely a manner as possible.

Please contact the Merck National Service Center at 1-800-672-6372 with any questions regarding this updated notice.

Sincerely,

A handwritten signature in black ink that reads "Tim Fratus".

Tim Fratus  
Executive Director, U.S. Commercial Supply Chain Strategy and Access  
Merck Sharp & Dohme Corp.