Frequently Asked Questions about Supply & Availability of *TICE® BCG* BCG LIVE (for Intravesical Use) in the U.S.

What is *TICE® BCG* BCG LIVE (for intravesical use)?
TICE BCG is approved by the U.S. FDA and in many countries around the world for the treatment of a certain type of bladder cancer, specifically for the treatment and prophylaxis of carcinoma *in situ* (CIS) of the urinary bladder and for the prophylaxis of primary or recurrent stage Ta and/or T1 papillary tumors following transurethral resection (TUR). TICE BCG is not recommended for stage TaG1 papillary tumors unless they are judged to be at high risk of tumor recurrence. TICE BCG is not indicated for papillary tumors of stages higher than T1.

What is the cause of the shortages and backorders for TICE BCG?
Merck is currently experiencing supply constraints of TICE BCG due to increased global use. In 2012, Merck became the only source of TICE BCG in many countries, including the United States. To meet the demands of being the sole or primary global supplier, Merck increased production of TICE BCG by more than 100 percent and has been producing TICE BCG to the full extent of manufacturing capacity over the past several years. However, even with the increased production, the increasing global demand is leading to supply constraints for TICE BCG impacting availability.

When will patients be able to reliably receive TICE BCG treatment in the U.S.?
Merck takes any disruption in access to our medicines and vaccines seriously. To minimize disruption to patient care and to address the current imbalance between supply and increasing demand, Merck has implemented a system for proportionally allocating the medicine across countries where the company is the sole or primary supplier. This approach will help enable TICE BCG to be made available in a manner that takes into account the needs of patients across countries based on historical demand.

Continuity of supplying our medicines and vaccines has been and remains one of our highest priorities. As a global health care company, we understand how important it is to get our medicines to the people who need them, and providing those medicines is at the center of what we do.

How are you determining how much TICE BCG each country will receive during this shortage?
For the existing quantity of our medicine, and as more of this medicine becomes available, we will be proportionally allocating the quantity of available supply across countries based on historical demand.

Why can't Merck make more TICE BCG?
While Merck has many years of experience producing TICE BCG, this medicine has a lengthy and inherently complex manufacturing process. As the only source of TICE BCG in many countries, including the United States, Merck increased production by more than 100 percent – which is the full extent of our manufacturing capacity. Despite this increase, with the growing use and need for this product, we still anticipate supply constraints.

When do you expect to have this resolved?
Merck anticipates the proportional allocation process will remain in place at least for 2019, and we will provide updates as more information concerning future supply becomes available.

We understand this is a challenge for patients, and we are working hard to improve production, so we can get this medicine to patients as quickly as possible.

Where can I find out more information about the availability of TICE BCG?
Your physician is in the best position to answer questions about the availability of the medicine in their practice. We encourage you to speak with your physician, who can inquire about the quantity and timing of product availability with his or her supplier.

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