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## **Merck Remains Committed to Producing TICE® BCG for the Treatment of Certain Forms of Bladder Cancer**

### **Terms:**

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KENILWORTH, N.J., March 13, 2019 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, recognizes the impact the current availability of TICE BCG (BCG LIVE FOR INTRAVESICAL USE) is having on patients and their caregivers and today provided an update on the company's long-term commitment to maintain increased production of and access to TICE BCG, a medicine for the treatment of certain forms of bladder cancer.

TICE BCG has been manufactured for 30 years and continuing production of this medically necessary medicine to the full extent of our manufacturing capacity remains a top priority for our company. Beginning in 2012, Merck unexpectedly became the sole supplier of this specific strain of BCG in many countries around the world, as Sanofi Pasteur and another company ran into manufacturing issues. Sanofi Pasteur has not reintroduced its BCG medicine. At the time, Merck was not the major supplier globally for BCG. In the United States, for example, the company provided approximately 28 percent of the total product in the marketplace. In response, over the past several years Merck increased production by more than 100 percent while reducing the lead time for the production of a batch by nearly 40 percent – all in recognition of the medical significance of this product and of the need to ensure availability of TICE BCG to help patients, as others have stopped production. In late 2016, Merck began operating at the full extent of the company's manufacturing capacity, which enables approximately 600,000 to 870,000 vials to be produced annually.

Despite our best efforts, increasing demand for this medicine globally and, unfortunately, occasional unanticipated issues within the lengthy and complex manufacturing process have led to the demand for TICE BCG to outpace our maximum supply. In January 2019, to minimize disruption to patient care and address the current imbalance between supply and increasing demand, Merck implemented a system for proportionally allocating the medicine across countries where the company is the sole or primary supplier, including the United States. This proportional allocation of TICE BCG will continue throughout 2019 and beyond. Our underlying principle is to allocate available supply across these countries in proportion to historical average ordered quantities. At this time, the company will be able to produce the majority of the total global demand over the course of this year based on recent forecasts; however, this could vary based on multiple factors.

In the U.S. specifically, Merck does not directly determine the amount of supply to individual hospitals, hospital pharmacies or medical practices for example. Merck has allocated available supply among its customers who purchase directly, which include its wholesalers and distributors. At no point in determining this allocation process has Merck considered profitability. In turn, the wholesalers and distributors allocate their inventory of TICE BCG to their own customers based on each customer's historical purchasing patterns. Physicians who have questions about the quantity or timing of supply available for their practice should contact their supplier for more information.

Over the past several years, Merck has worked collaboratively with regulators, including the U.S. Food and Drug Administration (FDA) and European health authorities; medical societies and patient advocacy groups, including the American Urological Association (AUA) and Bladder Cancer Advocacy Network (BCAN); and healthcare practitioners around the world to help inform and support awareness about the availability of TICE BCG. We appreciate the efforts of these organizations to help physicians and patients during this time. Merck also appreciates and is supporting ongoing clinical research intended to evaluate the effectiveness of alternative strains of BCG, such as the SWOG Cancer Research Network trial. In addition, the company has been working diligently to identify ways to improve and expand production of TICE BCG, which takes time due to complexity of the manufacturing process.

Merck recognizes the impact supply shortages can have on patients and how upsetting it is when patients cannot receive the medicines they need. We share the frustration patients and family members are facing due to the supply constraints around TICE BCG and have colleagues and family members who are facing similar circumstances. In these situations, patients and their caregivers should discuss the

best course of treatment with their physicians who is in the best position to help.

Our commitment to TICE BCG, while other companies have stopped production, is at the core of Merck's mission to save and improve lives – and our teams remain focused on producing this medicine to the best of our ability for our customers and patients.

For more information about TICE BCG please visit [Merck.com](http://Merck.com). For questions or to share your experience, please contact the Merck National Service Center at 1-800-672-6372.

### **About Merck**

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on [Twitter](#), [Facebook](#), [Instagram](#), [YouTube](#) and [LinkedIn](#).

### **Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA**

This statement of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2018 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

### **Media**

Pamela Eisele  
(267) 305-3558

Claire Mulhearn  
(908) 200-1889

### **Investors**

Teri Loxam  
(908) 740-1986

Peter Dannenbaum  
(908) 740-1037

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