



Company Statement

Media Contact: Mary-Jo Barr
Mary-Jo.Barr@Merck.com

Merck Canada will import 3,500 doses of U.S.-labelled OncoTICE® (marketed as TICE® BCG in the U.S.) to help alleviate a shortage of the medication in Canada

KIRKLAND, QC – June 18, 2019 – As the sole supplier of OncoTICE® (Bacillus Calmette-Guérin (BCG), Strain TICE®) in Canada, a medicine for the treatment of certain forms of bladder cancer, Merck Canada Inc. (“Merck Canada”) is working to fulfill an urgent need for the medication in Canada by importing 3,500 doses from the United States. Health Canada has agreed to this importation proposal.

Due to increased demand worldwide, loss of other manufacturers, and occasional unanticipated inventory constraints, as a result of the lengthy and complex manufacturing process for this medicine, OncoTICE® availability in Canada has been on allocation, based on customers’ historical consumption patterns, since October 2018. During that time, Merck Canada has fulfilled 75 to 100% of the normal demand. However, a recent manufacturing constraint has resulted in a temporary backorder of the product in Canada. As communicated on the drugshortagescanada.ca website on May 23, 2019, OncoTICE® was expected to be temporarily unavailable in Canada from late June to late July 2019.

Given the medical necessity of this product and the impact that a prolonged shortage of OncoTICE® could have on the Canadian health care system, Merck Canada has proposed to Health Canada that 3,500 doses of the medication be imported from the United States, which will help mitigate the disruption in Canada. Health Canada has agreed to this proposal. Merck Canada is currently finalizing the details for the logistics of the import and release of the U.S.-labelled OncoTICE®. Exporting this quantity of medicine from the U.S. to Canada will not impact the ongoing allocation process or quantities of TICE BCG available in the U.S. market.

We anticipate the imported stock should be available in Canada by the beginning of July. As soon as the stock is imported and released in Canada, Merck Canada will communicate the details to its

customers, health care practitioners, and patient groups. At that time, we will resume our allocation plan as we have been doing since October 2018.

The quality of the medicines manufactured by Merck is among our highest priorities. We recognize that the timing of this issue is particularly challenging given that OncoTICE® is already in limited availability due to increasing global demand. As the sole supplier of OncoTICE® in many countries, Merck is committed to supporting demand for OncoTICE® in Canada to our maximum capabilities.

Sole supplier of BCG, Strain TICE® in Canada:

In 2012, Merck unexpectedly became the sole supplier of OncoTICE® (BCG, Strain TICE®) in many countries, including Canada. Since then, to help fill the market void, Merck has increased production of OncoTICE® by more than 100 percent and has been producing it to the full extent of its manufacturing capacity. However, any unanticipated issue in the manufacturing process or increased demand may lead to shortages or backorders and impact availability.

More details about Merck's long-term commitment to OncoTICE® can be found at Merck.com.

About Merck Canada

For over 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 about our operations in Canada, visit www.merck.ca and connect with us on [YouTube](#) and [Twitter @MerckCanada](#).

###