Press release
For immediate distribution

Teva Canada Announces the Approval of HERZUMA®, a biosimilar to HERCEPTIN® for the treatment of adult patients with Early Breast Cancer, Metastatic Breast Cancer and Metastatic Gastric Cancer.

This is the second Notice of Compliance (NOC) issued for a biosimilar in 2019 that Teva Canada Innovation will add to its portfolio of brands, generics and biosimilars.

Montreal (Quebec) – September 11, 2019 – Teva Canada Innovation, G.P.-.S.E.N.C. announces that Health Canada has granted a notice of compliance (NOC)[1] for HERZUMA® (trastuzumab), biosimilar to HERCEPTIN® (trastuzumab)[2] in Canada for the treatment of adult patients with Early Breast Cancer (EBC), Metastatic Breast Cancer (MBC) and Metastatic Gastric Cancer (MGC).

"Canadians are becoming far more aware of biosimilars than in the past years and we are proud to be part of this new era in Canadian health care", said Christine Poulin, Senior Vice President and General Manager of Teva Canada. This Health Canada approval of HERZUMA® and the NOC issued for TRUXIMA™ last April leverage Teva's existing expertise in the oncology market and confirms our commitment to Canadians since Teva's biosimilars will have the potential to reduce costs by providing lower-cost treatment options for patients."

The Health Canada NOC issued for HERZUMA® is based on a review of a comprehensive data package that included efficacy, safety, quality, immunogenicity, pharmacodynamic and pharmacokinetic data from non-clinical and clinical studies.[3] The totality of evidence submitted to Health Canada demonstrated that HERZUMA® and HERCEPTIN® are highly similar and there were no clinically meaningful differences in purity, potency and safety between them for the three approved indications.

"The HERZUMA® NOC announcement is part of our commitment to a future in biosimilars. Teva Canada will continue to invest in biosimilar programs that includes informative material and educational activities to empower healthcare professionals to make the best choice of treatment for their patients", concluded Mrs. Poulin.

About biosimilars[4]

A biosimilar biologic drug, or a biosimilar, is a drug demonstrated to be highly similar to a biologic drug that was already authorized for sale (known as the reference biologic drug). Biosimilars are approved based on a thorough comparison to a reference biologic drug. A biosimilar may enter the market after the expiry of the reference biologic drug's patents and data protection.

[1] https://health-products.canada.ca/noc-ac/index-eng.jsp (search as Herzuma and select *aucune restriction* – in Submission class – for quick access)
[2] HERCEPTIN® is a registered trademark of Genentech Inc. and is currently marketed by Hoffmann-La Roche Limited.
[3] Source: Health Canada. https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/information-submission-requirements-biosimilar-biologic-drugs-1.html#info.
[4] Source: Health Canada https: www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html.

About HERZUMA® (trastuzumab)

HERZUMA® is a monoclonal antibody (mAB) biosimilar to HERCEPTIN® that selectively binds with high affinity to extra cellular domain (ECD) of the human epidermal growth factor receptor 2 (HER2). HER2 protein overexpression is observed in breast cancer and gastric cancer. HERZUMA® is the second HERCEPTIN® biosimilar approved by Health Canada for the treatment of adult patients with Early Breast Cancer (EBC), Metastatic Breast Cancer (MBC) and Metastatic Gastric Cancer (MGC).

HERZUMA® was first approved by the South Korea's Ministry of Food and Drug Safety (MFDS) in January 2014. Since October 2016, TEVA Pharmaceutical Industries Ltd. entered into an exclusive partnership with Celltrion Inc. to commercialize HERZUMA® in the U.S. and Canada. The European Commission granted marketing authorization for HERZUMA® in February 2018 and the drug was approved in all 28 EU member states, Norway, Liechtenstein and Iceland (non-members of the EU). In December 2018, HERZUMA® was approved by the Food and Drug Administration (FDA).

About Early and Metastatic Breast Cancer[5,6]

Breast Cancer is a cancer that starts in the cells of the breast. Those cells sometimes change and no longer grow or behave normally, which may lead to non-cancerous (benign) breast conditions such as atypical hyperplasia and cysts. It can also lead to a cancerous (malignant) tumour that can grow into and destroy nearby tissue.

Most often, breast cancer starts in cells that line the ducts, the tubes that carry milk from the glands to the nipple, and is called ductal carcinoma. When the cancer starts in the cells of the lobules, which are the groups of glands that make milk, it is called lobular carcinoma. Breast cancer has different stages that describe or classify a cancer based on how much cancer there is in the body and where it is when first diagnosed.

Early Breast Cancer (EBC) is the stage when the tumour is smaller than 5 cm and the cancer has not spread to more than 3 lymph nodes. This stage includes stages 1A, 1B and 2A.

Metastatic Breast Cancer (MBC) is the stage when the cancer has spread to other parts of the body, such as the bone, liver, lungs or brain. It is also called stage 4 breast cancer.

About Metastatic Gastric Cancer[7,8]

Gastric cancer is a malignant tumour that starts in cells of the stomach. The tumour may cause precancerous conditions in the stomach if not treated, such as gastric adenoma, or adenomatous polyps, and gastric epithelial dysplasia. In some cases, changes to stomach cells can cause cancer. Most often, cancer starts in gland cells in the inner layer of the stomach wall, which is called the gastric mucosa. This type of cancer is called adenocarcinoma of the stomach. It makes up about 95% of all stomach cancers.

Metastatic Gastric Cancer is when the cancer has spread to other parts of the body, such as to the lungs, bone, peritoneum or omentum. This is also called phase 4 stomach or gastric cancer.

[5] Source: The Canadian Cancer Society. https://www.cancer.ca/en/cancer-information/cancer-type/breast/breast-cancer/?region=on.
[6] Source: The Canadian Cancer Society. https://www.cancer.ca/en/cancer-information/cancer-type/breast/staging/?region=on.
[7] Source: The Canadian Cancer Society. https://www.cancer.ca/en/cancer-information/cancer-type/stomach/stomach-cancer/?region=on.
[8] Source: The Canadian Cancer Society. https://www.cancer.ca/en/cancer-information/cancer-type/stomach/staging/?region=on.

About Teva Canada

Teva Canada is a unique provider of generic and specialty medicines.

Teva Canada Limited, headquartered in Toronto, has provided affordable healthcare solutions for over 50 years, with sales of more than $1 billion in 2017 and over 249,000 prescriptions filled with our products every day.[9] Originally Novopharm Limited, Teva Canada Limited specializes in the development, production and marketing of high-quality generic prescription pharmaceuticals.

Teva Canada Innovation, our branded division, focuses on a diverse line of innovative products in a variety of therapeutic areas, including oncology, CNS, pain and respiratory.

Teva Canada employs almost 1,000 professionals, markets more than 400 products[10] in 1,700 SKUs in Canada and is a subsidiary of Teva Pharmaceutical Industries Ltd., the world's largest generic drug maker. For more information visit: www.tevacanada.com.

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[9] Source: IQVIA CDH & Compuscript MAT. January 2018.
[10] Idem.