

Health Canada approves Biocon and Mylan's Ogivri

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Ogivri is the first trastuzumab biosimilar approved in Canada



Biocon Ltd. and Mylan N.V. have announced that Health Canada has approved Mylan's Ogivri™ (trastuzumab), a biosimilar to Herceptin® (trastuzumab) co-developed with Biocon, for the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma).

Ogivri is the first trastuzumab biosimilar approved in Canada and the second biosimilar from Biocon and Mylan's joint portfolio approved in the market. Mylan plans to launch the product this quarter and anticipates potentially being the first company to offer a trastuzumab biosimilar in Canada.

Dr [Christiane Hamacher](#), CEO, Biocon Biologics said, "We are pleased to enable access to Ogivri, a high quality biosimilar trastuzumab co-developed and manufactured by Biocon as an affordable treatment option for HER2- positive breast and gastric cancer patients in Canada. The Health Canada approval granted to Ogivri, will pave the way for its commercialization by our partner Mylan. Thousands of patients in Europe, India and key emerging markets are benefitting from our biosimilar trastuzumab. Biocon Biologics is committed to address unmet patient needs through its high quality, affordable biologics, globally."

Mylan's Chief Commercial Officer [Tony Mauro](#) commented, "As a global leader in the development of complex products, including biosimilar medicines, we're pleased to reach this approval milestone for Ogivri and the opportunity to bring this important treatment option to market for Canadian patients with HER2-positive breast and gastric cancers. We look forward to continuing our reimbursement discussions with the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Pan-Canadian Pharmaceutical Alliance (pCPA) to ensure that patients have access to Ogivri."

Approval by Health Canada was based on robust data from structural and functional characterization using multiple orthogonal techniques, nonclinical studies and pharmacokinetic evaluation in healthy subjects and patients and a safety, efficacy and immunogenicity study in relevant patient populations, which compared Ogivri to Herceptin. The data demonstrated that Ogivri is highly similar to Herceptin with no clinically meaningful differences in terms of efficacy, safety,

purity and potency.

Biocon and Mylan's trastuzumab biosimilar is currently approved in more than 65 countries around the world, including the U.S.