



PRESS RELEASE

Servier Receives Health Canada Approval of FOLOTYN® for the Treatment of Relapsed or Refractory Peripheral T-cell Lymphoma

LAVAL, QC, November 1st, 2018

Servier Canada announced that Health Canada granted a Notice of Compliance with conditions (NOCc) for FOLOTYN® (pralatrexate) for the treatment of relapsed or refractory peripheral T-cell lymphoma (PTCL).

"We are very happy that FOLOTYN® is now available in Canada, offering a novel treatment option for patients with Peripheral T-cell Lymphoma" said Elizabeth Lye, Scientific Advisor at Lymphoma Canada. "PTCL is a subtype of lymphoma with a very poor prognosis, limited survival and few treatment options. FOLOTYN® will change the treatment landscape for PTCL patients" she added.

FOLOTYN® has a unique mechanism of action. It is a folate analog inhibitor depleting essential biological molecules leading to cancer growth inhibition and tumor cell death.

The efficacy and safety of FOLOTYN® was evaluated in PROPEL, an international multi-centre Phase II study, that enrolled 115 patients with relapsed or refractory PTCL. In this study, FOLOTYN® was administered once weekly at a dose of 30mg/m² for 6 weeks in 7-week cycles until progressive disease or unacceptable toxicity. Results of the PROPEL trial were published in the *Journal of Clinical Oncology*.

"We are very proud that FOLOTYN® is now approved in Canada, providing a novel treatment for a rare and aggressive cancer without many therapeutic options. Oncology is one of the top therapeutic area priorities for Servier and our team is fully committed to provide Canadian cancer patients with innovative treatments and solutions" underlined Frederic Fasano, Chief Executive Officer of Servier Canada Inc.

PTCLs are a rare and heterogeneous group of aggressive mature T-cell and natural killer (NK) cell non-Hodgkin's lymphomas (NHLs). PTCLs represent a small proportion of NHLs, accounting for 5-10% of all NHL cases.

For most PTCL subtypes, the course of disease is fairly aggressive with a poor prognosis and with limited overall survival. It is estimated that most PTCL patients will become refractory or will relapse. There is currently no standard of care in Canada for patients progressing after first-line therapy.

About Servier Canada

Servier Canada was established in 1978 and is celebrating its 40th anniversary of operation in Canada. Servier employs over 250 people across Canada and is currently marketing medicines in diabetes, cardiovascular disease and oncology. In 2016, Servier has established its Oncology division in Canada, based on a franchise of four hemato-oncology products. FOLOTYN[®] is the second of this franchise to be launched after ZEVALIN[®], which is indicated for the treatment of indolent non-Hodgkin's lymphoma. In 2018, Servier Canada has moved a step forward in strengthening its oncology portfolio with two other marketed products, ONCASPAR[®] indicated in acute lymphoblastic leukemia and ONIVYDE[®] in metastatic adenocarcinoma of the pancreas.

More information: www.servier.ca

About Servier

Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). With a strong international presence in 149 countries and a turnover of 4.152 billion euros in 2017, Servier employs 21,700 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (excluding generic drugs) in research and development and uses all its profits for development. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory and neuropsychiatric diseases, cancer and diabetes, as well as by its activities in high-quality generic drugs. Servier also offers eHealth solutions beyond drug development.

More information: www.servier.com

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