

Health Canada Approves Lonsurf® (trifluridine/tipiracil) for Adults With Metastatic Gastric Cancer During Stomach Cancer Awareness Month

New indication improves overall survival for end stage metastatic disease

OAKVILLE, ON, Nov. 21, 2019 /CNW/ - Taiho Pharma Canada, Inc., a Canadian subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), today announced that Health Canada approved LONSURF® (trifluridine and tipiracil [as tipiracil hydrochloride] tablets) for the treatment of adult patients with metastatic gastric (stomach) cancer or adenocarcinoma of the gastroesophageal junction, who have been previously treated with at least two prior lines of chemotherapy including a fluoropyrimidine, a platinum, and either a taxane or irinotecan and if appropriate with HER2/neu-targeted therapy.ⁱ LONSURF received a priority review by Health Canada given the high unmet medical need in this patient population. Currently, there is no drug approved in Canada as third-line therapy for metastatic gastric or GEJ carcinoma.

"Until the approval of LONSURF, available treatments for people with pre-treated metastatic gastric cancer were limited," said Dr. Yoo-Joung Ko, medical oncologist, Sunnybrook Health Sciences Centre, Toronto. "Now Canadian oncologists have a novel effective oral therapy that has been shown to improve overall survival which may have a significant impact on the lives of these patients."

Incidence of Gastric Cancer

In 2019, it is estimated that more than four thousand Canadians are diagnosed with stomach cancer and nearly two thousand will die from the disease.ⁱⁱ Worldwide, gastric cancer is the fifth most common malignancy worldwide and the third most common cause of cancer-related death.ⁱⁱⁱ Most gastric cancers are diagnosed when the disease is advanced and has spread to other sites of the body.^{iv}

"This announcement is good news for people living with stomach cancer. It is a devastating illness that has low survival rates,' said Teresa Tiano, Chair and Co-Founder of My Gut Feeling - Stomach Cancer Foundation of Canada. "We welcome any new treatments that can help patients with metastatic disease live longer and improve their quality of life."

November 30th is Stomach Cancer Awareness Day. My Gut Feeling will hold their annual conference in Toronto, bringing together the stomach cancer community and the medical community in order to open dialogue, educate each other and raise awareness. In addition, landmarks will light up in periwinkle blue from coast-to-coast to raise awareness and funds for stomach cancer.

About Clinical Trial TAGS^v

The approval for LONSURF is based on data from the global, pivotal, randomized, Phase III TAGS (*TAS-102 Gastric Study*) trial evaluating LONSURF plus best supportive care (BSC) versus placebo plus BSC in patients with previously treated metastatic gastric cancer or GEJ adenocarcinoma following progression or intolerance to previous lines of standard therapy. The primary endpoint in the TAGS trial is overall survival (OS), and the key secondary endpoint measures include progression-free survival (PFS), and safety and tolerability, as well as prospective quality of life (QOL). The trial met its primary and secondary endpoints demonstrating prolonged overall survival (OS) with LONSURF versus placebo, and a safety profile consistent with prior experience with this drug for colorectal cancer.

"The priority review and approval of LONSURF for metastatic gastric cancer represents another significant milestone for cancer patients. LONSURF has been shown to prolong survival in patients with this serious disease" said Ross Glover, General Manager, Taiho Pharma Canada, Inc. "With this new

indication approval by Health Canada for LONSURF, we have the opportunity to help more people with a convenient, oral medication."

About LONSURF²

LONSURF is an oral nucleoside antitumor agent discovered and developed by Taiho Pharmaceutical Co., Ltd. LONSURF consists of a thymidine-based nucleoside analog, trifluridine, and the thymidine phosphorylase (TP) inhibitor, tipiracil, which increases trifluridine exposure by inhibiting its metabolism by TP. Trifluridine is incorporated into DNA, resulting in DNA dysfunction and inhibition of cell proliferation.

LONSURF is also approved by the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA) as well as the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) as a treatment for adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma. In addition, LONSURF is approved for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with, or are not candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF biological agents, and, if RAS wild-type, anti-EGFR agents.^{vi} As of November 2019, LONSURF has been approved as a treatment for advanced metastatic colorectal cancer in 76 countries and regions worldwide.

Since 2015, Taiho Pharmaceutical and Servier have been in an exclusive license agreement for the co-development and commercialization of LONSURF in Europe and other countries outside of the United States, Canada, Mexico, and Asia.^{vii}

About Taiho Pharma Canada, Inc. (Canada) Taiho Pharma Canada, Inc., a Canadian subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), is located in Oakville, Ontario and managed by Taiho Oncology, Taiho's U.S. R&D and commercial operations, based in Princeton, New Jersey. Taiho Oncology has established world-class clinical development and commercial organizations that work urgently to develop and market innovative cancer treatments in the U.S. and Canada. Taiho Oncology Inc. has an oral oncology pipeline consisting of both novel anti-metabolic agents and selectively targeted agents. Advanced technology, dedicated researchers, and state of the art facilities are helping Taiho define the way the world treats cancer. It's our work; it's our passion; it's our legacy.

For more information about Taiho Pharma Canada, please visit: <https://www.taihopharma.ca/en/>.

LONSURF® (trifluridine and tipiracil [as tipiracil hydrochloride] tablets) monotherapy is indicated for the treatment of adult patients with metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction, who have been previously treated with at least two prior lines of chemotherapy including a fluoropyrimidine, a platinum, and either a taxane or irinotecan and if appropriate with HER2/neu-targeted therapy.

LONSURF® (trifluridine and tipiracil [as tipiracil hydrochloride] tablets) is indicated for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF biological agents, and, if RAS wild-type, anti-EGFR agents.

-
- ⁱ Taiho Pharma. LONSURF® Product Monograph. Updated 2019
- ⁱⁱ Canadian Cancer Society. Stomach Cancer Statistics. Available at: <https://www.cancer.ca/en/cancer-information/cancer-type/stomach/statistics/?region=on>
- ⁱⁱⁱ Ferlay J, Soerjomataram I, Ervik M, et al. GLOBOCAN 2012 v1.0. Cancer incidence and mortality worldwide. Available at: <https://gco.iarc.fr/today/data/factsheets/cancers/7-Stomach-fact-sheet.pdf>
- ^{iv} Shitara, K., Doi, T., Dvorkin, M., et al. Trifluridine/tipiracil versus placebo in patients with heavily pretreated metastatic gastric cancer (TAGS): a randomised, double-blind, placebo-controlled, phase 3 trial. The Lancet Oncology. 2018;19(11): 1437-1438. [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(18\)30739-3/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30739-3/fulltext)
- ^v Shitara, K., Doi, T., Dvorkin, M., et al. Trifluridine/tipiracil versus placebo in patients with heavily pretreated metastatic gastric cancer (TAGS): a randomised, double-blind, placebo-controlled, phase 3 trial. The Lancet Oncology. 2018;19(11): 1437-1438. [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(18\)30739-3/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30739-3/fulltext)
- ^{vi} Taiho Pharma. LONSURF® Product Monograph. Updated 2019
- ^{vii} Servier is an international pharmaceutical company governed by a non-profit foundation with its headquarters in France (Paris). For more information about Servier, please visit: <https://servier.com/en/>