

LONSURF® RECEIVES A POSITIVE RECOMMENDATION FROM QUEBEC'S INESSS FOR THE TREATMENT OF ADULTS WITH METASTASTIC GASTRIC CANCER

Oral medication addresses vital unmet need to significantly improve survival among patients with few treatment options

OAKVILLE, ON, May 19, 2020 – Taiho Pharma Canada, Inc., a Canadian subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), today announced a positive clinical recommendation by the Institut national d'excellence en santé et en services sociaux (INESSS) recommending that the Minister include LONSURF® (trifluridine and tipiracil [as tipiracil hydrochloride] tablets) on the List of Medications for the treatment of adult patients with metastatic gastric (stomach) cancer or adenocarcinoma of the gastroesophageal junction.ⁱ LONSURF is a treatment for patients 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.ⁱⁱ

The INESSS review concluded that LONSURF offered a modest, yet clinically significant benefit by extending overall survival.ⁱⁱⁱ LONSURF addresses a vital unmet medical need among people living with metastatic gastric cancer as it is the only drug approved in Canada to treat these patients in the third-line treatment setting.

“The positive recommendation by INESSS is welcome news to the metastatic gastric cancer community, as it means my patients will soon be able to access the treatment through public reimbursement,” said Dr. Thierry Alcindor, hematology oncologist at McGill University Health Centre and Director of Medical Oncology at Cedars Cancer Centre in Montreal, Québec. “We know that LONSURF provides metastatic patients with a treatment that has the potential to extend overall survival with good tolerability.”

Metastatic Gastric Cancer in Canada

It is estimated that more than four thousand Canadians are diagnosed with gastric cancer and nearly two thousand will die from the disease each year.^{iv} Most gastric cancers are diagnosed when the disease is advanced and has spread to other sites of the body.^v

“It is vital for those living with this advanced disease be able to access approved treatment options that may prolong their lives and allow them to spend more quality time with their loved ones,” said Teresa Tiano, Chair and Co-Founder of My Gut Feeling - Stomach Cancer Foundation of Canada. “We are hopeful that this positive recommendation from INESSS will encourage the Quebec health authority to provide public access to this important treatment option as soon as possible so patients may benefit from this therapy.”

“At Taiho Pharma, we are united in our goal of helping people with advanced cancers to live longer and with a better quality of life,” said Ross Glover, General Manager of Taiho Pharma

Canada Inc. “We applaud the INESSS decision as a positive step towards LONSURF being added to the Régie de l'assurance maladie (RAMQ) list of medications so patients living with metastatic gastric cancer and adenocarcinoma of the gastroesophageal junction in Quebec can benefit from this treatment.”

About LONSURFⁱⁱ

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 Ministry of Health, Labour and Welfare (MHLW), as a treatment for adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma. In addition, LONSURF is approved in Canada 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 March 2020, LONSURF has been approved as a treatment for advanced metastatic gastric cancer in 42 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/>.

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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 Institut national d'excellence en santé et en services sociaux (INESSS). LONSURF® – Gastric cancer or gastroesophageal junction adenocarcinoma. Notice sent to the Minister in April 2020. https://www.inesss.qc.ca/fileadmin/doc/INESSS/Inscription_medicaments/Avis_au_ministre/Mai_2020/20200414_AvisMinistre_Web.pdf

ⁱⁱ Taiho Pharma. LONSURF® Product Monograph. Updated 2019.

ⁱⁱⁱ Institut national d'excellence en santé et en services sociaux (INESSS). LONSURF® – Gastric cancer or gastroesophageal junction adenocarcinoma. Notice sent to the Minister in April 2020.

^{iv} Canadian Cancer Society. Stomach Cancer Statistics 2019. Available at: <https://www.cancer.ca/en/cancer-information/cancer-type/stomach/statistics/?region=on>

^v National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Gastric cancer. Version 1.2020. <http://www.nccn.org>. Accessed April 2020.

^{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 (Suresnes). More information: www.servier.com