

QUEBEC BECOMES FIRST PROVINCE TO LIST LONSURF® (trifluridine/tipiracil) FOR PUBLIC REIMBURSEMENT FOR ADULT PATIENTS WITH METASTATIC COLORECTAL CANCER

Cancer treatment taken orally shown to extend overall survival in patients whose disease has progressed following treatment with standard therapiesⁱ

OAKVILLE, ON, AUGUST 19, 2019 – Taiho Pharma Canada, Inc., a Canadian subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), today announced that Quebec is the first province to make LONSURF accessible with reimbursement under the Régie de l'assurance maladie du Québec (RAMQ).ⁱⁱ This critical listing follows 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 colorectal cancer (mCRC) who have failed on previous standard therapies.ⁱⁱⁱ

The INESSS review concluded that LONSURF improves median overall survival versus best supportive care, has an acceptable safety margin and meets an important health need as a last-line treatment for mCRC.ⁱⁱ This recommendation followed the UK's National Institute for Health and Care Excellence (NICE) 2016 recommendation for LONSURF as an option for treating metastatic colorectal cancer in adults who have had previous treatment with available therapies.^{iv} Despite these significant positive clinical recommendations, the pan-Canadian Oncology Drug Review (pCODR) issued a negative initial recommendation for LONSURF in July 2019.^v

“With metastatic colorectal cancer, patients often become resistant to standard treatment, severely impacting survival,” said Dr. Benoit Samson, a hematology oncologist at Charles LeMoyne Hospital Cancer Centre. “This is very positive news for people living with refractory metastatic colorectal cancer in Quebec. LONSURF is a novel treatment option that can extend overall survival while having a favourable and manageable safety profile.”

In advanced stages of colorectal cancer where the cancer has spread to distant parts of the body such as the liver, lungs, or distant lymph nodes (also called stage IV) the five-year survival rate is only 14 per cent.^{vi} In the past five years, only two new therapies for mCRC have been approved by Health Canada. Chemo-refractory mCRC remains an area of unmet therapeutic need.^{vii} LONSURF has been shown to extend overall survival in patients with mCRC.^{viii}

“The RAMQ public listing is welcome news for patients in Quebec who are living with this devastating disease,” said Barry D. Stein, President, Colorectal Cancer Canada. “It is unfortunate, however, that people living in the rest of Canada, are not yet able to receive public reimbursement for this drug which has the potential to provide additional valuable time and quality of life for patients with advanced colorectal cancer.” Last month the pan-Canadian Oncology Drug Review (pCODR) did not recommend the reimbursement of LONSURF, despite the positive input from Colorectal Cancer Canada, colorectal cancer patients and their

caregivers as well as from physicians from across Canada. “The pCODR decision will have the effect of depriving patients of access to an effective treatment and further demonstrates the unfairness of unequal access to cancer drugs in Canada,” added Mr. Stein.

“At Taiho Pharma Canada, we are determined to help patients with mCRC access LONSURF which has been shown to extend life and provide quality of life,” said Ross Glover, General Manager of Taiho Pharma Canada Inc. “We will continue to work diligently with all regulatory authorities – including pCODR and Cancer Agencies across Canada- so that any patient who may benefit from this treatment can have access to it.”

Advanced Colorectal Cancer in Canada^x

Colorectal cancer is the second most commonly diagnosed cancer in Canada (excluding non-melanoma skin cancers) and is the second leading cause of death from cancer in men and the third leading cause of death from cancer in women. It is estimated that in 2017, 26,800 patients in Canada were diagnosed with colorectal cancer (this represents 13% of all new cancer cases in 2017), and 9,400 Canadians died from colorectal cancer (this represents 12% of all cancer deaths in 2017). On average, an estimated 73 Canadians were diagnosed with colorectal cancer every day, and an estimated 26 Canadians died from colorectal cancer every day.

About LONSURF

LONSURF is an oral nucleoside antitumor agent discovered and developed by Taiho Pharmaceutical Co., Ltd. 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 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^x. As of July 2019, LONSURF has been approved as a treatment for advanced metastatic colorectal cancer in 68 countries and regions worldwide.

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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**Full product indication: 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 Robert J. Mayer, M.D., et al for the RECURSE Study Group. Randomized Trial of TAS-102 for Refractory Metastatic Colorectal Cancer. *N Engl J Med* 2015;372:1909-19.

ⁱⁱ <http://www.ramq.gouv.qc.ca/fr/professionnels/pharmaciens/medicaments/medicaments-patient-exception/Pages/index-formulaires-mc.aspx>

ⁱⁱⁱ INESSS:

https://www.inesss.qc.ca/fileadmin/doc/INESSS/Inscription_medicaments/Avis_au_ministre/Juin_2018/Lonsurf_2018_05.pdf?sword_list%5B0%5D=lonsurf&no_cache=1

^{iv} <https://www.nice.org.uk/guidance/TA405/chapter/1-Recommendations>

^v https://cadth.ca/sites/default/files/pcodr/Reviews2019/10173Trifluridine-TipiracilCRC_inRec_Chair%20approved_NOREDACT_Post_05Jul2019_final.pdf

^{vi} American Cancer Society. Colorectal cancer statistics. <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/survival-rates.html>

^{vii} *Curr Oncol*. 2019 April;26(2):e255-e259

^{viii} Robert J. Mayer, M.D., et al for the RECURSE Study Group. Randomized Trial of TAS-102 for Refractory Metastatic Colorectal Cancer. *N Engl J Med* 2015;372:1909-19.

^{ix} Canadian Cancer Society. Colorectal cancer statistics. <http://www.cancer.ca/en/cancer-information/cancer-type/colorectal/statistics/?region=on>. Accessed June 2019.

^x Servier is an international pharmaceutical company, governed by a non-profit foundation, with headquarters in the Paris metropolitan area. For more information about Servier, please visit: <https://servier.com/en/>