



## **Health Canada Grants Priority Review Status to trifluridine and tipiracil for Refractory Metastatic Colorectal Cancer**

*- New Drug Submission for a new important treatment option for patients with refractory metastatic colorectal cancer formally accepted for review -*

TORONTO, ON, October 20, 2017 – Taiho Pharma Canada, Inc., a Canadian subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), today announced that Health Canada accepted for review Taiho’s New Drug Submission (NDS) for trifluridine (FTD) and tipiracil (TPI), and that the NDS has been granted Priority Review status. Health Canada’s review of the NDS under Priority Review is expected to be completed in early 2018.

FTD and TPI is an oral combination investigational anticancer drug for the treatment of refractory metastatic colorectal cancer (mCRC). If approved by Health Canada, FTD and TPI could become a new important treatment option for adult patients in Canada with metastatic colorectal cancer who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents.

“Metastatic colorectal cancer persists as one of the foremost common cancers and a leading cause of cancer deaths among men and women in Canada,” said Dr. Ronald Burkes, a medical oncologist at Mount Sinai Hospital in Toronto, Ontario. “Patients with refractory metastatic colorectal cancer have had limited therapeutic options to treat their disease and, if approved, FTD and TPI could help address this unmet medical need by providing patients with a new therapeutic option that can help extend their overall survival.”

Priority Review status applies to a New Drug Submission (NDS) or Supplemental New Drug Submission (S/NDS) for a serious, life-threatening or severely debilitating disease or condition, for which there is substantial evidence of clinical effectiveness for the drug described in the submission. Priority Review for FTD and TPI was granted for the indication of refractory mCRC.

“The submission of our NDS to Health Canada and receipt of Priority Review status marks an important milestone for our company, and underscores the recognized need for new treatment options for patients with refractory metastatic colorectal cancer,” said Ross Glover, General Manager, Taiho Pharma Canada, Inc. “We are working closely with Health Canada to ensure FTD and TPI will be available as quickly as possible to patients in this country who are fighting this devastating disease.”

Results from the Phase III RECURSE trial of FTD and TPI in 800 mCRC patients, whose disease had progressed after or who were intolerant to standard therapies, were published in [The New England Journal of Medicine](#) and form the foundation for the NDS to Health Canada. In patients with refractory colorectal cancer, FTD and TPI plus Best Supportive Care (BSC), as compared with placebo plus BSC, was associated with a significant and clinically meaningful improvement in overall survival and demonstrated a safety profile consistent with that observed in earlier clinical trials.<sup>1</sup>

### **About Metastatic Colorectal Cancer<sup>2</sup>**

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 will be diagnosed with colorectal

cancer (this represents 13% of all new cancer cases in 2017), and 9,400 Canadians will die from colorectal cancer (this represents 12% of all cancer deaths in 2017). On average, 73 Canadians will be diagnosed with colorectal cancer every day, and 26 Canadians will die from colorectal cancer every day. There are no definitive data on the number of patients who are refractory to standard metastatic colorectal cancer treatments.

#### **About trifluridine (FTD) and tipiracil (TPI)**

FTD and TPI is an oral combination investigational anticancer drug for which the safety and efficacy have not been established in Canada. FTD is an antineoplastic nucleoside analog, which is incorporated directly into DNA, thereby interfering with the function of DNA. The blood concentration of FTD is maintained via TPI, which is an inhibitor of the FTD-degrading enzyme, thymidine phosphorylase. FTD and TPI is marketed as LONSURF® in other countries around the world.

In Japan, Taiho Pharmaceutical markets LONSURF for the treatment of unresectable advanced or recurrent colorectal cancer. In the United States, Taiho Oncology, Inc., a U.S. subsidiary of Taiho Pharmaceutical, markets the drug for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.

In Europe and other countries (excluding North America and Japan/Asia), France-based Servier is carrying out codevelopment and commercialization of the drug under a license agreement with Taiho Pharmaceutical. In parts of Asia outside Japan, Jeil Pharmaceutical and TTY Biopharm, which are Taiho Pharmaceutical's business partners in South Korea and Taiwan, respectively, are preparing to bring the drug to market.

As of October 2017, the drug has been approved as a treatment for advanced metastatic colorectal cancer in 39 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 Oncology, please visit: [www.taihooncology.com](http://www.taihooncology.com).

#### **About Taiho Pharmaceutical Co., Ltd. (Japan)**

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma focusing on the three fields of oncology, allergy and immunology, and urology. Its corporate philosophy takes the form of a pledge: "We strive to improve human health and contribute to a society enriched by smiles." In the field of oncology in particular, Taiho Pharmaceutical is known as a leading company in Japan that develops innovative medicines for the treatment of cancer, and is promoting business globally. In areas other than oncology, as well, the company creates quality products that effectively treat medical conditions and can help improve people's quality of life. Always putting customers first, Taiho Pharmaceutical aims to also offer over-the-counter medicinal products that support people's efforts to lead fulfilling and rewarding lives.

For more information about Taiho Pharmaceutical Company, please visit <https://www.taiho.co.jp/en/>.

### **About Otsuka Holdings Co., Ltd. (Japan)**

The Otsuka Group is a global organization of more than 180 healthcare companies with approximately 45,000 employees. Otsuka Holdings Co., Ltd. is the Group's holding company. The Group operates in 28 countries and regions, conducting diversified businesses in four segments all connected by a focus on health: pharmaceuticals, nutraceuticals, consumer products, and others.<sup>3</sup>

The Group's corporate philosophy of "Otsuka-people creating new products for better health worldwide," is supported by the corporate ethic of "JISSHO (Proof through Execution) and SOZOSEI (Creativity)." The Otsuka Group thus seeks to foster a culture and vitality appropriate to an enterprise involved with human health and to create innovative products that contribute to the health and wellness of people worldwide.

For more information, please visit the company's website at <http://www.otsuka.com/en/>.

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### **For more information, please contact:**

Fiona Cassidy

(416) 662-4783

[cassidycomms@gmail.com](mailto:cassidycomms@gmail.com)

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<sup>1</sup> Robert J. Mayer, M.D., et al for the RECOURSE Study Group. Randomized Trial of TAS-102 for Refractory Metastatic Colorectal Cancer. N Engl J Med 2015;372:1909-19. Accessed on July 25, 2017 at <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1414325>.

<sup>2</sup> Canadian Cancer Society. Colorectal cancer statistics. Accessed on July 20, 2017 at <http://www.cancer.ca/en/cancer-information/cancer-type/colorectal/statistics/?region=on>.

<sup>3</sup> Otsuka Holdings Annual Report for the year ending December 2016; [https://www.otsuka.com/en/ir/library/pdf/2016/2016\\_all.pdf](https://www.otsuka.com/en/ir/library/pdf/2016/2016_all.pdf). Accessed September 2017.