



## **Taiho Oncology Presents Real-World Adherence Data for LONSURF® (trifluridine and tipiracil) in Metastatic Colorectal Cancer at ASCO Quality of Care Symposium**

PRINCETON, N.J., September 28, 2018 – Taiho Oncology, Inc. today announced real-world adherence data for patients with metastatic colorectal cancer (mCRC) who were treated with LONSURF® (trifluridine and tipiracil) or Stivarga® (regorafenib).<sup>\*</sup> In this retrospective study, medication adherence was assessed among adult patients with mCRC receiving LONSURF (469) or regorafenib (311). Treatment with LONSURF was associated with significantly higher medication adherence and longer time to discontinuation compared to treatment with regorafenib. These data, from the IQVIA™ Real-World Data Adjudicated Claims-US database, will be presented by Anuj Patel, MD, Dana-Farber Cancer Institute, at the 2018 ASCO Quality of Care Symposium (ASCO QCS) in Phoenix during Poster Session A on Friday, September 28, from 11:30 AM to 1:00 PM and 5:15 PM to 6:15 PM PT.

“As with any retrospective analysis, we must recognize that there may be factors such as differences in patients’ baseline characteristics, that may contribute to the observed results,” said Dr. Patel. “However, these data provide important insight into patient adherence to treatment while helping us better understand the patient’s experience while on treatment for mCRC.”

Among patients who switched to another mCRC treatment (96 LONSURF to regorafenib; 83 regorafenib to LONSURF), those switching from LONSURF to regorafenib were more likely, overall, to have higher adherence than those switching from regorafenib to LONSURF (81% compared to 49% respectively). Additionally, patients receiving LONSURF before regorafenib remained on treatment longer than those receiving regorafenib followed by LONSURF.

### **About Metastatic Colorectal Cancer**

Colorectal cancer (CRC) is the third most commonly diagnosed cancer in the United States (U.S.).<sup>1</sup> In 2018, there were an estimated 140,250 new cases and 50,630 deaths in the U.S.<sup>1,2</sup> Approximately 20% of patients with CRC are diagnosed at the distant or metastasized stage, and between 50% and 60% of patients develop metastases. Metastatic CRC (mCRC) is associated with poor prognosis with a five-year survival rate of about 14%.<sup>1</sup>

Over the last decade, clinical outcomes for patients with mCRC have improved considerably due to the advent of novel treatment agents, predictive biomarkers, and a more strategic approach to the delivery of systemic therapies. Currently, the median overall survival for patients with mCRC being treated both in phase III trials and in large observational series or registries is 30 months – more than double that of 20 years ago.<sup>3-5</sup>

### **About LONSURF**



LONSURF is an oral anticancer drug, which utilizes the combination of trifluridine (FTD) and tipiracil (TPI), whose dual mechanism of action is designed to maintain clinical activity and differs from conventional fluoropyrimidines. FTD is an antineoplastic nucleoside analogue, which is incorporated directly into the 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.

In Japan, Taiho Pharmaceutical has been marketing LONSURF for the treatment of metastatic advanced or recurrent colorectal cancer since 2014. In the United States, beginning in 2015, Taiho Oncology, Inc., a U.S. subsidiary of Taiho Pharmaceutical, began marketing the drug for the treatment of patients with 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 June 2015, Taiho Pharmaceutical and Servier entered into 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. In parts of Asia outside of Japan, Taiho Pharmaceutical's business partner TYY Biopharm launched LONSURF in Taiwan in July 2018, and Jeil Pharmaceutical is preparing to bring the drug to market in South Korea.

As of August 2018, LONSURF has been approved as a treatment for advanced mCRC in 54 countries and regions worldwide.

### **Indications and Use<sup>6</sup>**

LONSURF is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, indicated for the treatment of patients with metastatic colorectal cancer 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.

### **Important Safety Information<sup>6</sup>**

*LONSURF may cause serious side effects, including:*

- **Low blood counts.** Low blood counts are common with LONSURF and can sometimes be severe and life-threatening. LONSURF can cause a decrease in your white blood cells, red blood cells, and platelets. Low white blood cells can make you more likely to get serious infections that could lead to death. Your healthcare provider should do blood tests before you receive LONSURF, at day 15 during treatment with LONSURF, and as needed to check your blood cell counts. Your healthcare provider may lower your dose of LONSURF or stop LONSURF if you have low white blood cell or platelet counts

Tell your healthcare provider right away if you get any of the following signs and symptoms of infection during treatment with LONSURF: fever, chills, or body aches.



*Before taking LONSURF, tell your healthcare provider about all of your medical conditions, including if you:*

- Have kidney or liver problems
- Are pregnant or plan to become pregnant. LONSURF can harm your unborn baby
  - **Females** who can become pregnant should use effective birth control during treatment with LONSURF. Tell your healthcare provider immediately if you become pregnant
  - **Males**, while on treatment and for 3 months after your last dose of LONSURF, you should use a condom during sex with female partners who are able to become pregnant. Tell your healthcare provider right away if your partner becomes pregnant while you are taking LONSURF
- Are breast-feeding or plan to breast-feed. It is not known if LONSURF passes into your breast milk. Do not breast-feed during treatment with LONSURF and for 1 day after your last dose of LONSURF

Tell your healthcare provider about all the prescription and over-the-counter medicines, vitamins, and herbal supplements you take.

The **most common side effects** with LONSURF include tiredness, nausea, decreased appetite, diarrhea, vomiting, abdominal pain, and fever.

Tell your doctor if you have nausea, vomiting, or diarrhea that is severe or that does not go away.

These are not all of the possible side effects of LONSURF. For more information, ask your healthcare provider. Call your doctor for medical advice about side effects.

**Please see full US Prescribing Information.**

[www.taihooncology.com/us/prescribing-information.pdf](http://www.taihooncology.com/us/prescribing-information.pdf)

#### **About Taiho Oncology, Inc. (U.S.)**

Taiho Oncology, Inc., a subsidiary of Taiho Pharmaceutical Co., Ltd. and Otsuka Holdings Co., Ltd., has established a world class clinical development organization that works urgently to develop innovative cancer treatments and has built a commercial business in the U.S. Taiho has an oral oncology pipeline consisting of both novel antimetabolic agents and selectively targeted agents. Advanced technology, dedicated researchers, and state of the art facilities are helping us to 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: <https://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 for developing innovative medicines for the treatment of cancer, a reputation that is rapidly expanding through their extensive global R&D efforts. In areas other than oncology, as well, the company creates and markets quality products that effectively treat medical conditions and can help improve people's quality of life. Always putting customers first, Taiho Pharmaceutical also aims to offer consumer healthcare products that support people's efforts to lead fulfilling and rewarding lives.

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

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

The Otsuka group of companies is a total-healthcare enterprise that aims to contribute to the health of people around world under the corporate philosophy, “Otsuka-people creating new products for better health worldwide.”

Healthcare is broadly and holistically addressed through the two main pillars – the pharmaceutical business for the diagnosis and treatment of diseases and the nutraceutical\*+ business to support the maintenance and promotion of everyday health. Our 46,000\*++ employees across 183 companies in 28 countries and regions take on challenges across various fields and themes to help fulfill the universal wish of people to be healthy. Our pursuit of these challenges is motivated by the Otsuka’ s corporate culture, articulated as “Ryukan-godo” (by sweat we recognize the way), “Jissho” (actualization) and “Sozosei” (creativity), and fostered by successive generations of Otsuka leaders. By striving to provide unique products and services, we seek to achieve sustainable growth and be an indispensable contributor to the world.

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

\*1. Nutraceuticals: nutrition + pharmaceuticals \*2. As of end of December 2017

\*Stivarga® (regorafenib) is a registered trademark of Bayer.

###

#### **Media Contact:**

Lori Rodney  
GCI Health on behalf of Taiho Oncology  
[Taihooncology@gcihealth.com](mailto:Taihooncology@gcihealth.com)  
212-798-9915

- 
1. National Cancer Institute Surveillance Epidemiology and End Results Program. Cancer Stat Facts: Colon and Rectum Cancer. <https://seer.cancer.gov/statfacts/html/colorect.html>. Accessed May 17, 2018.
  2. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2018. *CA: a cancer journal for clinicians*. 2018;68(1):7-30.
  3. Brenner H, Kloor M, Pox CP. Colorectal cancer. *Lancet (London, England)*. 2014;383(9927):1490-1502.
  4. Price TJ, Segelov E, Burge M, et al. Current opinion on optimal systemic treatment for metastatic colorectal cancer: outcome of the ACTG/AGITG expert meeting ECCO 2013. *Expert review of anticancer therapy*. 2014;14(12):1477-1493.
  5. Van Cutsem E, Cervantes A, Adam R, et al. ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. *Annals of Oncology: official journal of the European Society for Medical Oncology*. 2016;27(8):1386-1422.
  6. LONSURF [US prescribing information]; Princeton, NJ: Taiho Oncology, Inc.; 2017. 2017

LON-PM-US-1127 09/2018