

Taiho Oncology Announces Multiple LONSURF® (trifluridine and tipiracil) Presentations at ASCO 2018 Gastrointestinal Cancers Symposium

PRINCETON, N.J., January 12, 2018 – Taiho Oncology, Inc. will present a wide range of clinical data on LONSURF® (trifluridine and tipiracil, TAS-102) at the ASCO 2018 Gastrointestinal Cancers Symposium (ASCO-GI) in San Francisco, January 18-20, 2018.

“These data add to the body of knowledge and research exploring the benefits, utility and safety of LONSURF in people with metastatic colorectal cancer (mCRC),” said Timothy Whitten, President, Taiho Oncology, Inc. “We are extremely excited to present these data during ASCO-GI and look forward to continuing to contribute to ongoing scientific exchange and discovery in this area.”

Select Presentations

Key LONSURF® (trifluridine and tipiracil) data poster presentations are during Poster Session C: Cancers of the Colon, Rectum, and Anus on Saturday, January 20 from 7:00 AM to 7:55 AM PT and 11:30 AM to 1:00 PM PT, including:

Poster Details	Poster Title	Lead Author
Abstract #666 Board F3	Comparison of the real-world adherence and compliance patterns with trifluridine/tipiracil (FTD/TPI) and regorafenib (REG) for the treatment of metastatic colorectal cancer (mCRC)	Anuj Patel
Abstract #744 Board J10	Prognostic value of neutrophil to lymphocyte ratio (NLR) on Overall survival (OS), Progression free survival (PFS) and Disease control rate (DCR) in patients with metastatic colorectal cancer (mCRC) from the RECURSE study	Guillem Argiles
Abstract #752 Board J18	Safety of trifluridine/tipiracil (FTD/TPI) in elderly patients with metastatic colorectal cancer	Robert J. Mayer
Abstract #761 Board K6	Baseline characteristics in the international open-label early-access program of trifluridine/tipiracil in previously treated metastatic colorectal cancer (phase IIIb)	Timothy Price
Abstract #803 Board M2	Quality of life at baseline in the international open-label early-access program of trifluridine/tipiracil in previously treated metastatic colorectal cancer (phase IIIb)	Alfredo Falcone
Abstract #816 Board M15	Phase I multicenter, open-label study to establish the maximum tolerated dose (MTD) of trifluridine/tipiracil (TAS-102) and oxaliplatin combination in patients (pts) with metastatic colorectal cancer (mCRC)	Antoine Hollebecque
Abstract #TPS881 Board Q9	TRUSTY: A Randomized Multicenter Phase II/III Study of Trifluridine/Tipiracil and Bevacizumab versus Irinotecan, Fluoropyrimidine and Bevacizumab as Second-line Treatment in Patients with Metastatic Colorectal Cancer Progressive During or Following First-Line Oxaliplatin-based Chemotherapy	Takayuki Yoshino

About Metastatic Colorectal Cancer

Colorectal cancer is the third most common type of cancer, excluding skin cancers, in the United States, with an estimated 135,430 new patients diagnosed in 2017.¹ It is the second and third leading cause of cancer-related deaths among men and women, respectively.¹

Colorectal cancers that have spread to other parts of the body are often harder to treat and tend to have a poorer outlook.² Metastatic, or stage IV colon and rectal cancers, have a five-year relative survival rate of about 11 and 12 percent, respectively.² Still, there are often many treatment options available for people with this stage of cancer.² Further, treatments have improved over the last few decades.¹ As a result, there are now more than one million survivors of colorectal cancer in the United States.¹

About LONSURF (trifluridine and tipiracil)

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.³

Important Safety Information³

WARNINGS AND PRECAUTIONS

Severe Myelosuppression: In Study 1, LONSURF caused severe and life-threatening myelosuppression (Grade 3-4) consisting of anemia (18%), neutropenia (38%), thrombocytopenia (5%), and febrile neutropenia (3.8%). One patient (0.2%) died due to neutropenic infection. In Study 1, 9.4% of LONSURF-treated patients received granulocyte-colony stimulating factors.

Obtain complete blood counts prior to and on day 15 of each cycle of LONSURF and more frequently as clinically indicated. Withhold LONSURF for febrile neutropenia, Grade 4 neutropenia, or platelets less than 50,000/mm³. Upon recovery, resume LONSURF at a reduced dose as clinically indicated.

Embryo-Fetal Toxicity: LONSURF can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with LONSURF.

USE IN SPECIFIC POPULATIONS

Lactation: It is not known whether LONSURF or its metabolites are present in human milk. There are no data to assess the effects of LONSURF or its metabolites on the breast-fed infant or the effects on milk production. Because of the potential for serious adverse reactions in breast-fed infants, advise women not to breastfeed during treatment with LONSURF and for 1 day following the final dose.

Male Contraception: Because of the potential for genotoxicity, advise males with female partners of reproductive potential to use condoms during treatment with LONSURF and for at least 3 months after the final dose.

Geriatric Use: Patients 65 years of age or over who received LONSURF had a higher incidence of the following compared to patients younger than 65 years: Grade 3 or 4 neutropenia (48% vs 30%), Grade 3 anemia (26% vs 12%), and Grade 3 or 4 thrombocytopenia (9% vs 2%).

Hepatic Impairment: Patients with severe hepatic impairment (total bilirubin greater than 3 times ULN and any AST) were not studied. No adjustment to the starting dose of LONSURF is recommended for patients with mild hepatic impairment. Do not initiate LONSURF in patients with baseline moderate or severe (total bilirubin greater than 1.5 times ULN and any AST) hepatic impairment.

Renal Impairment: In Study 1, patients with moderate renal impairment (CLcr=30 to 59 mL/min, n=47) had a higher incidence (difference of at least 5%) of \geq Grade 3 adverse events, serious adverse events, and dose delays and reductions compared to patients with normal renal function (CLcr \geq 90 mL/min, n=306) or patients with mild renal impairment (CLcr=60 to 89 mL/min, n=178).

Patients with moderate renal impairment may require dose modifications for increased toxicity. Patients with severe renal impairment were not studied.

ADVERSE REACTIONS

Most Common Adverse Drug Reactions in Patients Treated With LONSURF (\geq 5%): The most common adverse drug reactions in LONSURF-treated patients vs placebo-treated patients with refractory mCRC, respectively, were asthenia/fatigue (52% vs 35%), nausea (48% vs 24%), decreased appetite (39% vs 29%), diarrhea (32% vs 12%), vomiting (28% vs 14%), abdominal pain (21% vs 18%), pyrexia (19% vs 14%), stomatitis (8% vs 6%), dysgeusia (7% vs 2%), and alopecia (7% vs 1%).

Additional Important Adverse Drug Reactions: The following occurred more frequently in LONSURF-treated patients compared to placebo: infections (27% vs 15%) and pulmonary emboli (2% vs 0%).

The most commonly reported infections which occurred more frequently in LONSURF-treated patients were nasopharyngitis (4% vs 2%) and urinary tract infections (4% vs 2%).

Interstitial lung disease (0.2%), including fatalities, has been reported in clinical studies and clinical practice settings in Asia.

Laboratory Test Abnormalities in Patients Treated With LONSURF: Laboratory test abnormalities in LONSURF-treated patients vs placebo-treated patients with refractory mCRC, respectively, were anemia (77% vs 33%), neutropenia (67% vs 1%), and thrombocytopenia (42% vs 8%).

Please see full Prescribing Information.

www.taihooncology.com/us/prescribing-information.pdf

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 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 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^{*1} business to support the maintenance and promotion of everyday health. Our 45,000^{*2} employees across 180 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, 2016

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¹ American Cancer Society; What are the key statistics about colorectal cancer? <http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-key-statistics>. Accessed December 2017.

² American Cancer Society; What Are the Survival Rates for Colorectal Cancer, by Stage? <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/survival-rates.html>. Accessed December 2017.

³ LONSURF [prescribing information]; Princeton, NJ: Taiho Oncology, Inc.; 2015.