

Taiho Oncology Eliminates Co-Pays for Many of the Patients Treated with LONSURF® (trifluridine and tipiracil)

Taiho's Patient Assistance Programs Commit to Addressing Patient Burden through New Program Enhancements

PRINCETON, N.J., June 7, 2018 – Taiho Oncology, Inc. today announced that, in an effort to further support access for patients and their LONSURF® treatment, the co-pay for all dose strengths of LONSURF has been reduced from \$30 to \$0 per treatment cycle. The co-pay reduction, which took effect on May 1, 2018, is available to all patients with commercial prescription insurance coverage for LONSURF.

For patients without insurance, or for those who are significantly underinsured for LONSURF, the drug may be made available at no cost through Taiho Oncology's Patient Assistance Program. The Taiho Oncology Patient Support service also provides information for patients and providers on LONSURF insurance coverage and specialty pharmacy availability.

Since the launch of LONSURF in October 2015, the Taiho Oncology Patient Support program has helped more than 10,000 patients afford their medication. More specifically, patients have utilized the Patient Assistance Program to receive more than 9,000 free prescriptions and the commercial Co-Pay Assistance Program on close to 6,000 prescriptions.

“For Taiho Oncology, patients and their well-being are at the center of everything we do as a company, so eliminating barriers to treatment is a high priority,” said Timothy Whitten, President and Chief Executive Officer of Taiho Oncology, Inc. “We understand that each patient has very specific support needs, and we are focused on providing – and regularly evaluating – our patient resources to see where we can further support access for patients. Our decision to eliminate the co-pay for LONSURF, for commercially insured patients, is another example of our commitment to easing the burden of people going through an incredibly challenging time in their lives.”

Reinvestment in research and development is also a high priority for Taiho, with an average of 26.7 percent of the Company's net sales, over the past five years, re-invested into research and development, primarily in the area of oncology. Taiho has a broad pipeline, with a focus on oral and molecularly targeted products for patients living with a range of cancer types.

LONSURF is currently indicated in the United States 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.

About Taiho Oncology Patient Support™

Taiho Oncology strives to meet the LONSURF access needs of all patients, regardless of insurance status, and has a customized one-stop, comprehensive, and fully integrated patient support program called Taiho Oncology Patient Support. The program's intent is to remove access barriers and ensure LONSURF is available to every appropriate patient. Taiho Oncology Patient Support offers the following services:

- **Access and Reimbursement Support** to help simplify access for those who have been prescribed LONSURF as part of their treatment. Taiho Oncology Patient Support can help determine insurance coverage, coordinate prescriptions and more.
- **Financial Support** for privately or commercially insured patients who have difficulty affording LONSURF. The Taiho Oncology Patient Support Program can help identify options for financial support, including:
 - **Co-pay Support** for eligible, privately insured patients. The Taiho Oncology Patient Support Co-pay Card can help to eliminate LONSURF out-of-pocket expenses per treatment cycle.
 - **Alternate Funding Support Referrals** for eligible, publicly insured patients to nonprofit foundations for co-pay assistance.
 - **Patient Assistance** to provide LONSURF at no cost, for eligible patients who have insufficient or no prescription insurance coverage for LONSURF, including Medicaid, Medicare, or any other public or private program, and who have insufficient personal financial resources to pay for their treatment.

This program is available to patients and their providers, with reimbursement specialists available Monday through Friday from 8:00 a.m. to 8:00 p.m. ET, who may be reached via phone at (844) TAIHO-4U or (844)-824-4648 or online at www.TaihoPatientSupport.com.

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.² As a result, there are now more than one million survivors of colorectal cancer in the United States.²

About LONSURF

LONSURF is an oral combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, anticancer drug indicated in United States 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.³ LONSURF is also available in EU,⁴ Japan, and other countries.

In June 2015, Taiho Pharmaceutical Co., Ltd. entered into an exclusive license agreement with Servier for the co-development and commercialization of LONSURF. Under the terms of the agreement, Taiho Pharmaceutical Co., Ltd. granted Servier the right to co-develop and commercialize LONSURF in Europe and other countries outside of the United States, Canada, Mexico and Asia. Taiho Pharmaceutical Co., Ltd. retains the right to develop and commercialize LONSURF in the United States, Canada, Mexico, and Asia and to manufacture and supply the product.

Important Safety Information³

WARNINGS AND PRECAUTIONS

Severe Myelosuppression: In RECOURSE Study, 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 RECURSE Study, 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 US Prescribing Information.

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 with a strong commercial business in the U.S. dedicated to bringing the company's approved medical innovations to patients. 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

* Nutraceuticals: nutrition + pharmaceuticals

[†] As of end of December 2017

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/>.

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LON-PM-US-1091/2018

¹ American Cancer Society; What are the key statistics about colorectal cancer?

<http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-key-statistics>. Accessed May 2018.

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 May 2018.

³ LONSURF [US prescribing information]; Princeton, NJ: Taiho Oncology, Inc.; 2017. 2017

⁴ Lonsurf EU Summary of Product Characteristics (SmPC); August 2017: <http://www.ema.europa.eu/ema/>.