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TAIHO ONCOLOGY

Taiho Oncology Presents Data on LONSURF® (trifluridine and tipiracil) and Key Investigational Compounds at the 109th Annual Meeting of the American Association for Cancer Research

PRINCETON, N.J., April 13, 2018 – Taiho Oncology, Inc. today announced clinical data for LONSURF® (trifluridine and tipiracil, TAS-102) for the treatment of patients with advanced gastrointestinal tumors, and two investigational compounds, TAS-120 and TAS-114, both currently in clinical development for the treatment of patients with a variety of advanced solid tumors. These data are being presented at the 109th Annual Meeting of the American Association for Cancer Research (AACR) in Chicago, April 14 to 18, in McCormick Place South, Exhibit Hall A.

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.[1]

“Taiho Oncology is a company grounded in innovative research and development in cancer, and these studies exemplify our commitment to advancing potential therapies to treat a range of difficult to treat cancers,” said Martin Birkhofer, senior vice president and Chief Medical Officer, Taiho Oncology, Inc. “We are committed to growing our knowledge of LONSURF and these novel compounds – alone or in combination with other therapies – to help impact the lives of people with cancer.”

A phase I dose-escalation study was conducted to determine the safety, maximum tolerated dose, and dose-limiting toxicity of LONSURF in combination with irinotecan in patients with advanced gastrointestinal tumors. The safety findings of LONSURF in combination with irinotecan were consistent with the existing safety profiles of each drug, and recommended dosing of LONSURF and irinotecan was identified for further study. This study is being presented as a poster on Monday, April 16 from 8:00 AM to 12:00 PM CST in Poster Section 42, Poster Board Number 15. The abstract for this presentation is available on the AACR website: http://www.abstractsonline.com/pp8/#!/4562/presentation/11199.

A phase I dose-escalation study examined the safety, dose-limiting toxicity, maximum tolerated dose and/or recommended Phase II dose of TAS-120, a highly selective, covalently bound fibroblast growth factor receptor (FGFR) inhibitor, in patients with advanced solid tumors, including cholangiocarcinoma (CCA), glioblastoma and urothelial carcinomas. In the dose-escalation phase, TAS-120 demonstrated a manageable safety profile and preliminary antitumor activity in heavily pretreated patients with CCA harboring FGFR2 fusions. This study is being presented as a poster

on Tuesday, April 17 from 8:00 AM to 12:00 PM CST in Poster Section 42, Poster Board Number 4. The abstract for this presentation is available on the AACR website: http://www.abstractsonline.com/pp8/#!/4562/presentation/11243.

A phase I study of TAS-114, a novel dual inhibitor of deoxyuridine triphosphatase (dUTPase) and dihydropyrimidine dehydrogenase (DPD), was conducted to further evaluate the combination of TAS-114 and capecitabine in patients with advanced solid tumors. The study found that TAS-114 combined with capecitabine (at 30% of its standard dose) achieved an equivalently efficacious 5-fluorouracil (5-FU) exposure as the standard capecitabine dose alone, with acceptable safety and preliminary efficacy in patients with advanced solid tumors. This study is being presented as a poster on Sunday, April 15 from 1:00 to 5:00 PM CST in Poster Section 42, Poster Board Number 5. The abstract for this presentation is available on the AACR website: http://www.abstractsonline.com/pp8/#!/4562/presentation/11163.

A second phase I study of TAS-114 further evaluated the safety and preliminary efficacy of the compound in combination with S-1 (an oral fluoropyrimidine derivative), in patients with advanced solid tumors. TAS-114, combined with S-1, demonstrated a manageable safety profile and preliminary efficacy in heavily pretreated patients with advanced solid tumors. This study is being presented as a poster on Sunday, April 15 from 1:00 to 5:00 PM CST in Poster Section 42, Poster Board Number 7. The abstract for this presentation is available on the AACR website: http://www.abstractsonline.com/pp8/#!/4562/presentation/11165.

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.[2] It is the second and third leading cause of cancer-related deaths among men and women, respectively.[2]

Colorectal cancers that have spread to other parts of the body are often harder to treat and tend to have a poorer outlook.[3] Metastatic, or stage IV colon and rectal cancers, have a five-year relative survival rate of about 11 and 12 percent, respectively.[3] Still, there are often many treatment options available for people with this stage of cancer.[3] 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 (TAS-102)

LONSURF is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, indicated in US 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.[1] 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 Information[1]

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/mm^3. 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 RECOURSE Study, patients with moderate renal impairment (CLcr=30 to 59 mL/min, n=47) had a higher incidence (difference of at least 5%) of ≥Grade 3 adverse events, serious adverse events, and dose delays and reductions compared to patients with normal renal function (CLcr ≥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

(≥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[1] business to support the maintenance and promotion of everyday health. Our 46,000[2] 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.

[1] Nutraceuticals: nutrition + pharmaceuticals
[2] As of end of December 2017

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

About Servier

Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). With a strong international presence in 148 countries and a turnover of 4.152 billion euros in 2017, Servier employs 21,600 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (excluding generic drugs) in research and development and uses all its profits for development. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory and neuropsychiatric diseases, cancer and diabetes, as well as by its activities in high-quality generic drugs.

Becoming a key player in oncology is part of Servier's long-term strategy. Currently, there are nine molecular entities in clinical development in this area, targeting gastric and lung cancers and other solid tumors, as well as different types of leukemia and lymphomas. This portfolio of innovative cancer treatments is being developed with partners worldwide, and covers different cancer hallmarks and modalities, including cytotoxics, proapoptotics, immune, cellular and targeted therapies, to deliver life-changing medicines to patients.

For more information about Servier, please visit www.servier.com and www.servier-oncology.com

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U.S. Media Contact:
Craig Heit
GCI Health on behalf of Taiho Oncology
Taihooncology@gcihealth.com
212-798-9919

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[1] LONSURF [US prescribing information]; Princeton, NJ: Taiho Oncology, Inc.; 2017. 2017.
[2] 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.

[3] 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.
[4] Lonsurf EU Summary of Product Characteristics (SmPC); August 2017: http://www.ema.europa.eu/ema/.