Taiho Oncology and Servier to Present Data on LONSURF® (trifluridine and tipiracil) and Key Investigational Compound TAS-120 at ESMO 20th World Congress on Gastrointestinal Cancer 2018

PRINCETON, N.J., June 14, 2018 – Taiho Oncology, Inc. and Servier today announced that clinical data for LONSURF® (trifluridine and tipiracil, TAS-102) are being presented at the ESMO 20th World Congress on Gastrointestinal Cancer 2018 (ESMO-GI) in Barcelona, Spain, June 20 to 23. In addition, Taiho announced that data for TAS-120, the Company's investigational compound being studied for the potential treatment of patients with cholangiocarcinoma, will be presented. Key presentations include:

- A pivotal Phase III trial (TAGS) evaluating LONSURF® plus best supportive care (BSC) versus placebo plus BSC in patients with previously treated metastatic gastric cancer refractory to standard therapies met its primary endpoint of prolonged overall survival (OS) (Abstract LBA-002). Results will be shared as an oral and poster presentation on Thursday, June 21 at 12:00 PM CEST in auditorium A, session VII. The abstract for this presentation is available on the ESMO-GI website: http://sched.co/DrlV.
- Primary analysis of data from a Phase II trial (TASCO-1) evaluating LONSURF in combination with bevacizumab versus capecitabine plus bevacizumab in first-line unresectable metastatic colorectal cancer (mCRC) patients who are non-eligible for intensive therapy (Abstract O-022). Results will be shared as an oral and poster presentation on Saturday, June 23 at 9:31 AM CEST in auditorium A, session XX. The abstract for this presentation is available on the ESMO-GI website: http://sched.co/DrmR.
- A phase I dose-escalation study examining the efficacy of TAS-120, an irreversible fibroblast growth factor receptor (FGFR) inhibitor, in cholangiocarcinoma (CCA) patients with FGFR pathway alterations who were previously treated with chemotherapy and/or other FGFR inhibitors (Abstract O-001). The results will be shared as an oral and poster presentation on Wednesday, June 20 at 2:50 PM CEST in auditorium A, session I. The abstract for this presentation is available on the ESMO-GI website: http://sched.co/Drky.

"Taiho is committed to progressing research that will, ultimately, help patients around the world living with a range of cancer types," said Martin J. Birkhofer, MD, senior vice president and Chief Medical Officer, Taiho Oncology, Inc. "The LONSURF data continues to build on our body of knowledge of the safety and efficacy profile of this important therapy in metastatic colorectal cancer and gastric cancer, and we are excited for the presentation of updated clinical data for TAS-120 in cholangiocarcinoma, a rare cancer with limited treatment options."

About TAGS
The TAGS (***TA***S-102 ***G***astric ***S***tudy) trial is a Taiho-sponsored pivotal Phase III multinational, randomized, double-blind study evaluating LONSURF® (trifluridine and tipiracil), also known as TAS-102, plus best supportive care (BSC) versus placebo plus BSC in patients with metastatic gastric cancer refractory to standard treatments. The primary endpoint in the TAGS trial is overall survival (OS), and secondary endpoint measures include progression-free survival (PFS), and safety and tolerability, as well as quality of life.

The TAGS trial aimed to enroll 500 adults 18 years and older with metastatic gastric cancer who had previously received at least two prior regimens for advanced disease. The trial enrolled 507 subjects and was conducted in Japan, North America, Europe, Russia and Turkey, among other locations.

For more information on the TAGS trial, please visit www.ClinicalTrials.gov (https://clinicaltrials.gov/ct2/show/NCT02500043). The ClinicalTrials.gov Identifier is NCT02500043.

About TASCO-1
TASCO-1 is a Servier-sponsored international, randomized, non-comparative Phase II study designed to evaluate efficacy of LONSURF® (trifluridine/tipiracil) in combination with bevacizumab and the current standard of care (capecitabine and bevacizumab) for patients with untreated metastatic colorectal cancer, who are not suitable for intensive therapy.

For more information on the TASCO-1 trial, please visit www.ClinicalTrials.gov (https://clinicaltrials.gov/ct2/show/NCT02743221). The ClinicalTrials.gov Identifier is NCT02743221.

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.[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 Metastatic Gastric Cancer

Gastric cancer, also known as stomach cancer, is a disease in which malignant cells form in the lining of the stomach. It is the fifth most common cancer worldwide and the third most common cause of cancer-related death (after lung and liver cancer), with an

estimated 723,000 deaths annually[3]. Approximately 50 percent of patients with gastric cancer have advanced disease at the time of diagnosis[4].

Standard chemotherapy regimens for advanced gastric cancer include fluoropyrimidines, platinum derivatives, and taxanes (with Ramucirumab), or irinotecan. The addition of trastuzumab to chemotherapy is standard of care for patients with HER2-neu-positive advanced gastric cancer. However, after failure of first- and second-line therapies, standard third line treatments are limited.

About Cholangiocarcinoma

Cholangiocarcinoma (CCA), also known as bile duct cancer, is not common. About 8,000 people in the United States are diagnosed with CCA each year. This includes both intrahepatic (inside the liver) and extrahepatic (outside the liver) cancers. CCA can occur at younger ages, but it is seen mainly in older people. The average age of people in the United States diagnosed with cancer of the intrahepatic bile ducts is 70, and for cancer of the extrahepatic bile ducts it is 72. The chances of survival for patients with CCA depend to a large extent on its location and how advanced it is when it is found.[5]

The main treatment for CCA is surgery. Radiation therapy and chemotherapy may be used if the cancer cannot be entirely removed with surgery and in cases where the edges of the tissues removed at the operation show cancer cells (also called a positive margin). Both stage III and stage IV cancers cannot be completely removed surgically. Currently, standard treatment options are limited to radiation, palliative therapy, liver transplantation, surgery, chemotherapy and interventional radiology.[6]

About LONSURF (TAS-102)

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.[7] LONSURF is also available in EU,[7] 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[8]

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.

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 percent 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

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

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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