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Taiho Pharmaceutical Co., Ltd.

Taiho Pharmaceutical Announces Positive Topline Results from Pivotal Phase 3 Trial of LONSURF® (trifluridine/tipiracil) in Metastatic Gastric Cancer

Taiho Pharmaceutical Co. Ltd. and Servier announced today that the pivotal Phase 3 (TAGS) trial evaluating LONSURF® (trifluridine and tipiracil) plus best supportive care (BSC) versus placebo plus BSC in patients with previously treated metastatic gastric cancer, met its primary endpoint of prolonged overall survival (OS).

These results will be presented at an upcoming medical conference and will be submitted to a peer-reviewed journal for publication.

Taiho remains committed to making further contributions to patients and to medical practitioners engaged in the treatment of cancer.

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 enrolled 507 adults 18 years and older with metastatic gastric cancer who had previously received at least two prior regimens for advanced disease. The TAGS trial 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 Metastatic Gastric Cancer

Gastric cancer 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[1]. Nivolumab and irinotecan are recommended in Japan as the standard third line treatment for metastatic gastric cancer.

In recent years, the outcome for gastric cancer has improved remarkably, and survival has increased dramatically over the past 10 years. As cancer progresses, however, numerous complications can limit the usable drugs and preclude intensive chemotherapy. Prolonging survival and relieving symptoms in late-stage treatment for metastatic gastric cancer are issues for which it is thought important to increase the options for new therapeutic drugs.

About LONSURF

LONSURF is an oral anticancer drug, comprising 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 markets LONSURF for the treatment of unresectable advanced or recurrent colorectal cancer. In the United States, Taiho Oncology, Inc., a U.S. subsidiary of Taiho Pharmaceutical, markets 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. Under the terms of the agreement, Servier has the rights to co-develop and commercialize LONSURF in Europe and other countries outside of the United States, Canada, Mexico and Asia. In parts of Asia outside Japan, Jeil Pharmaceutical and TTY Biopharm, which are Taiho Pharmaceutical's business partners in South Korea and Taiwan, respectively, are preparing to bring the drug to market.

As of April 2018, the drug has been approved as a treatment for advanced mCRC in 48 countries including Japan, USA, and EU.

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

1. Ferlay J, Soerjomataram I, Dikshit R, et al. Int J Cancer. 2015;136:E359-86.