



Phase III Study Evaluating the Efficacy and Safety of Lonsurf (trifluridine/tipiracil) in Patients with Metastatic Gastric Cancer Refractory to Standard Therapies (The TAGS Trial) Meets Primary Endpoint

09 May, 2018 – Servier and Taiho Pharmaceutical Co., Ltd. announced today that the pivotal Phase III trial (TAGS) evaluating Lonsurf® (trifluridine/tipiracil) plus best supportive care (BSC) versus Placebo plus BSC in patients with advanced metastatic gastric cancer (mGC) met its primary objective to improve overall survival (OS).

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

About TAGS

The TAGS trial is a global, randomized, double-blind, placebo-controlled trial evaluating Lonsurf® versus Placebo in patients with pretreated metastatic gastric cancer (mGC).

The TAGS trial enrolled 507 patients who had received at least two prior regimens for mGC and who were refractory to, or unable to, tolerate further chemotherapy. Patients were randomized to receive Lonsurf® plus Best Supportive Care or placebo plus BSC in order to investigate the efficacy and safety. The primary endpoint is overall survival (OS) and secondary endpoint measures include progression free survival (PFS), safety and tolerability, as well as quality of life.

For more information on the TAGS trial, please visit

<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 estimate of 723,000 deaths annually¹. Approximately 50% of patients with gastric cancer have advanced disease at the time of diagnosis². Standard chemotherapy regimens for advanced gastric cancer include fluoropyrimidines, platinum derivatives, taxanes, 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 Lonsurf

Lonsurf® is an oral anticancer drug, comprising a combination of trifluridine (FTD) and tipiracil (TPI), whose dual mechanism of action is designed to maintain clinical activity. Lonsurf® is registered in Japan, USA, European Union and in many other countries. In the European Union, Lonsurf is indicated for the treatment of adult patients with metastatic



colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents.³

Lonsurf® is recommended by the National Institute for Health and Care Excellence (NICE),⁴ NCCN2 and ESMO Guidelines⁵ for the treatment of adult patients with metastatic colorectal cancer.

In June 2015, Servier and Taiho Pharmaceutical entered into an exclusive license agreement for the co-development and commercialization of Lonsurf®.

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.

More information visit: www.servier.com/en/ and www.servier-oncology.com

About Taiho Pharmaceutical Co., Ltd. (Japan)

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd. (<https://www.otsuka.com/en/>), 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/>



Media Contact:

Servier Media Relations

Sonia MARQUES: media@servier.com – Tel.: +33 (0)1 55 72 40 21 / + 33 (0) 7 84 28 76 13

Karine BOUSSEAU: media@servier.com – Tel.: +33 (0)1 55 72 60 37

More information is available at: <https://servier.com/en/>

1. Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: <http://globocan.iarc.fr>
2. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Gastric cancer. V.1.2018.
3. European Medicines Agency. EPAR Lonsurf. Available from: <http://www.ema.europa.eu/ema/>
4. NICE TA405. Available at: www.nice.org.uk/guidance/TA405
5. ESMO consensus guidelines for the management of patients with metastatic colorectal cancer: Van Cutsem E et al. Ann Oncol. 2016;27:1386-422