Servier and Taiho Oncology Announce Phase III (trifluridine/tipiracil) Study Has Met Primary and Secondary Endpoints Demonstrating Prolonged Overall Survival and Progression-Free Survival in Patients with Refractory Metastatic Gastric Cancer

Positive Results from TAGS presented at ESMO 2018 Congress and Published in The Lancet Oncology

PARIS, France, 21 October. 2018 – Servier and Taiho Oncology, Inc. (U.S.), a subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), jointly announced today clinical data from the pivotal Phase III TAS-102 Gastric Study (TAGS) evaluating (trifluridine/tipiracil, TAS-102) versus placebo and best supportive care in patients with heavily pre-treated metastatic gastric cancer who have progressed or are intolerant to previous lines of therapy. The study met its primary endpoint of prolonged overall survival (OS) and secondary endpoint measures of progression-free survival (PFS) consistently supported the OS results, as well as continuing to demonstrate the predictable safety and tolerability profile of trifluridine/tipiracil. Data from TAGS was presented by Dr. Hendrik-Tobias Arkenau, Executive Medical Director of the Sarah Cannon Research Institute UK and an investigator for TAGS, at the ESMO 2018 Congress in Munich, Germany during an oral session (Abstract #LBA25). The study results were simultaneously published in *The Lancet Oncology*.

In TAGS patients treated with trifluridine/tipiracil showed a clinically meaningful and statistically significant improvement in OS compared with placebo and a 31 percent risk reduction of death (HR 0.69 one sided p=0.00029), which translated into a prolonged median survival of 2.1 months (5.7 months for trifluridine/tipiracil versus 3.6 months for placebo). In addition, trifluridine/tipiracil demonstrated a statistically significant improvement in PFS and time to deterioration of ECOG performance status versus placebo, as well as a predictable and manageable safety profile consistent with that previously reported in patients with metastatic colorectal cancer.

Trifluridine/tipiracil is currently indicated in 61 countries, including those of the European Union, for the treatment of adult patients with metastatic colorectal cancer 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.[1]

The abstract for the trifluridine/tipiracil presentation is available on the ESMO website and the manuscript is published online in *The Lancet Oncology*.

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

TAGS enrolled 507 adult patients with metastatic gastric cancer who had previously received at least two prior regimens for advanced disease. The study was conducted in Japan, the United States, the European Union, Russia, Belarus, Israel, and Turkey.

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

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 149 countries and a turnover of 4.152 billion euros in 2017, Servier employs 21,700 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. Servier also offers eHealth solutions beyond drug development.

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

For more information about Servier, please visit www.servier.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/.

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