PRESS RELEASE

Drug Combination Meets Survival Endpoint in Phase III Pivotal Trial Involving Participants With Refractory Metastatic Colorectal Cancer

Results from the primary analysis of the SUNLIGHT trial to be presented at an upcoming scientific conference

Paris - September 12, 2022 – Servier, Taiho Oncology, Inc., and Taiho Pharmaceutical Co., Ltd., announced today that the investigational combination of trifluridine/tipiracil plus bevacizumab showed a statistically significant improvement in the primary endpoint of overall survival (OS) compared to trifluridine/tipiracil alone in a Phase III clinical trial of participants with refractory metastatic colorectal cancer (mCRC) following two chemotherapy regimens.

Further details about the OS benefit and other results from the primary analysis of the global SUNLIGHT trial will be presented at an upcoming international scientific conference.

“Findings from the SUNLIGHT trial could potentially represent a significant advancement in the treatment of patients with metastatic colorectal cancer who have progressed after two lines of standard chemotherapy,” said Nadia Caussé-Amellal, M.D., Head of Global Development, GI Indications, Oncology and Immuno-Oncology Therapeutic Area, Servier. “Combining trifluridine/tipiracil with bevacizumab demonstrated the potential to extend survival in these patients who have limited therapeutic options.”

Fabio Benedetti, M.D., Global Chief Medical Officer for Oncology at Taiho Pharmaceutical said: “Trifluridine/tipiracil – discovered by Taiho and developed in our partnership with Servier with the cooperation of many patients and healthcare professionals – has had a significant impact on the management of colorectal cancer for thousands of patients. The results of this study may represent another advancement in the management of this disease, and we now look forward to the further analysis of secondary endpoints.”

Nearly 1.4 million people are diagnosed with colorectal cancer (CRC) each year worldwide,[1] equating to 10% of the global cancer cases.[1] CRC is the second most common cause of cancer mortality, accounting for 881,000 deaths globally in 2018,[2] and patients with metastatic disease have a five-year survival rate of just 11%.[3] Standard chemotherapy regimens for mCRC usually include a fluoropyrimidine plus irinotecan and/or oxaliplatin, with a targeted treatment – an antivascular endothelial growth factor or antiepidermal growth factor receptor –frequently added.

"The worldwide incidence of colorectal cancer is forecasted to exceed 3 million cases annually by 2040,[4] and the number of deaths is predicted to increase by 69% to approximately 1.6 million per year,[5]" said Professor Josep Tabernero, M.D., Ph.D., Head of Medical Oncology, Vall d'Hebron University Hospital, Barcelona, Spain, and Primary Investigator for the SUNLIGHT trial. "New treatment options are urgently needed as we seek to reduce the growing global burden of colorectal cancer."

#ENDS#

About SUNLIGHT

SUNLIGHT is a multinational, open-label, active-controlled, two-arm Phase III trial to investigate the efficacy and safety of trifluridine/tipiracil plus bevacizumab versus trifluridine/tipiracil alone, in patients with refractory mCRC following two chemotherapy regimens. A total of 492 patients were randomly allocated (in a 1:1 ratio) to receive trifluridine/tipiracil plus bevacizumab or trifluridine/tipiracil monotherapy. The primary objective was to demonstrate the superiority of trifluridine/tipiracil plus bevacizumab over trifluridine/tipiracil alone, in terms of OS (primary endpoint). Key secondary objectives were to compare the regimens in terms of progression-free survival (PFS), overall response rate (ORR), disease control cate (DCR) and quality of life (QoL), as well as the safety and tolerability of trifluridine/tipiracil plus bevacizumab in comparison with trifluridine/tipiracil monotherapy.

For more information on SUNLIGHT, please visit:
https://clinicaltrials.gov/ct2/show/NCT04737187.

About trifluridine and tipiracil

Trifluridine and tipiracil is an oral nucleoside antitumor agent discovered and developed by Taiho Pharmaceutical Co., Ltd. Trifluridine and tipiracil consists of a thymidine-based

nucleoside analog, trifluridine, and the thymidine phosphorylase (TP) inhibitor, tipiracil, which increases trifluridine exposure by inhibiting its metabolism by TP. Trifluridine is incorporated into DNA, resulting in DNA dysfunction and inhibition of cell proliferation.

About Servier
Servier is a global pharmaceutical group governed by a Foundation. With a strong international presence in 150 countries and a total revenue of 4.7 billion euros in 2021, Servier employs 21,800 people worldwide. Servier is an independent group that invests over 20% of its brand-name revenue in Research and Development every year. To accelerate therapeutic innovation for the benefit of patients, the Group is committed to open and collaborative innovation with academic partners, pharmaceutical groups, and biotech companies. It also integrates the patient's voice at the heart of its activities.

A leader in cardiology, the ambition of the Servier Group is to become a renowned and innovative player in oncology. Its growth is based on a sustained commitment to cardiovascular and metabolic diseases, oncology, neuroscience and immuno-inflammatory diseases. To promote access to healthcare for all, the Servier Group also offers a range of quality generic drugs covering most pathologies.

More information: www.servier.com.

Follow us on social media: LinkedIn, Facebook, Twitter.

About Taiho Oncology, Inc.
The mission of Taiho Oncology, Inc. is to improve the lives of patients with cancer, their families and their caregivers. The company specializes in the development of orally administered anti-cancer agents and markets these medicines for a range of tumor types in the U.S. Taiho Oncology's growing pipeline of selectively targeted anti-cancer agents is led by a world-class clinical development organization. Taiho Oncology is a subsidiary of Taiho Pharmaceutical Co., Ltd. which is part of Otsuka Holding Co., Ltd. Taiho Oncology is headquartered in Princeton, New Jersey and oversees its parent company's European and Canadian operations, which are located in Zug, Switzerland and Oakville, Ontario, Canada.

For more information, visit www.taihooncology.com.

About Taiho Pharmaceutical Co., Ltd.
Taiho Pharmaceutical Co., Ltd., a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma company with a focus on oncology. Taiho Pharmaceutical also has development programs in allergy and immunology, urology and consumer healthcare products. Our corporate philosophy is simple: "We strive to improve human health and contribute to a society enriched by smiles."

For more information about Taiho Pharmaceutical Co., Ltd., please visit: https://www.taiho.co.jp/en/.

Servier Media Contact:
Sonia Marques
+33 (0)1 55 72 40 21
presse@servier.com

Taiho Oncology Media Contact:
Judy Kay Moore
574-526-2369
jumoore@taihooncology.com

Taiho Pharmaceutical Media Contact:
Strategic Communications
+81 (0)3-3293-2878
th-koho@taiho.co.jp

References

[1] Digestive Cancers Europe. Prevalence of Colorectal Cancer. Available at: https://digestivecancers.eu/colorectal-cancer/prevalence-of-colorectal-cancer-prevalence/?menu_id=13873. Last accessed: September 2022.
[2] Tabernero J., Taieb J., Prager G., et al. Trifluridine/tipiracil plus bevacizumab for third-line management of metastatic colorectal cancer: SUNLIGHT study design. *Future Oncol.* 2021.17(16): 1977–1985.
[3] World Health Organization. GLOBOCAN. Cancer Today. Estimated age-standardized mortality rates (World) in 2020, colorectum, both sexes, all ages. Available at: https://gco.iarc.fr/today/online-analysis-map?v=2020&mode=population&mode_population=continents&population=900&populations=900&key=asr&sex=0&cancer=41&type=1&statistic=5&prevalence=0&population_group=0&ages_group%5B%5D=0&ages_group%5B%5D=17&nb_items=10&g. Last accessed: September 2022.
[4] Xi Y, Xu P. Global colorectal cancer burden in 2020 and projections to 2040. Transl Oncol. 2021;14(10):101174. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8273208/. Last accessed September 2022.
[5] World Health Organization. International Agency for Research on Cancer. Colorectal Cancer Awareness Month 2022. Available at: https://www.iarc.who.int/featured-news/colorectal-cancer-awareness-month-2022/. Last accessed: September 2022.