TAIHO PHARMA TAIHO ONCOLOGY

News Release

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Taiho Pharmaceutical Co., Ltd.
Taiho Oncology, Inc.

U.S. Food and Drug Administration Accepts for Priority Review Supplemental New Drug Application for the Use of Trifluridine/Tipiracil (LONSURF®) in Combination With Bevacizumab for Refractory Metastatic Colorectal Cancer

Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. announced today that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the supplemental new drug application (sNDA) for trifluridine/tipiracil (LONSURF®) as monotherapy or in combination with bevacizumab for the treatment of adult 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. A Priority Review designation by the FDA reduces the review period of the sNDA by four months. In this case, the FDA provided an anticipated Prescription Drug User Fee Act (PDUFA) action date of August 13, 2023.

The sNDA in the US is based on data from the pivotal Phase 3 SUNLIGHT trial, which demonstrated that the investigational combination use of trifluridine/tipiracil plus bevacizumab provided statistically significant improvements in overall survival (OS), which was the primary endpoint, and progression-free survival (PFS), one of the secondary endpoints, for patients with refractory mCRC following disease progression or intolerance on two prior chemotherapy regimens compared to trifluridine/tipiracil alone.

Results from the SUNLIGHT trial were presented by Professor Josep Tabernero, MD, PhD, Head of Medical Oncology, Vall d'Hebron University Hospital, Barcelona, Spain, and Principal Investigator for the SUNLIGHT trial, at the 2023 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI), held January in San Francisco.

"The poor prognosis for patients with previously treated late-stage metastatic colorectal cancer has been an ongoing challenge in the oncology community,

which has driven our pursuit of a potential new treatment option," said Volker Wacheck, MD, PhD, Vice President, Clinical Development, Taiho Oncology, Inc. "We believe the combination of trifluridine/tipiracil plus bevacizumab may represent a significant advance in the treatment of refractory disease, and we look forward to working with the FDA as it considers this application."

Through research and development of innovative treatments, the Taiho group aims to contribute to patients and healthcare professionals around the world.

【About Colorectal Cancer】

Colorectal cancer is the fourth most commonly diagnosed cancer in the U.S.[1] In 2022, there were an estimated 151,030 new cases and 52,580 deaths in the U.S.[2] Approximately 22% of U.S. patients with colorectal cancer are diagnosed at the distant or metastasized stage.[2] Metastatic colorectal cancer is associated with a poor prognosis, with a five-year survival rate of approximately 15.1%.[2]

【About LONSURF】

LONSURF is an oral nucleoside antitumor agent discovered and developed by Taiho Pharmaceutical Co., Ltd. LONSURF 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.

＊LONSURF®

Generic name：Trifluridine/ tipiracil

Product Name in Japan：LONSURF® combination tablet T15, T20

Indications in Japan:

・Unresectable advanced or recurrent colorectal cancer

・Unresectable advanced or recurrent gastric cancer that has progressed after chemotherapy

【About the SUNLIGHT Trial】

SUNLIGHT is a multinational, randomized, active-controlled, open-label two-arm Phase 3 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 assess trifluridine/tipiracil plus bevacizumab versus trifluridine/tipiracil alone, in terms of OS (primary endpoint). Key secondary endpoints were progression free survival (PFS), overall response rate (ORR), disease control rate (DCR) and quality of life (QoL), as well as the safety and tolerability of trifluridine/tipiracil used in combination with bevacizumab in comparison with trifluridine/tipiracil

monotherapy.
The SUNLIGHT trial was conducted by Servier and Taiho Oncology, Inc. For more information on SUNLIGHT, please visit:
https://clinicaltrials.gov/ct2/show/NCT04737187

SUNLIGHT：An open-label, randomised, phase III study comparing trifluridine/tipiracil in combination with bevacizumab to trifluridine/tipiracil monotherapy in patients with refractory metastatic colorectal cancer. (SUNLIGHT Study)

【About Taiho Pharmaceutical Co., Ltd.】

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd. (https://www.otsuka.com/en/), is an R&D-driven specialty pharma focusing on the 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 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 antimetabolic and 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 Holdings 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: https://www.taihooncology.com/us/

[1] U.S. Centers for Disease Control and Prevention. Division of Cancer Prevention and Control. Colorectal Cancer Statistics. 2022. Available at: https://www.cdc.gov/cancer/colorectal/statistics/index.htm. Last accessed: March 2023.

[2] National Cancer Institute Surveillance Epidemiology and End Results Program. Cancer Stat Facts: Colon and Rectum Cancer. https://seer.cancer.gov/statfacts/html/colorect.html. Last accessed: March 2023.