



For Immediate Release

Taiho Oncology, Inc. Announces TAS-102 New Drug Application for Refractory Metastatic Colorectal Cancer Accepted for Review by FDA

Princeton, NJ – February 23, 2015 – Taiho Oncology, Inc., a subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), today announced the New Drug Application (NDA) for TAS-102 (nonproprietary names: trifluridine and tipiracil hydrochloride), has been accepted for review by the U.S. Food and Drug Administration (FDA). TAS-102 is an oral combination investigational anticancer drug for the treatment of refractory metastatic colorectal cancer (mCRC).

“The FDA’s filing of the TAS-102 NDA represents a significant milestone for our company and underscores the need for new treatment options for patients with refractory metastatic colorectal cancer,” said Eric Benn, Taiho Oncology’s president and chief executive officer. “Today, we are one step closer to our ultimate goal of gaining regulatory approval for TAS-102 and making it available to patients in the USA with this serious medical condition. We look forward to working closely with the FDA during the NDA review.”

Taiho Oncology submitted the final portion of the rolling NDA for U.S. marketing approval of TAS-102 on December 19, 2014. The PDUFA goal date is December 19, 2015.

“Metastatic colorectal cancer persists as one of the foremost common cancers among men and women,” said Robert J. Mayer, MD, a principal investigator of the RECURSE study and Faculty Vice President for Academic Affairs at the Dana Farber Cancer Institute and Professor of Medicine at Harvard Medical School. “If approved, TAS-102 has the potential to become an important new treatment option for patients in the U.S. who are living with refractory metastatic colorectal cancer.”

Results from the Phase III RECURSE trial of TAS-102 in 800 mCRC patients, whose disease had progressed after or who were intolerant to standard therapies, form the foundation for the NDA. The TAS-102 RECURSE trial met the primary efficacy endpoint of statistically significant improvement in overall survival versus placebo (HR = 0.68, $p < 0.0001$) and demonstrated a safety profile consistent with that observed in earlier clinical trials.

About TAS-102

TAS-102 is an oral combination investigational anticancer drug of trifluridine (FTD) and tipiracil hydrochloride (TPI). FTD is an antineoplastic nucleoside analog, which is incorporated directly into 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.

About Refractory Metastatic Colorectal Cancer

There are no definitive data on the number of patients who are refractory to standard metastatic colorectal cancer treatments; however, colorectal cancer is the third most common cancer worldwide. In 2014, it was estimated that 136,830 patients (71,830 men and 65,000 women) would be diagnosed with, and 50,310 patients would die from, cancer of the colon or rectum in the United States.ⁱ Colorectal cancer was the second most common cancer in Europe in 2012. In addition, it was estimated that 447,000 patients (242,000 men and 205,000 women) were diagnosed with and 215,000 patients died of colorectal cancer in Europe during 2012.ⁱⁱ

About Taiho Oncology, Inc.

Taiho Oncology, Inc., a subsidiary of Taiho Pharmaceutical Co., Ltd. and Otsuka Holdings Co., Ltd., has built a world class clinical development organization that works urgently to develop innovative cancer treatments and is in the process of building commercial businesses in the USA and Europe. Taiho has an oral oncology pipeline consisting of both novel antimetabolic agents and selectively targeted agents. Advanced technology, dedicated researchers, and state of the art facilities are helping us to define the way the world treats cancer. It's our work; it's our passion; it's our legacy.

For more information about Taiho Oncology, please visit: www.taihooncology.com

About Taiho Pharmaceutical Co., Ltd.

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma focusing on the three fields of oncology, allergies 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 and around the world for developing innovative medicines for the treatment of cancer. In areas other than oncology, as well, the company creates 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 over-the-counter medicinal products that support people's efforts to lead fulfilling and rewarding lives.

For more information about Taiho Pharmaceutical, please visit <http://www.taiho.co.jp/english/>.

About Otsuka Holdings Co., Ltd.

The Otsuka Group is a global organization of 176 healthcare companies with nearly 43,000 employees (including unconsolidated subsidiaries). Otsuka Holdings Co., Ltd. is the Group's holding company. The Group operates in 27 countries and regions, conducting diversified businesses in four segments all connected by a focus on health: pharmaceuticals, nutraceuticals, consumer products, and others.

The Group's corporate philosophy of "Otsuka-people creating new products for better health worldwide," is supported by the corporate ethic of "JISSHO (Proof through Execution) and SOZOSEI (Creativity)." The Otsuka Group thus seeks to foster a culture and vitality appropriate to an enterprise involved with human health and to create innovative products that contribute to the health and wellness of people worldwide.

For more information, please visit the company's website at <http://www.otsuka.com/en/>.

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References

ⁱ Cancer facts & figures 2014. American Cancer Society.

ⁱⁱ Ferlay, J. et. al. Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012. European Journal of Cancer. 49; 1374-1403.