



For Immediate Release

Taiho Oncology Completes Submission of TAS-102 New Drug Application to the US Food and Drug Administration for the Treatment of Refractory Metastatic Colorectal Cancer

Princeton, NJ – December 22, 2014 – Taiho Oncology, Inc., a subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), announced that it has completed its rolling New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) for TAS-102 (nonproprietary names: trifluridine and tipiracil hydrochloride). TAS-102 is an oral combination anticancer drug under investigation for the treatment of refractory metastatic colorectal cancer (mCRC).

“The TAS-102 NDA submission represents a major milestone for the company as we seek FDA approval for our lead product candidate,” said Fabio Benedetti, M.D., Taiho Oncology’s Senior Vice President and Chief Medical Officer. “If approved by the FDA, TAS-102 could become an important new treatment option for patients with metastatic colorectal cancer whose disease has progressed after treatment with standard therapies.”

TAS-102 was granted Fast Track Designation on September 12, 2014, with the first sections of the rolling submission accepted by the FDA on October 16, 2014. Taiho Oncology’s NDA submission is supported by the 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. 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 Metastatic Colorectal Cancer

Colorectal cancer is the third most common cancer worldwide. In 2014, it is estimated that 136,830 patients (71,830 men and 65,000 women) will be diagnosed with, and 50,310 patients will 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 There are no definitive data on the number of patients who are refractory to standard metastatic colorectal cancer treatments.

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 166 healthcare companies with nearly 44,000 employees. Otsuka Holdings Co., Ltd. is the Group's holding company. The Group operates in 26 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.