



For Immediate Release

Taiho Oncology, Inc. Receives FDA Fast Track Designation for TAS-102 as a Potential Treatment for Refractory Metastatic Colorectal Cancer

– Taiho Oncology Initiates Rolling NDA Submission for TAS-102 –

Princeton, NJ – October 20, 2014 – Taiho Oncology, Inc., a subsidiary of Taiho Pharmaceutical Co., Ltd. (Japan), announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for TAS-102 (nonproprietary names: trifluridine and tipiracil hydrochloride), an oral combination anticancer drug under investigation for the treatment of refractory metastatic colorectal cancer (mCRC), and that the Company has initiated a rolling NDA submission to the FDA. According to the American Cancer Society, an estimated 136,830 people will be diagnosed with, and 50,310 people will die from, cancer of the colon or rectum during 2014 in the United States.¹

The FDA established the Fast Track designation process to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions, and that demonstrate the potential to address unmet medical needs. Fast Track designated drugs are afforded a rolling review of their New Drug Application (NDA) filing by the FDA.

“We are pleased that TAS-102 has been granted Fast Track designation” said Fabio Benedetti, Senior Vice President and Chief Medical Officer at Taiho Oncology. “Patients with metastatic colorectal cancer, whose disease has progressed after treatment with standard therapies, have limited treatment options to manage their disease. We have initiated our rolling NDA submission to the FDA, and are committed to submitting the rest of the filing as efficiently as possible.”

The results from the Phase III RECURSE trial of TAS-102 in 800 patients affected with mCRC, whose disease had progressed after or who were intolerant to standard therapies, are the foundation for Taiho Oncology’s NDA submission to the FDA.

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.ⁱⁱ 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.ⁱⁱⁱ 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/>.

###

Media Contact:

Edie DeVine
Sentry Health for Taiho Oncology, Inc.
edie.devine@sentryhealth.com
415-403-8316

References

ⁱ Cancer facts & figures 2014. American Cancer Society.

ⁱⁱ Cancer facts & figures 2014. American Cancer Society.

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