



**For Immediate Release**

## **Taiho Oncology, Inc. Marks Transition to a Commercial Entity with Key Management Appointment**

*– Chief Commercial Officer, Tim Whitten, to lead commercialization effort –*

**Princeton, NJ – May 12, 2014** – Taiho Oncology, Inc., a division of Taiho Pharmaceutical Co., Ltd. (Japan), today announced the appointment of Tim Whitten to the position of Senior Vice President and Chief Commercial Officer. The appointment of Mr. Whitten represents the initial step in the transition of the company to a more fully integrated clinical development and commercial entity as it prepares for the potential marketing approval of its lead compound, TAS-102, an oral combination anticancer drug (nonproprietary names: trifluridine and tipiracil hydrochloride). Taiho Oncology, Inc. announced earlier today that TAS-102, in the global Phase III RECOURSE trial, met its primary endpoint of demonstrating improvement in overall survival (OS) in patients with refractory metastatic colorectal cancer (mCRC) whose disease had progressed after approved standard therapies.

“Taiho Oncology has been making significant changes to its operations in preparation for the potential commercialization of our lead product, TAS-102, most importantly the appointment of Tim Whitten as our Chief Commercial Officer,” said Eric Benn, President and CEO of Taiho Oncology, Inc. “Tim’s extensive commercial experience, which includes having launched the highly successful chemotherapy, TAXOL®\*, as well as other oncology compounds, makes him particularly well suited to build our commercial organization in the USA and a critical addition to our executive leadership team. Over the past 12 years, Taiho Oncology has built a world class clinical development organization supporting the regional and global development of Taiho’s exciting pipeline of compounds. As we prepare for this next important chapter in Taiho’s history, we are dedicated to hiring the best talent the industry has to offer and allocating the resources necessary to achieve this same high standard with our commercial organizations as our globalization extends to the major western markets of the United States and Europe.”

Prior to joining Taiho Oncology, Mr. Whitten spent 17 years at Bristol-Myers Squibb, where he served in various sales, marketing, and strategic planning roles, including Vice President, Marketing, US Oncology and Immunology, and Vice President, Global Marketing, Oncology, Immunology, and Pulmonary Diseases. Among his accomplishments, he has led several product launches including the successful introduction of TAXOL in the United States. Mr. Whitten was previously employed by Pharmacyclics, where he served in various roles, including Senior Vice President Marketing & Sales and Business Development. From 2006 to 2012, he served as President and CEO of Transave/Insmmed. During this time he guided the company’s lead product from preclinical development to a global Phase III program. In 2010, he took Transave, a private venture capital backed company, into the public marketplace via a merger with Insmmed, a company traded on the NASDAQ.

*– more –*

I'm excited about the opportunity that TAS-102 represents for Taiho Oncology," said Mr. Whitten. "We plan to build a strong, patient-centered commercial organization around TAS-102 and our promising oral oncology pipeline."

Taiho Oncology, formerly Taiho Pharma USA, Inc., today also announced that it has launched a new website that will showcase its oncology pipeline and provide a detailed overview of its vision and goals. To find out more information about Taiho Oncology, please visit the company's new website at [www.taihooncology.com](http://www.taihooncology.com).

### **About RECURSE**

The RECURSE trial is a global, randomized, double-blind, placebo-controlled Phase III comparison trial evaluating the efficacy and safety of orally administered TAS-102 in patients with refractory mCRC. The trial enrolled 800 patients who received at least two prior regimens of standard chemotherapies for mCRC and were refractory to, or failed, those chemotherapies. The trial was conducted in North America, Europe, Japan and Australia. Patients were randomly assigned to receive either TAS-102 or placebo in order to investigate the efficacy of TAS-102. The primary objective of the RECURSE trial was improvement in overall survival (OS) versus placebo. The principal researchers are Dr. Robert J. Mayer of the Dana Farber Cancer Institute (USA), Dr. Eric Van Cutsem of the University Hospital Gasthuisberg (Belgium) and Dr. Atsushi Ohtsu, Director of the Clinical Development Center of the National Cancer Center Hospital East (Japan).

### **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.<sup>i</sup> 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.<sup>ii</sup>

### **About TAS-102**

TAS-102 is an oral combination 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 Taiho Oncology, Inc.**

Taiho Oncology, Inc., a division 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. 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](http://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 158 healthcare companies with nearly 42,000 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/>.

\*Taxol is a registered trademark of Bristol-Myers Squibb Company

###

**Media Contact:**

Edie DeVine  
Sentrix Health for Taiho Oncology, Inc.  
[edie.devine@sentrixhealth.com](mailto:edie.devine@sentrixhealth.com)  
415-403-8316

---

<sup>i</sup> Cancer facts & figures 2014. American Cancer Society.

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