



## **Taiho Pharmaceutical Co., Ltd. and Servier Enter Into a License Agreement for Development and Commercialization of an Oral Anticancer Drug TAS-102 in Europe**

Tokyo – June 15, 2015 – Taiho Pharmaceutical Co., Ltd.(Japan) and Servier (France) announced today that they have entered into an exclusive license agreement on June 12, 2015 for the development and commercialization of TAS-102 (nonproprietary names: trifluridine and tipiracil hydrochloride) in Europe and other countries. Taiho Pharmaceutical Co., Ltd. retains the right to develop and commercialize TAS-102 in the United States, Canada, Mexico and Japan/Asia and to manufacture and supply the product. TAS-102 is an oral combination anticancer drug initially developed by Taiho Pharmaceutical Co., Ltd. for use in the treatment of refractory metastatic colorectal cancer (mCRC).

Under this agreement, Taiho Pharmaceutical Co., Ltd. will receive a total of US\$ 130 million in an upfront payment and for MAA approval in the EU. In addition, Taiho will receive further regulatory and sales event milestone payments and royalties based on net sales. Taiho and Servier will also collaborate on the further global development of TAS-102 sharing effort and cost on an equal basis.

TAS-102 is currently under review by Health Authorities in Europe and the United States and in 2014 was approved for marketing in Japan. In the United States, Taiho Oncology Inc., a subsidiary of Taiho Pharmaceutical Co., Ltd., will market TAS-102.

“We are very pleased to enter into this agreement for TAS-102 with Servier who has a strong presence around the world especially in Europe as a research-based pharmaceutical company and has made a long term commitment to oncology,” said Masayuki Kobayashi, President and Representative Director of Taiho Pharmaceutical Co., Ltd. “Taiho and Servier will work vigorously in close cooperation to accelerate development and commercialization of TAS-102 and make it available to patients globally.”

“This partnership with Taiho will hopefully allow us to rapidly bring a new therapeutic option to patients suffering from refractory metastatic colorectal cancer in Europe and other countries, ” said Olivier Laureau, President of Servier. “We respect and value Taiho’s well-known expertise in the development of oral cancer drugs and hence this collaboration will contribute to develop Servier’s capabilities in oncology. Such a landmark agreement confirms Servier’s strong ambition in oncology and our willingness to bring to cancer patients new therapeutic solutions through Servier’s

extensive portfolio of innovative treatments currently in clinical development. This is in line with our commitment to therapeutic progress for the benefit of patients. ”

Taiho Pharmaceutical Co., Ltd. and Servier anticipate that TAS-102, as a new treatment option, will make an even greater contribution to cancer patients in Europe and other countries through their partnership.

### **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. TAS-102 is commercially available in Japan and is under regulatory review in the United States of America and the European Union for the treatment of refractory metastatic colorectal cancer.

### **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 one of the most common cancers in the European Union<sup>i</sup> and the third most common cancer worldwide.<sup>ii</sup> In 2013, a study published in the *European Journal of Cancer* revealed that an estimated 447,000 patients (242,000 men and 205,000 women) were diagnosed with and 215,000 patients died of colorectal cancer in Europe in 2012.<sup>i</sup> In addition, the American Cancer Society estimated that 136,830 patients (71,830 men and 65,000 women) were diagnosed with and 50,310 patients died of cancer of the colon and rectum in the United States in 2014.<sup>iii</sup>

### **About Servier**

Servier is an independent French research-based pharmaceutical company. Its development is driven by the pursuit of innovation in the therapeutic areas of cardiovascular, metabolic, central nervous system, psychiatric, bone, muscle and joint diseases, as well as cancer.

In 2014, the company recorded a turnover of 4 billion euros. 92% of Servier medicines are prescribed outside of France. 28% of turnover from Servier drugs was reinvested in Research and Development in 2014. With a strong international presence in 146 countries, Servier employs more than 21,400 people worldwide.

Oncology is one of the key priorities of Servier in terms of research and development with currently 8 new molecular entities in clinical development in breast cancer, lung cancer, other solids tumors and various types of lymphomas and leukemias. This portfolio of innovative cancer treatments is being developed with various partners worldwide, and covers different hallmarks of cancer including cytotoxics, pro-apoptotic, targeted, immune and cellular therapies. Hence, Servier aims at delivering a significant and positive impact on cancer patients' lives.

More information is available at: [www.servier.com](http://www.servier.com)

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### **About Taiho Pharmaceutical Co., Ltd.**

Taiho Pharmaceutical Co., Ltd., 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 Co., Ltd. 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 Co., Ltd. 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 Co., Ltd. please visit <http://www.taiho.co.jp/english/>.

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<sup>i</sup> Ferlay, J. et. al. Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012. *European Journal of Cancer*. (2013) 49; 1374-1403

<sup>ii</sup> World Cancer Research Fund International. Worldwide Data. 2013. <http://www.wcrf.org/int/cancer-facts-figures/worldwide-data>. Accessed February 2015. *GLOBOCAN 2012 Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012*.

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