TAIHO ONCOLOGY

Taiho Oncology To Share Data in Advanced Solid Tumors at ESMO Congress 2021

- Data highlight Company's commitment to advancing patient care including those with less common and especially difficult-to-treat cancers

- Data include pooled safety analysis for futibatinib (TAS-120) in patients with advanced solid tumors, including intrahepatic cholangiocarcinoma (iCCA)

PRINCETON, N.J., September 13, 2021 – Taiho Oncology, Inc. which specializes in orally administered anti-cancer medicines and whose mission is to improve the lives of patients with cancer, their families and their caregivers, today announced data presentations from several studies for two of its investigational agents at the European Society for Medical Oncology (ESMO) Congress 2021.

Three abstracts have been selected for poster presentations, including for futibatinib (TAS-120) in advanced solid tumors, including intrahepatic cholangiocarcinoma (iCCA) and gastric cancer, and for TAS-117 in advanced solid tumors.

"These presentations support the Company's focus on developing agents that target the underlying genetic abnormalities in a variety of tumors," said Martin J. Birkhofer, MD, Senior Vice President and Chief Medical Officer, Taiho Oncology, Inc. "The burden for patients living with different forms of cancers continues to remain high, and we are committed to advancing the science to address ongoing and unmet therapeutic needs."

Key data on investigational anti-cancer agents from Taiho Oncology at the ESMO Congress 2021 include:

- **Pooled analysis safety profile of futibatinib in patients with advanced solid tumors, including intrahepatic cholangiocarcinoma (iCCA):** Funda Meric-Bernstam, MD, Chair of the Department of Investigational Cancer Therapeutics – the Phase I Program at MD Anderson Cancer Center and Medical Director of the Institute for Personalized Cancer Therapy (IPCT) (51P). Results will be shared as a poster presentation on September 16, 2021. The abstract for this presentation is available on the ESMO website: https://cslide.ctimeetingtech.com/esmo2021/attendee/confcal_4/presentation/list?q=51P&c=pnr
- **Assessment of futibatinib exposure–response (E–R) relationships in patients with advanced solid tumors, including cholangiocarcinoma (CCA):** Antoine Hollebecque, MD, Senior Medical Physician, Gustave Roussy Cancer Center, Paris (52P). Results will be shared as a poster presentation on September 16, 2021. The abstract for this presentation is available on the ESMO website: https://cslide.ctimeetingtech.com/esmo2021/attendee/confcal_4/presentation/list?q=52P&c=pnr

- **A Phase 2 Study of TAS-117 in Patients with Advanced Solid Tumors Harboring Germline PTEN Inactivating Mutations:** Jordi Rodon Ahnert, MD, PhD, Associate Professor, Department of Investigational Cancer Therapeutics, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX (559TiP). Results will be shared as a poster presentation on September 16, 2021. The abstract for this presentation is available on the ESMO website: https://cslide.ctimeetingtech.com/esmo2021/attendee/confcal_4/presentation/list?q=tas-117&c=pt

The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for the investigational anti-cancer futibatinib for the treatment of patients with previously treated locally advanced or metastatic cholangiocarcinoma harboring *FGFR*2 gene rearrangements, including gene fusions. The FDA Office of Orphan Drug Development has also granted futibatinib orphan drug status for the treatment of cholangiocarcinoma.

Taiho Pharmaceutical Co., Ltd., Taiho Oncology's parent company, will also present the following data:

- **Phase 1 study of the irreversible FGFR inhibitor futibatinib in Japanese patients with advanced solid tumors: updated dose expansion results and activity in gastric cancer**: Y. Kuboki, MD, PhD, Chief Physician, Department of Experimental Therapeutics and Head, Clinical Research Coordination Division, National Cancer Center Hospital East, Kashiwa, Japan (1383P). Results will be shared as a poster presentation on September 16, 2021. The abstract for this presentation is available on the ESMO website: https://cslide.ctimeetingtech.com/esmo2021/attendee/confcal_4/presentation/list?q=1383P&c=pnr

About Futibatinib (TAS-120)
Futibatinib (TAS-120) is an investigational, oral, potent, selective, and irreversible small-molecule inhibitor of *FGFR*1, 2, 3 and 4 being studied as a potential treatment for patients with advanced solid tumors with *FGFR*1-4 genetic aberrations, including cholangiocarcinoma, who were previously treated with chemotherapy or other therapies. Futibatinib was designed to selectively and irreversibly bind to the ATP binding pocket of FGFR1-4. It aims to inhibit FGFR-mediated signal transduction pathways, reduce tumor cell proliferation and increase tumor cell death in tumors with FGFR1-4 genetic aberrations.

Futibatinib has not been approved by the U.S. FDA or any other regulatory agency worldwide for the uses under investigation.

About Cholangiocarcinoma

Cholangiocarcinoma (CCA) is also known as bile duct cancer. It includes both intrahepatic (inside the liver) and extrahepatic (outside the liver) cancers. CCA can occur at younger ages, but it is seen mainly in older people.

About TAS-117
TAS-117 is a highly potent and selective oral allosteric AKT inhibitor that inhibits kinase activity of AKT1/2/3 and phosphorylation of downstream substrates. TAS-117 is currently being investigated globally in multiple clinical trials in patients with advanced solid tumors.

TAS-117 has not been approved by the U.S. FDA or any other regulatory agency worldwide for the uses under investigation.

About Taiho Oncology, Inc. (U.S.)
The mission of Taiho Oncology, Inc. is to improve the lives of patients with cancer, their families and their caregivers. The company specializes in the development of orally administered cancer agents and markets these medicines for a range of tumor types in the U.S. Taiho Oncology's growing pipeline of antimetabolic and selectively targeted anti-cancer agents are led by a world-class clinical development organization. Taiho Oncology is a subsidiary of Taiho Pharmaceutical Co., Ltd. which is part of Otsuka Holdings Co., Ltd. Taiho Oncology is headquartered in Princeton, New Jersey and oversees its parent company's European and Canadian operations, which are located in Zug, Switzerland and Oakville, Ontario, Canada. For more information, visit www.taihooncology.com

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