



Taiho Oncology To Present Phase 2 Data for Futibatinib (TAS-120) in Advanced Intrahepatic Cholangiocarcinoma at Virtual AACR Annual Meeting 2021

PRINCETON, N.J., April 2, 2021 – Taiho Oncology, Inc. today announced that Phase 2 clinical data, along with preclinical and Phase 1 clinical data for futibatinib (TAS-120) will be presented during the American Association for Cancer Research (AACR) Annual Meeting 2021 Week 1, taking place virtually from April 10-15, 2021. Futibatinib is a covalently-binding *FGFR* inhibitor being investigated for the potential treatment of patients with previously treated locally advanced or metastatic cholangiocarcinoma harboring *FGFR2* gene rearrangements including gene fusions. Key presentations include:

- **Primary results of phase 2 FOENIX-CCA2: the irreversible *FGFR1-4* inhibitor futibatinib in intrahepatic cholangiocarcinoma (iCCA) with *FGFR2* fusions/rearrangements:** Lipika Goyal, MD, MPhil, Massachusetts General Hospital Cancer Center (Presentation Number CT010). Results will be shared online as an oral plenary presentation from 2:00 – 3:45 PM ET on April 11, 2021.
- **Acquired resistance to ATP-competitive and irreversible *FGFR* inhibitors (*FGFRi*'s): A library-based approach:** Hiroshi Sootome, MS, Manager, Translational Research Planning & Management group, Taiho Pharmaceutical Co., Ltd. (1117). Results will be shared online as a poster presentation from 8:30 AM – 11:59 PM ET on April 10, 2021.
- **Effect of futibatinib on QT/QTc interval: a randomized, controlled, double-blind study:** Ikuo Yamamiya, PhD, Associate Director, Bioanalytics & DMPK, Taiho Oncology, Inc. (CT128). Results will be shared online as a poster presentation from 8:30 AM – 11:59 PM ET on April 10, 2021.
- **Evaluation of potential drug-drug interactions (DDIs) between futibatinib and CYP3A inhibitors/inducers, CYP3A substrates, or proton pump inhibitors (PPIs):** Ikuo Yamamiya, PhD, Associate Director, Bioanalytics & DMPK, Taiho Oncology, Inc. (CT125). Results will be shared online as a poster presentation from 8:30 AM – 11:59 PM ET on April 10, 2021.

Please visit Taiho Oncology's virtual Medical Booth when the exhibit opens on April 10, 2021.

“We are pleased to present these clinical and pre-clinical data for futibatinib in patients with advanced intrahepatic cholangiocarcinoma (iCCA) who have failed at least one line of therapy, including primary results from the Phase 2 FOENIX-CCA2 trial,” said Martin J. Birkhofer, MD, Senior Vice President and Chief Medical Officer, Taiho Oncology, Inc.

“These data add to the body of evidence for futibatinib and support this investigational compound as a potential treatment option for patients with iCCA whose disease has progressed following previous therapies.”

The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) for futibatinib for the treatment of patients with previously treated locally advanced or metastatic cholangiocarcinoma harboring *FGFR2* gene rearrangements, including gene fusions, in February 2021 based on efficacy and safety results from the FOENIX-CCA2 study. The FDA Office of Orphan Drug Development granted futibatinib orphan drug status for the treatment of cholangiocarcinoma in May 2018.

About Futibatinib (TAS-120)

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

About Cholangiocarcinoma

Cholangiocarcinoma (CCA), also known as bile duct cancer, is not common. About 8,000 people in the U.S. are diagnosed with CCA each year.¹ This 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. The average age of people in the U.S. diagnosed with cancer of the intrahepatic bile ducts is 70, and for cancer of the extrahepatic bile ducts it is 72.¹ The five-year survival rates of intrahepatic CCA (all SEER stages combined) is 9%.²

The main treatment for CCA is surgery. Radiation therapy and chemotherapy may be used if the cancer cannot be entirely removed with surgery and in cases where the edges of the tissues removed at the operation show cancer cells (also called a positive margin). Both stage III and stage IV cancers cannot be completely removed surgically. Currently, standard treatment options are limited to radiation, palliative therapy, liver transplantation, surgery, chemotherapy and interventional radiology.³

About Taiho Oncology, Inc. (U.S.)

Taiho Oncology, Inc., a subsidiary of Taiho Pharmaceutical Co., Ltd. and Otsuka Holdings Co., Ltd., has established a world class clinical development organization that works urgently to develop innovative cancer treatments and has built a commercial business in the U.S. Taiho Oncology has an oral oncology pipeline consisting of 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:

<https://www.taihooncology.com/us>

For more information about Taiho Pharmaceutical Co., Ltd., please visit:

<https://www.taiho.co.jp/en/>

For more information about Otsuka Holdings Co., Ltd., please visit:

<https://www.otsuka.com/en/>

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FUTI-PM-US-0001 04/21

¹ American Cancer Society. Key statistics for bile duct cancer. <https://www.cancer.org/cancer/bile-duct-cancer/about/key-statistics.html#references>. Accessed March 2021.

² American Cancer Society. Survival rates for bile duct cancer.. <https://www.cancer.org/cancer/bile-duct-cancer/detection-diagnosis-staging/survival-by-stage.html>. Accessed March 2021.

³ The Cholangiocarcinoma Foundation. Treatment options. <https://cholangiocarcinoma.org/the-disease/treatment-options>. Accessed March 2021.