Taiho Oncology To Present Futibatinib (TAS-120) Data In Advanced Intrahepatic Cholangiocarcinoma at ESMO Virtual Congress 2020

PRINCETON, N.J., September 15, 2020 – Taiho Oncology, Inc. today announced data from three abstracts for futibatinib (TAS-120) in intrahepatic cholangiocarcinoma (iCCA) and in advanced solid tumors will be presented during the European Society for Medical Oncology (ESMO) Virtual Congress 2020 from September 19-21, 2020. Key presentations include:

- Efficacy and Safety of Futibatinib in Intrahepatic Cholangiocarcinoma (iCCA) Harboring *FGFR2* Fusions/Other Rearrangements: Subgroup Analyses of a Phase 2 Study (FOENIX-CCA2) (Abstract 4493). Results will be shared online as a poster presentation on September 17, 2020. The abstract for this presentation is available on the ESMO website: https://cslide.ctimeetingtech.com/esmo2020/attendee/confcal_2/presentation/list?q=futibatinib
- Quality of Life (QOL) Outcomes With Futibatinib Treatment in FOENIX-CCA2, a Phase 2 Study in Patients (Pts) With Intrahepatic Cholangiocarcinoma (iCCA) Harboring *FGFR*2 Gene Fusions/Rearrangements (Abstract 4513). Results will be shared online as a poster presentation on September 17, 2020. The abstract for this presentation is available on the ESMO website: https://cslide.ctimeetingtech.com/esmo2020/attendee/confcal_2/presentation/list?q=futibatinib
- Phase 1 Study of the Irreversible *FGFR* inhibitor (i) Futibatinib (FBN; TAS-120) in Japanese Patients (pts) With Advanced (adv) Solid Tumors (Abstract 2243). Results will be shared online as a poster presentation on September 17, 2020. The abstract for this presentation is available on the ESMO website: https://cslide.ctimeetingtech.com/esmo2020/attendee/confcal_2/presentation/list?q=futibatinib

Additional information can be found here: https://virtualcongress2020.esmo.org/IndustryLandingPage/esmo/esmo2020/en-GB/profile/f1b7f52e-c2d0-47ef-88fd-282d5ffdde37

“We are pleased to present these new analyses of futibatinib in intrahepatic cholangiocarcinoma, as well as the results of our Phase 1 experience in Japanese patients. said Martin J. Birkhofer, MD, Senior Vice President and Chief Medical Officer, Taiho Oncology, Inc. “We look forward to further exploration of safety, efficacy and quality of life outcomes of this investigational compound to determine who may see the most benefit from it.”

In May 2018, the U.S. Food and Drug Administration Office of Orphan Drug Development granted futibatinib orphan drug status for the treatment of cholangiocarcinoma.

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.[2] The five-year survival rates of localized iCCA is 24%.[1]

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.[2]

About Futibatinib (TAS-120)
Futibatinib (TAS-120) is an investigational, oral, 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 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 *FGFR*1-4 genetic aberrations.

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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[1] American Cancer Society. What are the key statistics about bile duct cancer? https://www.cancer.org/cancer/bile-duct-cancer/about/key-statistics.html#references. Accessed August 2020.
[2] The Cholangiocarcinoma Foundation. Treatment Options. https://cholangiocarcinoma.org/the-disease/treatment-options. Accessed August 2020.