TAIHO ONCOLOGY

Taiho Oncology Announces Updated Efficacy and Safety Data for Futibatinib in Cholangiocarcinoma at 2022 ASCO Annual Meeting

These data are part of a New Drug Application that has been granted priority review by the U.S. Food and Drug Administration

PRINCETON, N.J., June 3, 2022 – Taiho Oncology, Inc. announced today updated results of the Phase 2 FOENIX-CCA2 trial of futibatinib, confirming results observed in an earlier analysis. The trial was conducted in patients with locally advanced or metastatic unresectable intrahepatic (inside the liver) cholangiocarcinoma (iCCA) harboring *FGFR*2 gene rearrangements including fusions. These data were presented as an oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

“Updated data from the pivotal FOENIX-CCA2 Phase 2 trial reinforce the durable efficacy and continued tolerability of futibatinib in previously treated patients with locally advanced or metastatic iCCA harboring *FGFR*2 gene rearrangements including fusions,” said medical oncologist Lipika Goyal, MD, MPhil, of the Massachusetts General Hospital Cancer Center in Boston, and lead investigator on the study. “These data add to the body of evidence supporting futibatinib as a potential treatment option for patients living with this rare cancer that traditionally has had limited treatment options.”

Each year, approximately 8,000 individuals in the U.S. are diagnosed with cholangiocarcinoma (CCA),[1] a cancer of the bile ducts of the liver. Worldwide, approximately 0.3-6 people per 100,000 individuals live with CCA.[2] CCA is mainly seen in people 65 years of age or older,[3] and treatment options are limited. *FGFR2* gene rearrangements, including gene fusions, which can form a hybrid gene and promote tumor proliferation, are observed more frequently in the iCCA patient population, with approximately 10-16% of patients having tumors with these rearrangements.[4,5,6,7,8]

The Phase 2 FOENIX-CCA2 trial included 103 patients with locally advanced or metastatic unresectable iCCA harboring *FGFR*2 gene rearrangements including fusions who had received one or more prior lines of systemic therapy. Patients received futibatinib 20 mg once daily until disease progression or unacceptable toxicity. The primary endpoint of the trial was objective response rate (ORR) as assessed by independent central review.

At the time of the data cutoff for this updated analysis, with a median follow-up of 25.0 months, the ORR was 41.7%. Responses were durable, with a median duration of response (DoR) of 9.5 months (74% of responses lasted greater than six months). In addition, the disease control rate was 82.5%, median progression-free survival was 8.9 months and median overall survival was 20.0 months.

The most common treatment-related adverse events (TRAEs) were hyperphosphatemia (85%), alopecia (33%), dry mouth (30%), diarrhea (28%), dry skin (27%) and fatigue

(25%). Most TRAEs were of mild or moderate intensity and manageable. There were two patients with grade 4 TRAEs and four patients discontinued treatment due to TRAEs. No treatment-related deaths occurred.

“Taiho Oncology remains committed to addressing unmet treatment needs in patients living with a broad range of cancers, and these data from the FOENIX-CCA2 trial demonstrate the clinical activity of futibatinib,” said Volker Wacheck, Vice President, Clinical Development, Taiho Oncology, Inc. “We are looking forward to continued discussions with regulatory authorities around this important investigational therapy.”

In March 2022, the U.S. Food and Drug Administration (FDA) accepted for priority review the New Drug Application (NDA) for futibatinib in the treatment of patients with previously treated locally advanced or metastatic CCA harboring *FGFR*2 gene rearrangements, including gene fusions. The FDA provided an anticipated Prescription Drug User Fee Act (PDUFA) action date of September 30, 2022. The FDA previously granted Breakthrough Therapy Designation (BTD) for futibatinib in CCA in February 2021.

About Futibatinib
Futibatinib (TAS-120) is an investigational, oral, potent, selective and irreversible tyrosine kinase inhibitor of *FGFR*1, 2, 3 and 4. This irreversible binding to the ATP binding pocket of *FGFR*1-4 results in the inhibition of *FGFR*-mediated signal transduction pathways, reduced tumor cell proliferation and increased cell death in tumors with *FGFR*1-4 genetic aberrations. Futibatinib is being studied alone as a potential treatment for patients with advanced solid tumors with *FGFR*1-4 genomic aberrations, including cholangiocarcinoma, or in combination with chemotherapy or other therapies.

About Taiho Oncology, Inc.
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 anti-cancer agents and markets these medicines for a range of tumor types in the U.S. Taiho Oncology’s growing pipeline of selectively targeted anti-cancer agents is 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 http://www.taihooncology.com

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FUTI-PM-US-0051 06/22

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