News Release

July 5, 2023
Taiho Pharmaceutical Co., Ltd.
Taiho Oncology Europe GmbH

European Commission Grants Conditional Marketing Authorization for Taiho's LYTGOBI® Tablets for the Treatment of Adults With Cholangiocarcinoma

Taiho Pharmaceutical Co., Ltd. and its European subsidiary Taiho Oncology Europe GmbH announced today that the European Commission has granted conditional marketing authorization for LYTGOBI® (futibatinib) monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma (CCA) with a fibroblast growth factor receptor (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.
CCA is an aggressive cancer of the bile ducts of the liver. While rare – in Europe, approximately 6,000-8,000 people are diagnosed with CCA[1]– this disease is associated with poor outcomes and is growing in prevalence worldwide[2], underscoring the need for new treatment options.

"Today※1 is an important day for current and future patients with CCA as well as the healthcare providers who treat them," said Peter Foertig, MD, Vice President, Medical Affairs, Taiho Oncology Europe. "LYTGOBI is an oral molecularly targeted medication that may provide clinically meaningful outcomes for patients undergoing treatment for CCA."

※1 Date of conditional marketing authorization: July 4, 2023

Added John Bridgewater, MD, PhD, Investigator and Senior Author of the recently

published FOENIX-CCA2※2 pivotal trial in the *New England Journal of Medicine*: "*FGFR2* fusions/rearrangements are one of the most frequent actionable alterations in CCA. As an irreversibly binding FGFR inhibitor, LYTGOBI targets FGFR in a unique way and offers new hope in a disease that, for me, has been among the most challenging to treat in my career." Professor Bridgewater is a Clinical Researcher and Medical Oncologist at University College London Cancer Institute and University College London Hospitals NHS Foundation Trust.

The European Commission's conditional marketing authorization for LYTGOBI is based on the data from the aforementioned FOENIX-CCA2 trial※2, a global open label trial evaluating 103 patients with unresectable, locally advanced or metastatic intrahepatic (inside the bile ducts of the liver) CCA harboring *FGFR2* gene rearrangements, including fusions.
In this trial, patients received LYTGOBI orally once daily at a dose of 20mg until disease progression or unacceptable toxicity. Within Europe, patients enrolled from France, Germany, Italy, the Netherlands, Spain and the United Kingdom.

※2 FOENIX-CCA2 : PHASE 1/2 STUDY OF TAS-120 IN PATIENTS WITH ADVANCED SOLID TUMORS Harboring FGF/FGFR Aberrations; ***F***GFR ***O***ral S***E***lective ***N***ovel ***I***nhibitor ***X*** [across] tumors

"I believe that LYTGOBI may be part of a new era in the treatment of CCA, one in which the power of personalised medicine may touch the lives of patients in ways we haven't seen before with traditional chemotherapy," said Helen Morement, CEO of the AAMF – The Cholangiocarcinoma Charity and the UK's only charity dedicated to this cause.

"We thank the many patients and healthcare professionals who participated in the FOENIX-CCA2 trial," said Atsushi Azuma, Managing Director of Taiho Pharmaceutical and Chairman of Taiho Oncology Europe. "Patients with CCA are often diagnosed at an advanced stage when surgery is not an option. We are pleased that LYTGOBI now will be a new treatment option for patients with CCA."

A conditional marketing authorization in Europe is granted for medicines that fulfill an unmet medical need to treat serious diseases, and the benefits of having them available earlier outweighs any risks associated with using the medicines while waiting for further evidence. Under the specific obligation to complete post-authorization measures for the conditional marketing authorization, Taiho has

until October 2027 to provide additional clinical data on LYTGOBI.

About LYTGOBI®

LYTGOBI (futibatinib,TAS-120) is an oral, potent, selective, and irreversible tyrosine kinase inhibitor of FGFR1, 2, 3 and 4. LYTGOBI covalently binds to the ATP binding pocket of FGFR1-4 resulting in the inhibition of FGFR-mediated signal transduction pathways, reduced tumor cell proliferation in tumors with FGFR1-4 genetic aberrations.

In Japan, LYTGOBI has been approved by the Japanese Ministry of Health, Labour and Welfare, as a treatment for unresectable biliary tract cancer harboring *FGFR2* gene fusions that has progressed after chemotherapy, in June 2023. In September 2022, the U.S. Food and Drug Administration (FDA) approved LYTGOBI for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

About Taiho Oncology Europe GmbH

The mission of Taiho Oncology Europe is to improve the lives of patients with cancer, their families, and their caregivers. The company specializes in orally administered anti-cancer agents and has a growing pipeline of selectively targeted anti-cancer agents. Taiho Oncology Europe GmbH (Zug, Switzerland) is the European subsidiary of Taiho Pharmaceutical Co., Ltd. (Tokyo, Japan).
For more information, visit www.taihooncology.eu

1: Kirstein MM, Vogel A. Epidemiology and Risk Factors of Cholangiocarcinoma. Visc Med. 2016 Dec;32(6):395-400. Erratum in: *Visc Med*. 2017 Jun;33(3):226.

2: Banales, J M, Marin, J JG, Lamarca, A, et al. Cholangiocarcinoma 2020: the next horizon in mechanisms and management. *Nature Reviews Gastroenterology & Hepatology*. 17: 557–588 (2020).