Taiho Oncology Europe Announces Availability of Lytgobi® (futibatinib) in France for the Treatment of Cholangiocarcinoma

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Availability of Lytgobi (futibatinib) marks the first medicine launched by Taiho Oncology Europe

BAAR, Switzerland, 1 August 2024 – Taiho Oncology Europe GmbH announced today the introduction of Lytgobi® (futibatinib), a novel irreversibly binding fibroblast growth factor receptor (FGFR) inhibitor,[1] in France. This milestone follows the conditional marketing authorisation in the European Union for futibatinib monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma (CCA) with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.[2] The Haute Autorité de Santé (HAS) has approved funding for Lytgobi more specifically for patients presenting with intrahepatic CCA and non-eligible to receive FOLFOX chemotherapy.[3]

CCA is an aggressive cancer of the bile ducts that carry bile inside the liver and from the liver and gallbladder to the small intestine. In France, it is estimated between 1,328 and 1,825 people are diagnosed with CCA each year,[3] and the disease is growing in incidence worldwide.[4] CCA is usually diagnosed at an advanced stage, with a very poor prognosis. Relative survival rates at 1, 3 and 5 years after diagnosis are estimated at 25%, 10% and 7%, respectively and new treatment options such as futibatinib are urgently needed.[5,6]

“The availability of futibatinib provides healthcare professionals in France with a new treatment option for patients with CCA” said Dr Antoine Hollebecque, Medical Oncologist at Gustave Roussy, Villejuif, and an investigator in futibatinib clinical development. “This medication targets one of the most frequent underlying genomic alterations observed in CCA, and I believe represents a meaningful advancement in what is a difficult-to-treat disease.”

Futibatinib is a molecularly targeted drug which binds irreversibly to FGFR and targets FGFR fusions or rearrangements.[1,2] The medicine is taken orally, once daily, on a continuous basis.[2]

The conditional marketing authorisation* in the European Union is based on data from the pivotal Phase 2 FOENIX-CCA2† global open-label trial evaluating 103 patients with unresectable, locally advanced or metastatic CCA with a FGFR2 fusion or rearrangement. The trial showed that futibatinib provided a clinically meaningful benefit, including an objective response rate of 42%, and a median duration of response of 9.7 months.[7] The mature follow-up data demonstrated median overall survival was 20.0 months[7] and the 12-month overall survival rate was 73.1%.[8]

The most common treatment-related adverse events with futibatinib are hyperphosphatemia (89.7%), nail disorders (44.1%), constipation (37.2%), alopecia (35.2%), diarrhoea (33.8%), dry mouth (31.0%), fatigue (31.0%), nausea (28.3%), dry skin (27.6%), increased aspartate transaminase (26.9%), abdominal pain (24.8%), stomatitis (24.8%), vomiting (23.4%), palmar-plantar erythrodysaesthesia syndrome (22.8%), arthralgia (21.4%), and decreased appetite (20.0%).[2]

The results of the FOENIX-CCA2 trial were published in *The New England Journal of Medicine.*[7] Within Europe, patients were enrolled in this trial from France, Germany, Italy, the Netherlands, Spain and the United Kingdom.

“This milestone is the culmination of extensive and productive collaboration among researchers, healthcare professionals, and patients, all united in their commitment to advance care in cholangiocarcinoma and to improve the lives of patients," said Dr. Peter Foertig, General Manager of Taiho Oncology Europe. "The introduction of futibatinib marks a significant achievement as it is the first product Taiho Oncology has introduced in Europe on our own. This signifies a crucial first step in establishing a strong presence and reinforcing our ongoing commitment to bring innovative oral therapies to patients with cancer."

Futibatinib was developed by Taiho Oncology Europe’s parent company, Taiho Pharmaceutical Co., Ltd., Tokyo. The larger Taiho family of companies continues to investigate its benefits for solid tumours in combination with pembrolizumab.

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*A conditional marketing authorisation is granted for medicines that fulfil an unmet medical need to treat serious diseases, and the benefits of having them available earlier outweigh any risks associated with using the medicines while waiting for further evidence.[9]

† The FOENIX-CCA2 trial is a Phase 1 / 2 Study of TAS-120 in Patients with Advanced Solid Tumors Harboring FGF/FGFR Aberrations: FGFR Oral SElective Novel Inhibitor X [across] tumors.

About Lytgobi (futibatinib)

Futibatinib is an oral, potent, selective, and irreversible tyrosine kinase inhibitor of FGFR1, 2, 3 and 4. Futibatinib irreversibly binds to the adenosine triphosphate-binding pocket of FGFR1–4 resulting in the inhibition of FGFR-mediated signal transduction pathways, reduced tumour-cell proliferation and increased tumour-cell death in tumours with FGFR1–4 genetic aberrations.[1,2]

About Taiho Oncology Europe
The mission of Taiho Oncology Europe is to improve the lives of patients with cancer, their families, and their caregivers. The company specialises in orally administered anti-

cancer agents and has a growing pipeline of selectively targeted anti-cancer agents. Taiho Oncology Europe GmbH (Baar, Switzerland) is the European subsidiary of Taiho Pharmaceutical Co., Ltd. (Tokyo, Japan). For more information, visit www.taihooncology.eu

Lytgobi is a registered trademark of Taiho Pharmaceutical Co., Ltd.

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References:

1. Sootome H, Fujita H, Ito K, et al. Futibatinib is a novel irreversible FGFR 1–4 inhibitor that shows selective anti-tumor activity against FGFR-deregulated tumors. *Cancer Res.* 2020;80:4986-4997. Available at: https://aacrjournals.org/cancerres/article/80/22/4986/645861/Futibatinib-Is-a-Novel-Irreversible-FGFR-1-4 Last accessed: July 2024
2. Taiho Oncology Europe GmbH. Lytgobi® (futibatinib): Summary of Product Characteristics. Available at https://www.ema.europa.eu/fr/documents/product-information/lytgobi-epar-product-information_fr.pdf Last accessed: July 2024
3. Haute Autorité de Santé. LYTGOBI (futibatinib) - Cholangiocarcinome. Saint-Denis La Plaine: HAS; 2024. Available at: https://www.has-sante.fr/upload/docs/evamed/CT-20313_LYTGOBI_PIC_INS_AvisDef_CT20313.pdf Last accessed: July 2024
4. Banales JM, Marin JJG, Lamarca A, et al. Cholangiocarcinoma 2020: the next horizon in mechanisms and management. *Nat Rev Gastroenterol Hepatol.* 2020;17:557-588. Available at: https://www.nature.com/articles/s41575-020-0310-z#:~:text=CCA%20is%20a%20rare%20cancer,in%20the%20past%20few%20decades Last accessed: July 2024
5. Chapter 8. Biliary tract cancer. The National Digestive Cancer Thesaurus (TNCD). Available at: www.snfge.org/files/tncd/2024-01/tncd_chap-08-cancer-voies-biliaires_2023-09-28_0.pdf Last accessed: July 2024
6. Valle JW, Bai LY, Orlova R, et al. Ramucirumab (RAM) or merestinib (MER) or placebo (PL) plus gemcitabine (GEM) and cisplatin (CIS) as first-line treatment for advanced or metastatic biliary tract cancer (BTC): a randomized, double-blind, phase II study. *J Clinical Oncol*. 2020;38(4):Abstract 477. Available at: https://ascopubs.org/doi/10.1200/JCO.2020.38.4_suppl.477 Last accessed: July 2024
7. Goyal L, Meric-Bernstam F, Hollebecque A, et al. Futibatinib for FGFR2-rearranged intrahepatic cholangiocarcinoma. *N Engl J Med*. 2023 Jan 19;388(3):228-239. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2206834 Last accessed: July 2024
8. Goyal L, Meric-Bernstam F, Hollebecque A, et al. Updated results of the FOENIX-CCA2 trial: efficacy and safety of futibatinib in intrahepatic cholangiocarcinoma (iCCA) harboring FGFR2 fusions/rearrangements. *Journal of Clinical Oncology.* June 2022;40(16):Abstract 4009. Available at: https://ascopubs.org/doi/10.1200/JCO.2022.40.16_suppl.4009#:~:text=Conclusions%3A%20Findings%20from%20the%20final,iCCA%20harboring%20FGFR2%20fusion%2Frearrangements. Last accessed: July 2024
9. Conditional marketing authorisation. European Medicines Agency. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/conditional-

marketing-authorisation#:~:text=Conditional%20marketing%20authorisation%20is%20a,is%20still%20generated%20post%2Dapproval. Last accessed: July 2024