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Advice document
SMC2661

futibatinib film-coated tablets (Lytgobi®)

Taiho Oncology

07 March 2025

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

futibatinib (Lytgobi®) is accepted for use within NHSScotland.

Indication under review: as monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Futibatinib offers an additional treatment choice in the therapeutic class of fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitors.

Another FGFR tyrosine kinase inhibitor was accepted for use under the end of life and orphan process.

This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Futibatinib is a small molecule protein kinase inhibitor that irreversibly inhibits FGFR 1,2,3 and 4.[1] It is licensed as monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy. It is administered orally at a starting dose of 20mg once daily, continued until disease progression or unacceptable toxicity. Dose modification or interruption should be considered to manage toxicities; refer to the Summary of Product Characteristics. Futibatinib has a conditional marketing authorisation from the MHRA.[1]

1.2. Relevant comparator(s)

Pemigatinib is another FGFR tyrosine kinase inhibitor that is licensed as monotherapy for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

There is no direct evidence comparing futibatinib with a relevant comparator. The evidence to support the conditional marketing authorisation was from a phase II open-label study (FOENIX-CCA2).[2]

The submitting company carried out a matched adjusted indirect comparison to compare the results for progression-free survival (PFS) and overall survival between futibatinib (using data from FOENIX-CCA2[2]) and pemigatinib (using data from the FIGHT-202[3] study). The results for the comparisons for both outcomes were similar, with credible intervals that included one. The company concluded that futibatinib and pemigatinib had similar efficacy with respect to both PFS and overall survival.

3. Company Estimate of Eligible Population, Uptake and Budget Impact

3.1. Company's number of patients assumed to be eligible for treatment

The company estimated that there would be 3 patients eligible for treatment with futibatinib each year, with uptake estimated to be 1 patient in years 1 and 2, and 3 patients in years 3 to 5.

3.2. Budget Impact assumption

Medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.

References

1. Taiho Pharma Europe Limited, Summary of product characteristics, futibatinib 4mg film-coated tablets (Lytgobi®)
2. Goyal L, Meric-Bernstam F, Hollebecque A, Valle JW, Morizane C, Karasic TB et al. Futibatinib for FGFR2-Rearranged Intrahepatic Cholangiocarcinoma. N Engl J Med 2023; 388:228-239.
3. Ghassan K, Abou-Alfa GK, Sahai V, Hollebecque A, Vaccaro GM, Melisi Det al. Pemigatinib for previously treated locally advanced/metastatic cholangiocarcinoma (CCA): Update of FIGHT-202. Journal of Clinical Oncology 2021; 39: 4086.

This assessment is based on data submitted by the applicant company up to and including 17 February 2025**.**

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice is based on the estimation of at least similar comparative efficacy and limited net budget impact compared with other medicinal products, within the same therapeutic class, that are in routine use within NHSScotland.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their

clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.