swissmedic

Summary report on authorisation dated 20 December 2024

Lytgobi® (active substance: futibatinib)

Temporary authorisation in Switzerland: 8 October 2024

Film-coated tablets for the treatment of adults with locally advanced or metastatic bile duct cancer (cholangiocarcinoma) combined with a rearrangement of FGFR2 when the disease has spread after at least 1 previous treatment

About the medicinal product

The medicinal product Lytgobi contains the active substance futibatinib.

Lytgobi is used for the treatment of adults with locally advanced or metastatic cholangiocarcinoma.

This is an aggressive type of cancer that occurs in the bile ducts.

Lytgobi is intended specifically for patients whose tumours have an abnormal form of fibroblast growth factor receptor 2 (FGFR2) on their surface and whose disease has progressed after at least 1 previous cancer treatment.

Futibatinib blocks FGFR and therefore prevents the growth of these cancer cells.

Since locally advanced or metastatic cholangiocarcinoma is a rare, life-threatening disease, the medicinal product Lytgobi has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Lytgobi has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in at least 1 other country with comparable medicinal product control.
In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Lytgobi in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA) and has only conducted a limited scientific review.
Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report issued by the

reference authority: EMA Procedure Number EMEA/H/C/005627/0000 (www.ema.europa.eu).

The medicinal product Lytgobi has been authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an authorisation without special conditions in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

At the time of publication of the Summary report on authorisation for Lytgobi, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals and the Patient information will be made available on the following website: www.swissmedicinfo.ch

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.