swissmedic

Public Summary SwissPAR dated 04 November 2021

Gavreto® (active substance: pralsetinib)

Temporary authorisation in Switzerland: 12 August 2021

Medicinal product for second-line treatment of certain types of cancer caused by an abnormal RET gene

Information on authorisation

Gavreto, with the active substance pralsetinib, is used for treatment in the following patients whose cancer has spread after previous treatment:

1. Adults with non-small cell lung cancer (NSCLC) that has spread and that was caused by an abnormal change in the genetic material of the tumour (known as a RET gene fusion).
2. Adults with advanced medullary thyroid cancer (MTC) or MTC that has spread and was caused by an abnormal change in the genetic material of the tumour (known as a RET gene mutation).
3. Adults with advanced thyroid cancer or thyroid cancer that has spread and was caused by an abnormal change in the genetic material of the tumour (known as a RET gene fusion) and in whom treatment with radioactive iodine is not effective or no longer effective.

Gavreto may only be used if a mutation of the RET gene has been identified using a test suitable for the specific mutation.

Since these cancers are rare, life-threatening diseases, Gavreto has been authorised as an orphan drug. "Orphan drug" is a designation given to important medicinal products for rare diseases.

Gavreto was authorised under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control. In this case, Swissmedic takes into consideration the results of checks carried out by the foreign regulatory agency, 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 Gavreto in Switzerland, Swissmedic accepted parts of the assessment and approval decision of the U.S. Food and Drug Administration (FDA).

During the review, Swissmedic focused on the second-line treatment indications submitted, which differ from the indications approved by the FDA.

The medicinal product Gavreto was authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials 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 ordinary authorisation.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professions Gavreto®

Information for patients (package leaflet): Information for patients Gavreto®

Healthcare professionals (doctors, pharmacists and others) 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 Public Summary SwissPAR.

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.