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Zepzelca® (active substance: lurbinectedin)

Temporary authorisation in Switzerland: 7 March 2023

Powder for concentrate for solution for infusion for second-line treatment of adults with metastatic small-cell lung cancer (SCLC)

About the medicinal product

Zepzelca, containing the active substance lurbinectedin, is used in adult patients with small-cell lung cancer (SCLC) that has spread (metastatic). Zepzelca is given as a second-line treatment[1]. In SCLC patients, the disease must have progressed following platinum-containing chemotherapy and a chemotherapy-free interval of at least 30 days, and there must be no metastases in the central nervous system

Patients with small-cell lung cancer have a poor prognosis. The cancer cells grow quickly and have a high rate of metastasis. There are frequently relapses or progression of the disease after platinum-containing chemotherapy that is largely initially successful.

Mode of action

The active substance lurbinectedin is a cytotoxin (cell poison) and an alkylating agent. Alkylating agents bind to specific structures of the DNA. In doing so, they impair certain cell processes such as growth and replication, ultimately resulting in cell death of the cancer cells.

Indication

Zepzelca, containing the active substance lurbinectedin, is a prescription-only medicine.

Zepzelca is available in a vial containing 4 mg lurbinectedin. The powder is dissolved before use. The solution contains 0.5 mg/mL lurbinectedin. This solution is injected into the veins. The recommended dose is 3.2 mg/m2 body surface area and is administered over a period of 1 hour every 21 days.

[1] Second-line treatment: This is used when first-line therapy is unsuccessful.

Efficacy

The efficacy of Zepzelca was investigated in a study without a control arm[2] with 105 SCLC patients. There were more men (60%) in the study population. The mean age was 60 years. The study included SCLC patients who had previously undergone platinum-containing chemotherapy. Patients with metastases in the central nervous system were excluded from the study. An independent committee evaluated the study results. The objective response rate[3] (ORR) of the population in the approved indication was 33.7%, and the median[4] overall survival (OS) at the time of the data analysis was 10.2 months.

Precautions, undesirable effects & risks

Zepzelca must not be used in those with moderate or severe liver failure or in those who are hypersensitive to the active substance or any of the excipients.

The most frequent undesirable effects are neutropenia, lymphopenia and leukopenia (lack of different types of white blood cells), anaemia (lack of red blood cells), loss of appetite, nausea, vomiting, constipation and diarrhoea, and fatigue.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Patients with SCLC have a poor chance of survival. Although those affected initially respond well to platinum-based chemotherapy, many SCLC patients suffer a relapse or progression of the disease. No progress has been made in second-line treatment for these patient groups in decades. The current standard second-line treatment is toxic. There is therefore a great medical need for other treatment options. Zepzelca has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Compared with the published data for the current second-line treatment option, the results of the study submitted are considered to be clinically promising. The significance of the results is limited by the single-arm study and requires further confirmatory data from a controlled study.

Taking all the risks and precautions into account, and based on the available data, the benefits of Zepzelca outweigh the risks. Swissmedic has authorised the medicinal product Zepzelca 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 ordinary authorisation if the benefit-risk assessment of the results remains positive.

[2] Controlled study: The results of the study group are compared with data from a control group, who have received either a placebo (dummy drug) or standard medication.

[3] ORR (objective response rate) is defined as the percentage of patients who respond to the treatment.

[4] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Zepzelca®

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 Public Summary SwissPAR.

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