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Tecvayli® (active substance: teclistamab)

Temporary authorisation in Switzerland: 22 December 2022

Medicinal product (solution for injection) for the fourth-line treatment of adults with relapsed and refractory multiple myeloma

About the medicine

The medicinal product Tecvayli, containing the active substance teclistamab, is used for the treatment of multiple myeloma ("bone marrow cancer") in adults who have completed at least three previous treatment phases, including treatment with drugs in the three standard therapeutic classes, and who have demonstrated disease progression after the last treatment phase.

Multiple myeloma (MM) is a rare form of cancer that accounts for around 1-2% of all cancers. The frequency of new cases of MM increases with age. Two thirds of new sufferers are aged over 65. The disease is characterised by excessive replication of plasma cells, which are a type of white blood cell responsible for producing antibodies in the body's defence system (immune system). In MM, the plasma cells multiply in an uncontrolled way in the bone marrow and occasionally in other organs as well. This prevents the normal formation of blood cells and can destroy, or disrupt the function of, bones and other organs.

Tecvayli was authorised temporarily in connection with "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. Currently, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic) and the United Kingdom (MHRA) are represented in Project Orbis.

Mode of action

Teclistamab is an antibody (an immunologically active protein) that binds both to the myeloma cell, via the so-called B cell maturation antigen (BCMA), and the CD3 receptor (binding site) on the T cells (cells of the immune system). As a result, teclistamab links the myeloma cells with the T cells, in turn activating the T cells, which are then able to kill the multiple myeloma cells.

Use

Tecvayli, containing the active substance teclistamab, is a prescription-only medicine.

Tecvayli is available as a solution for injection in a vial containing either the 30 mg dose dissolved in 3 ml or the 153 mg dose dissolved in 1.7 ml. Tecvayli is injected under the skin, and the dosage is increased gradually up to the treatment dose.

Tecvayli should be administered only under the supervision of a healthcare professional with experience in the intensive care treatment of the potential side effects. At the start of treatment with Tecvayli, and also at a later stage of the treatment if necessary, inpatient monitoring is needed for at least 48 hours after administration.

Efficacy

The efficacy of Tecvayli was investigated in an open-label study, without a control arm, with 163 MM patients after at least three previous treatment phases, including treatment with drugs in the three standard treatment classes.

Historically, patients with relapsed (recurrent) or refractory (treatment-resistant) MM who have already received treatment with the three standard classes of drugs have had a poor prognosis. The overall response rate (ORR)[1] used to be approx. 30%. The median[2] progression-free survival (PFS)[3] was approx. 3 to 6 months and overall survival (OS) approx. 6 to 12 months.

With Tecvayli, the study population achieved an ORR of almost 60%. Based on the data available at the time of authorisation, the median PFS of patients receiving Tecvayli is estimated to be approx. 10 months and survival approx. 16 months. However, the study has not yet been concluded.

Precautions, undesirable effects & risks

Tecvayli must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects include cytopenia[4], infections, cytokine release syndrome (CRS)[5] and adverse neurological reactions.

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

Why the medicinal product has been authorised

Since multiple myeloma is a rare, life-threatening disease, Tecvayli has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Patients with relapsed or refractory and heavily pretreated MM have a poor

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

[2] 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.

[3] PFS: progression-free survival. Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

[4] Cytopenia: reduction in the number of cells in the blood.

[5] Cytokine release syndrome is a systemic inflammatory response to the excess secretion of cytokines (proteins), which activate the white blood cells.

prognosis. Another therapeutic strategy for these individuals is known as anti-BCMA CAR-T cell therapy. However, since this treatment is not appropriate for all affected patients, there is a great need for new therapeutic options.

The data from the submitted study showed a high response rate for Tecvayli compared to the historical data. The significance of the results for survival is limited, since the duration of the study was not long enough at the time of the data analysis.

Taking the risks and precautions into account, and based on the available data, Swissmedic has temporarily authorised the medicinal product Tecvayli, with the active substance teclistamab, in Switzerland (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.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tecvayli®

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 in 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.