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Summary report on authorisation dated 21 March 2025

Abecma® (active substance: idecabtagene vicleucel)

Authorisation in Switzerland: 20 August 2021

Dispersion for infusion for the treatment of adults with relapsed and refractory multiple myeloma who have already received at least 3 treatments

About the medicinal product

Abecma contains the active ingredient idecabtagene vicleucel.

It is used for the treatment of advanced multiple myeloma ("bone marrow cancer") in adults whose multiple myeloma (MM) has not responded to 3 previous treatments (refractory), including an immunomodulatory active ingredient, a proteasome inhibitor, and an anti-CD38 antibody, and whose disease has progressed after the last treatment (relapsed).

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.

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

Mode of action

The active ingredient in Abecma, idecabtagene vicleucel, is an immunotherapy using genetically modified autologous[1] T cells (T lymphocytes, belonging to the white blood cells). This therapy uses the patients' own T cells that have been modified so that they can recognise and fight B cell maturation antigen (BCMA) on the surface of myeloma cells. When the modified T cells are reintroduced into the body, they bind to the cancer cells, activate, and multiply, thereby helping to destroy these cells.

Use

Abecma is a prescription-only medicine.

Abecma is administered intravenously (into a vein) as an infusion, which is supplied in one or more infusion bags, each containing 260 to 500 x 10^6 CAR-positive viable patient-specific T cells. The recommended treatment comprises a single infusion of Abecma, which is administered in a qualified treatment centre under the supervision and guidance of a doctor.

Efficacy

The efficacy of Abecma was investigated in study KarMMa, in which 128 patients with relapsed and refractory multiple myeloma were treated. The participants had previously received at least 3 lines of treatment, including a proteasome inhibitor, an immunomodulator, and an anti-CD38 antibody.

The patients received one dose of Abecma with 150 to 450 x 10^6 CAR-positive, viable T cells.

The primary endpoint of the study was the objective response rate (ORR[2]), which was 73.4%, with 32.8% of patients achieving complete remission. In this context, remission means the reduction of the illness or its symptoms.

The median[3] time to achieve the response was 1 month. In the patients who achieved a partial remission or more, the duration of response (DOR)[4] was 10.6 months. For patients who achieved a complete remission, the DOR was 23.3 months.

[1] Autologous: belonging to the same person, i.e. here the patient's own T cells

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

[3] 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 less than the median, the other half are always greater.

[4] DOR (duration of response) describes the period during which a patient responds to a treatment, i.e. the time during which tumour size is stably reduced or the tumour disappears altogether.

Precautions, undesirable effects, & risks

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

The most common undesirable effects were neutropenia (reduced count of certain groups of white blood cells) (91%), anaemia (deficiency of red blood cells) (71%), thrombocytopenia (reduced platelet count) (67%), infections (54%), fatigue (42%), diarrhoea (36%), hypokalaemia (low blood potassium level) (34%) and hypophosphataemia (low blood phosphate level) (33%).

There is also a risk of cytokine release syndrome (CRS)[5], which occurred in 81% of patients.

Serious neurological side effects such as confusion, tremor (movement disorder), aphasia (speech disorder) and encephalopathy (brain disease or damage) were also reported.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

At the time of authorisation of Abecma, there were limited treatment options for patients with relapsed and refractory multiple myeloma who had received at least 3 lines of treatment, including a proteasome inhibitor, an immunomodulator, and an anti-CD38 antibody.

Abecma enables further treatment for this patient group by offering targeted immunotherapy that eliminates malignant cells using genetically modified autologous T cells.

The study performed shows a rapid and significant response rate and continuing effectiveness, with the majority of patients showing no disease progression over longer periods.

While the medicinal product can have potentially severe side effects, these can generally be controlled with close monitoring and timely intervention. Overall, the positive effects of Abecma on the health and quality of life of patients outweigh the known risks. Based on these findings, Swissmedic has authorised the medicinal product Abecma, which contains the active substance idecabtagene vicleucel, in Switzerland for the treatment of relapsed and refractory multiple myeloma.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Abecma®

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

Healthcare professionals can answer any further questions.

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

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.

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