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# Talvey (*talquetamab*)

An overview of Talvey and why it is authorised in the EU

## What is Talvey and what is it used for?

Talvey is a cancer medicine used to treat adults with multiple myeloma (a cancer of the bone marrow) when the cancer has come back (relapsed) and has not responded to treatment (refractory).

It is used in patients who have received at least three previous therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and whose disease has worsened since the last treatment.

Multiple myeloma is rare, and Talvey was designated an 'orphan medicine' (a medicine used in rare diseases) on 20 August 2021. Further information on the orphan designation can be found on the EMA website.

Talvey contains the active substance talquetamab.

## How is Talvey used?

The medicine can only be obtained with a prescription and treatment should be started and monitored by a doctor experienced in the management of multiple myeloma. It should be given in a setting with appropriate medical support to manage possible severe side effects such as cytokine release syndrome (a potentially life-threatening condition that causes fever, vomiting, shortness of breath, headache and low blood pressure) and neurological toxicity (complications relating to the brain or nerves; see risks section below for further information).

Talvey is given as an injection under the skin, either once a week or every 2 weeks. Treatment should continue for as long as the patient benefits from it or until side effects become unmanageable. Several medicines are given before Talvey to reduce the risk of cytokine release syndrome. Doctors should monitor patients for serious side effects for 2 days after each of the first 3 or 4 doses. The doctor may delay doses if certain side effects occur or stop treatment altogether for certain severe side effects.

For more information about using Talvey, see the package leaflet or contact your doctor or pharmacist.

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## How does Talvey work?

The active substance in Talvey, talquetamab, is an antibody (a type of protein) that is designed to recognise and attach to two targets simultaneously: one called GPRC5D on myeloma cells and one called CD3 on the surface of T cells (a type of cell in the immune system). By attaching to these target proteins, Talvey brings the cancer cells and T cells together. This activates the T cells, which then kill the multiple myeloma cells.

## What benefits of Talvey have been shown in studies?

Talvey was investigated in one main study involving 288 patients with relapsed or refractory multiple myeloma that had returned and who had been given 3 or more previous treatments. Patients were given either Talvey 4 mg/kg bodyweight once a week or Talvey 8 mg/kg once every two weeks. Several markers were used to measure response to treatment, including urine and blood levels of an antibody called M protein. Talvey was not compared to another medicine in this study.

The study showed that 74.1% (106 out of 143) of patients given Talvey 4 mg/kg once a week had at least a partial response to treatment (meaning their blood level of M protein had decreased by at least 50%); in 51.5% of responders, the response lasted for at least 9 months. Among patients given Talvey 8 mg/kg once every two weeks, 71.7% (104 out of 145) had at least a partial response to treatment, which lasted for at least 9 months in 76% of responders.

## What are the risks associated with Talvey?

For the full list of side effects and restrictions with Talvey, see the package leaflet.

The most common side effects with Talvey (which may affect more than 6 in 10 people) include cytokine release syndrome (CRS), dysgeusia (taste disturbance) and hypogammaglobulinaemia (low levels of antibodies in the blood). More than 2 in 10 people may be affected by the following side effects: nail disorder, pain in muscles and bones, anaemia (low levels of red blood cells), skin disorder, tiredness, decreased weight, rash, dry mouth, neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), fever, xerosis (severely dry skin), thrombocytopenia (low levels of blood platelets), nose and throat infection, lymphopenia (low levels of lymphocytes, a type of white blood cell), dysphagia (difficulty swallowing), diarrhoea, pruritus (itching), cough, pain, decreased appetite and headache.

Serious side effects include CRS, fever, immune effector cell-associated neurotoxicity syndrome (ICANS, a neurological disorder with symptoms including problems with speech and writing, confusion and depressed level of consciousness), sepsis (blood poisoning), COVID-19, bacterial infection, pneumonia (lung infection), viral infection, neutropenia and pain.

## Why is Talvey authorised in the EU?

Patients with multiple myeloma whose cancer has returned and not responded to at least 3 previous treatments have limited treatment options. in these patients. Talvey was shown to produce high response rates in these patients and could represent an additional treatment option.

Although serious side effects, particularly cytokine release syndrome and ICANS, can occur, they were considered manageable with appropriate measures. The European Medicines Agency therefore decided that Talvey's benefits are greater than its risks and it can be authorised for use in the EU.

Talvey has been given 'conditional authorisation'. This means that the European Medicines Agency decided that the benefits of Talvey are greater than its risks, but the company will have to provide additional evidence after authorisation.

Conditional authorisation is granted on the basis of less comprehensive data than are normally required. It is granted for medicines that fulfil an unmet medical need to treat serious diseases and when the benefits of having them available earlier outweigh any risks associated with using the medicines while waiting for further evidence. Every year, the Agency will review any new information that becomes available until data become comprehensive, and this overview will be updated as necessary.

Since Talvey was given conditional authorisation, at the time of authorisation the company marketing Talvey was required to provide data from an additional study in order to confirm the effectiveness and safety of the medicine. The company was also required to provide further data to characterise the long-term safety of Talvey.

## What measures are being taken to ensure the safe and effective use of Talvey?

The company that markets Talvey will provide educational materials to healthcare professionals expected to prescribe or give the medicine, containing important information on the risk of neurological toxicity including ICANS; an alert card will be provided to patients receiving the medicine, containing important information on the risk of CRS and neurological toxicity, including ICANS, and recommendations to help minimise these risks.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Talvey have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Talvey are continuously monitored. Suspected side effects reported with Talvey are carefully evaluated and any necessary action taken to protect patients.

## Other information about Talvey

Talvey received a conditional marketing authorisation valid throughout the EU on 21 August 2023.

Further information on Talvey can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/talvey.

This overview was last updated in 08-2023.