Myeloma Patients Europe

FACTSHEET

MYELOMA PATIENTS EUROPE

TECLISTAMAB (TECVAYLI®)

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Edition: Myeloma Patients Europe (MPE)
Updated: March 2023

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FACTSHEET

MYELOMA PATIENTS EUROPE

Myeloma Patients Europe (MPE) has developed a series of factsheets for patients and patient advocates, providing an overview of available treatment options for myeloma and covering some topics related to the disease.

The factsheets cover important issues around the treatment, so that patients can feel safe and ask their doctor specific questions.

For each of the available therapies, the following topics will be addressed:

- What is myeloma?
- What is the particular treatment?
- How does the treatment work?
- What are the benefits?
- What are the side-effects?
- How and when is the treatment given?

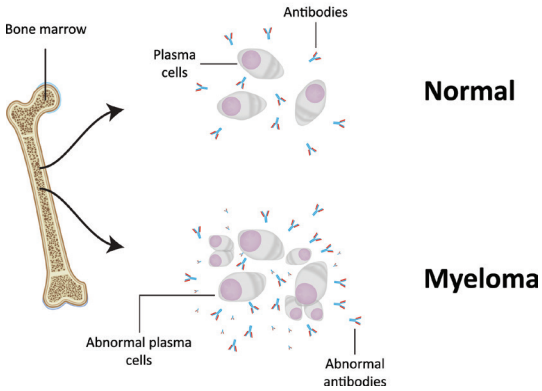
Myeloma treatment is constantly evolving and the factsheets will be updated regularly to reflect the latest developments.

What is myeloma?

Myeloma is a rare cancer of the bone marrow that causes the formation of abnormal plasma cells, known as cancerous myeloma cells, which divide uncontrollably. Usually, plasma cells help the body fight infections by making antibodies that recognise and attack viruses, bacteria, and other cancer cells. Myeloma affects multiple places in the body (this is why it is sometimes referred to as 'multiple myeloma') where bone marrow is normally active, such as the bones of the spine, pelvis, rib cage, and the areas around the shoulders and hips.

Myeloma causes pain, anaemia (low red blood cells), fatigue, fractures, recurring infections, bruising, and high blood calcium (hypercalcaemia). These symptoms usually require treatment. After treatment, most myeloma symptoms may subside and not require treatment (also known as remission). Many patients may also be on treatment during remission to ensure their myeloma is kept at bay (known as maintenance treatment). After some time, the patient's symptoms may reappear, requiring treatment (also known as relapse). Myeloma usually occurs with periods of remission and relapse, and after some time, the patient's disease no longer responds to treatment (known as refractory myeloma).

Treatment may involve combining more drugs, often three or four, which is considered more effective than a single drug. Myeloma generally cannot be cured, but survival rates are increasing due to the availability of new treatments, and many patients can enjoy a good quality of life. Several new therapies have recently been approved or are under consideration for use following relapse or refractory myeloma.



What is teclistamab (Tecvayli®)?

Teclistamab is a laboratory-made, bispecific monoclonal antibody (BsAb). It was approved by the European Medicines Agency (EMA) in August 2022 and is indicated for treating adult multiple myeloma patients whose disease has worsened despite receiving at least three prior lines of therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

The EMA granted teclistamab conditional marketing authorisation in 2022. Conditional marketing authorisations allow medications to be approved with less comprehensive data than is normally required because the medicines will address areas of unmet medical needs, and the expected benefits appear to outweigh the risks. Teclistamab is under additional monitoring by the EMA and, therefore, will be monitored closely[1].

How does teclistamab work?

Teclistamab is a bispecific monoclonal antibody that attaches to two protein targets on the surface of cells: B cell maturation antigen (BCMA) on myeloma cells and CD3 on T cells (immune cells). When teclistamab binds to these two targets, it brings immune cells and myeloma cells together to stimulate the killing of the cancerous myeloma cells.

What are the benefits of teclistamab?

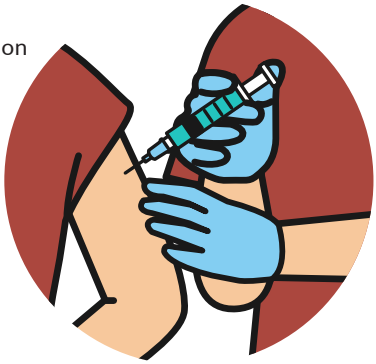
The safety and efficacy of teclistamab have been investigated in the MajesTEC-1 clinical trial of 165 myeloma patients from nine countries. Participants had received at least three prior lines of therapy, including exposure to an immunomodulatory drug, a proteasome inhibitor, and an anti-CD38 antibody. Patients received a weekly subcutaneous injection (an injection under the skin) of teclistamab after receiving two step-up doses. In this study, 63% (104/165) of the patients who participated responded to treatment with teclistamab, including 39.4% having a complete response or better, with a median duration of response of 18.4 months. The median progression-free survival (the time from treatment to the progression of disease or death) was 11.3 months[2,3].

How is teclistamab given?

Teclistamab is given by subcutaneous injection. It is initially given using a step-up dosing schedule to reduce the risk of severe side effects such as cytokine release syndrome (CRS) and/or ICANS. Step-up dosing means that over several days teclistamab will be given in gradually increasing doses. A sample schedule of step-up dosing is as follows[4,1]:

- "Step up dose #1" (the smallest dose) is given on day one of treatment
- "Step up dose #2" (a higher amount than dose #1) is given 2-7 days after first step-up dose
- The first "treatment dose" (the dose you will remain on) is given 2-7 days after second step-up dose

Step-up dosing schedules may vary depending on how you respond to teclistamab and whether you experience any side effects. Step-up dosing is usually done in the hospital and the following doses are given in the outpatient department. Your doctor will monitor you for side effects after each of your first three doses. They will do this for two days after each dose. You should stay close to a healthcare facility after the first three doses in case you have side effects such as CRS and neurologic symptoms that can be severe. Hospitalisation is not mandatory.



Also, premedication is recommended for all patients to reduce the risks of CRS. Premedication includes corticosteroids, antihistamines and antipyretics.

What are the side-effects of teclistamab?[1]

The safety of teclistamab was evaluated in the MajesTEC-1 trial of 165 patients[3]:

The most common laboratory abnormalities or blood changes reported in at least 15% of the patients included:

- Hypogammaglobulinemia (low serum immunoglobulin or antibody levels; 75% of patients)
- Neutropenia (low levels of a type of white blood cell called neutrophils; 71%)

- Anaemia (low levels of red blood cells or haemoglobin; 52%)
- Thrombocytopenia (low levels of platelets, which help blood clot; 40%)
- Lymphopenia (low levels of a type of white blood cell called lymphocytes; 35%)
- Leukopenia (low levels of white blood cells; 18%)

Changes in blood levels can be seen throughout treatment with teclistamab. Your doctor will monitor your blood levels closely and treat accordingly. Taking teclistamab may increase your risk of infection, therefore, you may be advised to take precautions to prevent infection such as handwashing, wearing a mask and avoiding large crowds. Your provider may also recommend that you be up to date on vaccinations before treatment. In addition, you may be advised to take precautions to limit your risk of falling (e.g., removing trip hazards from your home), as low platelets can increase your risk of bleeding.

The other most common adverse reactions seen with teclistamab (reported in at least 15% of patients) are:

- Cytokine release syndrome (CRS; an over-activation of the immune system that can lead to fevers and potentially life-threatening organ damage; 72%)
- Infections (76% of patients)
    - Pneumonia (18%)
    - Covid-19 (18%)
- Diarrhoea (29%)
- Fatigue (28%)
- Nausea (27%)
- Injection site reactions (36%)
- Fever (27%)
- Headache (24%)
- Arthralgia (pain in a joint; 22%)
- Constipation (21%)
- Cough (20%)
- Neurotoxic event (15%)

In the MajesTEC-1 trial, five patients out of 165 experienced immune effector cell–associated neurotoxicity syndrome (ICANS). No patient discontinued treatment because of neurotoxic events.

Teclistamab can cause severe and life-threatening side effects in some people. Severe side-effects include grade 3-4 side effects, where one is very mild and five is death. Among the most common side effects, the following were severe for more than 10% of patients:

- Neutropenia (64% of patients)
- Anaemia (37%)
- Thrombocytopenia 21%)
- Lymphopenia (32%)
- Infections (45%)
  - Pneumonia (13%)
  - Covid-19 (12%)

A total of 19 patients died from adverse events during the trial, including 12 deaths from COVID-19. Five deaths were considered by investigators to be related to teclistamab.

Side effects can occur at any point throughout treatment with teclistamab, however, they are most common during the initial phase of treatment. Following a step-up dosing schedule (as described above) can reduce the risk of severe side effects. Though many of them can be severe in nature, many can also be resolved if treated early. For example, CRS can be treated with steroids, or a monoclonal antibody called tocilizumab, a medicine inhibiting interleukin-6 (a pro-inflammatory cytokine). Neurotoxicity may be treated with supportive care, including steroids and anti-seizure medications. Additionally, doses can be delayed or reduced because of adverse reactions. In the MajesTEC-1 trial, 64% of patients skipped a dose, one patient (out of 165) had a dose reduction and two discontinued teclistamab because of adverse events.

Patients on teclistamab need to carry a Tecvayli patient card at all times and show this card to healthcare professionals, and in case of a hospital visit. The patient card provides information on teclistamab side effects such as CRS.

References

1. EMA. Tecvayli. European Medicines Agency. Published July 18, 2022. Accessed February 15, 2023. https://www.ema.europa.eu/en/medicines/human/EPAR/tecvayli

2. EMA. New medicine for multiple myeloma patients with limited treatment options. European Medicines Agency. Published July 22, 2022. Accessed February 16, 2023. https://www.ema.europa.eu/en/news/new-medicine-multiple-myeloma-patients-limited-treatment-options

3. Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in Relapsed or Refractory Multiple Myeloma. N Engl J Med. 2022;387(6):495-505. doi:10.1056/NEJMoa2203478. **See plain language publication: https://www.futuremedicine.com/doi/epdf/10.2217/fon-2023-0171**

4. TECVAYLITM (teclistamab-cqyv). Accessed February 16, 2023. https://www.tecvayli.com

MPE is a network of European myeloma patient organisations. It supports national patient organisations to improve treatment and access for patients in their countries and helps inform and raise awareness on a European level through its educational programmes. Please note, this information does not replace the information provided by your doctor. If there is anything that is not clear to you, please always ask your clinical team.

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