Myeloma Patients Europe

FACTSHEET

MYELOMA PATIENTS EUROPE

SELINEXOR (NEXPOVIO®)

www.mpeurope.org

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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 informed when asking 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?

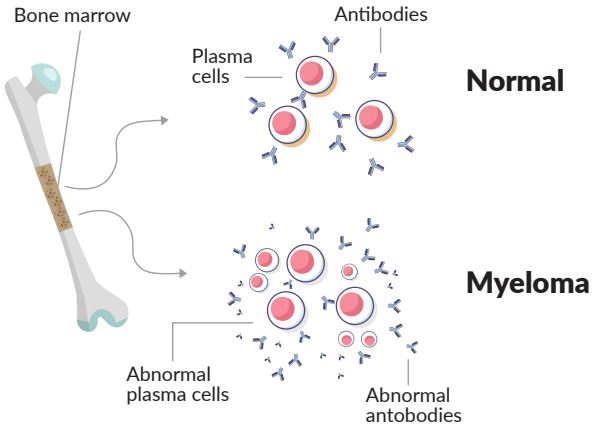
Myeloma treatment is constantly evolving and the factsheets will be updated regularly to reflect the latest developments.

What is myeloma?

Myeloma is a rare cancer of the bone marrow. It causes the formation of abnormal plasma cells, also called myeloma cells, which divide uncontrollably. Usually, plasma cells help the body to fight infections by making antibodies that recognise and attack viruses, bacteria and fungi. 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 infection, bruising and high blood calcium (hypercalcaemia). These symptoms usually require treatment and could be followed by a period of remission where symptoms subside and may not require any treatment. This cycle of remission and recurrence (relapse) often occurs several times. Many patients, particularly in relapse setting, will receive treatment for a long period of time to ensure that their myeloma is kept at bay.

Treatment may involve taking a combination of drugs that have been found to be more effective than single drugs. Myeloma generally cannot be cured, but survival rates are increasing, due to the availability of new treatments and many patients are able to enjoy a good quality of life. A number of other new treatments have recently been approved or are under consideration for use following relapse, or for refractory myeloma.



What is Selinexor (Nexpovio®)?

Selinexor is a first-in-class selective inhibitor of nuclear export (SINE) drug that was granted conditional marketing authorisation from the European Commission in March 2021[1]. Conditional marketing authorisation is granted to new drugs based on less comprehensive data than normally required if the medicines address unmet medical needs and if the medicines' benefits are thought to outweigh their risks. The researchers must provide more comprehensive clinical data in the future to maintain approval status.

Selinexor is indicated in combination with dexamethasone for the treatment of multiple myeloma in adult patients, who have received at least four prior lines of therapy and whose disease is refractory to two immunomodulatory agents, an anti-CD38 monoclonal antibody, as well as at least two proteasome inhibitors, and whose disease progressed during their last therapy[2].

How does selinexor work?

Selinexor binds to a nuclear export factor protein called exportin 1, thus blocking the transport of several proteins involved in cancer-cell growth from the cell nucleus to the rest of the cell. This may lead to cancerous myeloma cells being unable to grow and divide, therefore leading to death of the cancer cells[3].

What are the benefits of selinexor?

Selinexor has been evaluated in several clinical studies, known as the STORM, STOMP and BOSTON trials. The STOMP and BOSTON studies are still ongoing[3].

The phase 2 STORM clinical trial[4] led to the approval of Selinexor for use in Europe. 122 relapsed/refractory multiple myeloma patients in the United States and Europe received 80mg of selinexor plus 20mg of dexamethasone twice weekly. 26% of patients saw an improvement in their myeloma and went about 3.7 months without their myeloma worsening. The overall survival of patients in the study was 8.6 months.

What are the side-effects of selinexor?

The most common side effects of selinexor are[4]:

- Nausea
- Thrombocytopenia (low levels of platelets, a component of blood important for clotting)
- Fatigue
- Anaemia (low red blood cell count)
- Decreased appetite
- Decreased weight
- Diarrhoea
- Vomiting
- Hyponatraemia (low blood sodium level)
- Neutropenia (low levels of neutrophils, a type of white blood cell)
- Leukopenia (low white blood cell count)

How and when is selinexor given?

Selinexor is orally administered in the form of 20mg film coated tablets. The recommended dose is 80mg[4] per week. Selinexor is given on days 1 and 3 on a weekly basis in 4-week treatment cycles.

References

1. Nexpovio: European Medicines Agency." European Medicines Agency, 2021: https://www.ema.europa.eu/en/medicines/human/EPAR/nexpovio

2. Nexpovio: Pending EC decision | European Medicines Agency. https://www.ema.europa.eu/en/medicines/human/summaries-opinion/nexpovio

3. "Oral Selinexor: First-In-Class Anti-Cancer Agent." Karyopharm, https://www.karyopharm.com/pipeline/oral-selinexor/

4. "Chari Et AL Oral Selinexor–Dexamethasone For Triple-Class Refractory Multiple Myeloma | NEJM." New England Journal Of Medicine, 2019: https://www.nejm.org/doi/full/10.1056/NEJMoa1903455

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 at 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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