28 January 2021
EMA/636723/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nexpovio

selinexor

On 28 January 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Nexpovio[3] intended for the treatment of relapsed and refractory multiple myeloma. The applicant for this medicinal product is Karyopharm Europe GmbH.

Nexpovio will be available as 20 mg film-coated tablets. The active substance of Nexpovio is selinexor, a reversible covalent selective inhibitor of nuclear export (SINE) that specifically blocks exportin 1 (XPO1) (ATC code: L01XX66). XPO1 is the major mediator of the nuclear export of many cargo proteins including tumour suppressor proteins (TSPs), growth regulators and mRNAs of growth-promoting (oncogenic) proteins. XPO1 inhibition by selinexor leads to marked accumulation of TSPs in the nucleus, cell cycle arrest, reductions in several oncoproteins such as c-Myc and cyclin D1, and apoptosis of cancer cells.

The benefits with Nexpovio is its ability to bring about a response in penta-refractory patients with relapsed and refractory multiple myeloma. The most common side effects are nausea, thrombocytopenia, fatigue, anaemia, decreased appetite, decreased weight, diarrhoea, vomiting, hyponatraemia, neutropenia and leukopenia.

The full indication is:

> NEXPOVIO is indicated in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.
[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.
[3] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Nexpovio should be prescribed by physicians experienced in the treatment of multiple myeloma.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.