21 March 2014
EMA/165158/2014
Press Office

Press release

EMA recommends approval of new treatment for platinum-resistant ovarian cancer together with companion diagnostic

Vynfinit (vintafolide) offers treatment for women with limited therapeutic options; two diagnostic medicines recommended for approval will help identify patients most likely to respond

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended granting a marketing authorisation for Vynfinit (vintafolide) for the treatment of women with a subtype of platinum-resistant ovarian cancer for which there is limited approved treatment option. The CHMP has recommended approval of Vynfinit as well as two companion diagnostic medicines, Folcepri (etarfolatide) and Neocepri (folic acid) that will help identify patients who will benefit from a treatment with Vynfinit.

The recommendation for the approval of Vynfinit, together with Folcepri and Neocepri, all of which are designated orphan medicines, illustrates the current trend towards the development of medicines targeted at specific patient populations, which is based on a better understanding of the underlying molecular mechanisms of the disease. By targeting specific patient groups who are likely to better respond to a treatment, the response rate in the population treated can be improved and treatment can be avoided in patients who are unlikely to respond to the treatment, sparing them potential side effects.

Ovarian cancer is the fifth most common type of cancer in women and the fourth most common cause of cancer death in women. Patients whose disease is resistant to platinum-based therapy have a poor prognosis and very limited therapeutic options. Among these patients, women whose tumours express high levels of certain proteins called folate receptors have an overall worse prognosis and only one treatment option, pegylated liposomal doxorubicin (PLD), as standard of care. There is therefore a high unmet medical need for these patients.

Vynfinit was designed to specifically target this sub-type of cancer. The medicine binds to the folate receptors that are present on the surface of cancer cells. Vynfinit is a drug conjugate that contains folic acid, which delivers the medicine to the target, and an active substance (desacetylvinblastine hydrazide) which acts on cancer cells by blocking their division and eventually killing them.

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In order to identify which patients express folate receptors on their tumour cells, patients are first given the diagnostic agents Neocepri and Folcepri. The active substance in Folcepri binds to folate receptors on cancer cells, and since it is labelled with a small amount of radioactivity, allows detection of the cells using an imaging technique called SPECT. Neocepri, which contains folic acid, is given before Folcepri to enhance the image quality of the scan by reducing the background.

The CHMP recommended that the three products, Vynfinit, Folcepri and Neocepri, be granted conditional marketing authorisations. This early access mechanism allows the Agency to recommend marketing authorisation for medicines that address an unmet medical need for life-threatening diseases even if comprehensive clinical data are not yet available. Phase-2 clinical trial data for Vynfinit demonstrate that the medicine's benefits outweigh its risks; in combination with pegylated liposomal doxorubicin (PLD), Vynfinit improved progression-free survival in patients with platinum-resistant ovarian cancer when compared with treatment with PLD alone. The sponsor is expected to provide results from an ongoing phase-3 clinical trial as soon as they become available.

The applicant for Vynfinit, Folcepri and Neocepri is Endocyte Europe. The company received scientific advice from the Agency with regard to the development of the three products. In addition, as Endocyte Europe is a registered SME, a micro, small or medium-sized enterprise, it benefited from regulatory and procedural assistance in addition to incentives and fee reductions from the Agency. The Agency put in place the SME initiative in 2005 to promote innovation and development of medicines by SMEs, who are considered a major driver of innovation in the pharmaceutical industry in the European Union.

The CHMP opinions on Vynfinit, Folcepri and Neocepri will now be sent to the European Commission for adoption of a decision on an EU-wide marketing-authorisation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Vynfinit, Folcepri and Neocepri are all medicinal products. Folcepri and Neocepri are for diagnostic use only.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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