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Press Office

Press release

EMA fast-tracks treatment of multiple myeloma for approval in EU

Empliciti to help activate the body's immune system against rare blood cancer

The European Medicines Agency (EMA) has recommended granting a marketing authorisation for Empliciti (elotuzumab) for the treatment of multiple myeloma. It is to be used in combination with lenalidomide and the anti-inflammatory medicine dexamethasone for the treatment of patients who have received at least one prior therapy.

Empliciti is a monoclonal antibody that works by activating the body's immune system to attack and kill multiple myeloma cells.

Multiple myeloma is a rare malignant disease of a type of white blood cells called plasma cells. In multiple myeloma, the division of plasma cells becomes out of control, resulting in abnormal, immature plasma cells multiplying and filling up the bone marrow. The abnormal cells interfere with the production of normal white blood cells, red blood cells and platelets, and patients develop complications such as infections, anaemia, bone pain and fractures, raised blood calcium levels and kidney dysfunction.

Multiple myeloma is generally an incurable disease that leads to bone destruction and kidney failure. In 2012, around 39,000 people had multiple myeloma in the European Union (EU). Only half of patients diagnosed with multiple myeloma are still alive after five years under currently available treatment. Therefore new medicines are needed for patients whose disease returns after treatment.

The Committee for Medicinal Products for Human Use (CHMP) reviewed Empliciti under EMA's accelerated assessment programme. Accelerated assessment is one of the Agency's main mechanisms to facilitate earlier access by patients to medicines that fulfill unmet medical needs.

The CHMP's recommendation is based on a randomised, open-label Phase 3 study evaluating Empliciti in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone alone in patients with relapsed or refractory multiple myeloma. The trial enrolled 646 patients whose multiple myeloma came back after, or did not respond to, previous treatment. In patients also taking Empliciti, the disease progressed more slowly (difference in medians of 4.2 months) than in patients taking only lenalidomide and dexamethasone.

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In addition, 78.5% of patients taking Empliciti with lenalidomide and dexamethasone saw a complete or partial shrinkage of their tumours compared to 65.5% in those only taking lenalidomide and dexamethasone.

The most common side effects of Empliciti are infusion-related reactions, diarrhoea, cough, herpes zoster (shingles), nasopharyngitis (infection of the nose and throat), pneumonia, upper respiratory tract infection, lymphopenia (lowered counts of a type of white blood cell called lymphocytes) and weight loss.

Because multiple myeloma is rare, Empliciti received an orphan designation from the Committee for Orphan Medicinal Products (COMP) in 2012. Orphan designation is the key instrument available in the EU to encourage the development of medicines for patients with rare diseases. Orphan-designated medicines qualify for ten years' market exclusivity. In addition orphan designation gives medicine developers access to incentives, such as fee reductions for marketing authorisation applications and scientific advice.

The applicant received scientific advice from the CHMP pertaining to quality and clinical aspects of the dossier.

The opinion adopted by the CHMP at its January 2016 meeting is an intermediary step on Empliciti's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Empliciti is Bristol-Myers Squibb.
3. Following this positive CHMP opinion, the COMP will assess whether the orphan designation should be maintained.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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