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Press Office

Press release

New treatment option for patients with rare blood cancer

Kyprolis recommended under accelerated assessment for patients with relapsed multiple myeloma

The European Medicines Agency (EMA) has recommended granting a marketing authorisation for Kyprolis (carfilzomib) to treat patients with multiple myeloma whose disease has relapsed (i.e. the cancer has come back after receiving at least one prior course of therapy). Kyprolis is for use in combination with the cancer medicines lenalidomide and dexamethasone.

Over the last decade, new therapies have become available, which have improved the outlook for patients with multiple myeloma. However, there is still an urgent need to provide treatment options for patients who no longer respond to the available therapies. EMA's Committee for Medicinal Products for Human Use (CHMP) therefore decided to review Kyprolis under the accelerated assessment programme, a tool which aims to speed up patients' access to medicines that address unmet medical needs.

Multiple myeloma is a rare and life-threatening cancer of a type of white blood cell, called plasma cells, which originate in the bone marrow. In multiple myeloma the division of plasma cells becomes uncontrolled, 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, leading to complications such as anaemia, bone pain and fractures, raised blood calcium levels and kidney disease. In 2012 approximately 39,000 people in the EU were diagnosed with multiple myeloma.

Carfilzomib belongs to a class of medicines called proteasome inhibitors. Proteasome inhibitors block the proteasome, a system in cells that breaks down proteins when they are no longer needed. When proteins in the cancer cells are not broken down by the proteasome, the cells eventually die, slowing down the growth of the cancer.

Carfilzomib is the first irreversible, highly-selective, proteasome inhibitor for multiple myeloma. The irreversible binding to the targeted proteasome leads to a more sustained inhibition with minimal inhibition of other non-targeted enzymes.

The efficacy of Kyprolis was demonstrated in one main open-label, multicentre phase III trial. In this study, 792 patients with relapsed multiple myeloma were randomly assigned to receive Kyprolis

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combined with lenalidomide and dexamethasone or lenalidomide and dexamethasone. The study found that patients who received the Kyprolis combination had an average increase of 8.7 months during which their disease did not progress compared with lenalidomide and dexamethasone (26.3 months versus 17.6 months).

Regarding safety, the CHMP considered that the adverse event profile appeared acceptable and manageable. Some of the most common side effects of Kyprolis are anaemia, fatigue, diarrhoea, thrombocytopenia (low blood platelet counts), nausea and dyspnoea (difficulty in breathing). More serious side effects include blood abnormalities and cardiac events. A follow-up plan to monitor the safety and efficacy of Kyprolis was agreed by the CHMP.

Because multiple myeloma is rare, Kyprolis was designated as an orphan medicine by the Committee for Orphan Medicinal Products (COMP). Orphan designation gives medicine developers access to incentives, such as fee reductions for scientific advice, and is the key instrument available in the EU to encourage the development of medicines for patients with rare diseases.

The opinion adopted by the CHMP at its September 2015 meeting is an intermediary step on Kyprolis' 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 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 Kyprolis is Amgen Europe B.V.
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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