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Press office

Press release

New treatment for patients with multiple myeloma

Darzalex recommended for conditional approval

The European Medicines Agency (EMA) has recommended granting a conditional marketing authorisation for Darzalex (daratumumab) for the treatment of adults with relapsed and refractory multiple myeloma. Darzalex is to be used in patients whose previous treatment included a proteasome inhibitor and an immunomodulatory agent (other types of cancer medicines) and whose disease worsened after treatment.

Darzalex 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 cancer of a type of white blood cells called plasma cells. In multiple myeloma, the division of plasma cells is 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 the patients diagnosed with the disease live longer than 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 Darzalex under EMA's accelerated assessment program and recommended conditional approval for the medicine. These are two of the Agency's main mechanisms to facilitate early access to medicines that fulfill unmet medical need. Conditional approval allows EMA to recommend a medicine for marketing authorisation in the interest of public health where the benefit of its immediate availability to patients outweighs the risk inherent in the fact that additional data are still required.

The CHMP's recommendation is based on two studies. In one study of 106 patients receiving Darzalex, tumours shrank or could no longer be seen in 29% of the patients over an average of 7.4 months. In the second study of 42 patients receiving Darzalex, tumours shrank or could no longer be seen in 36% of patients.

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The most common side effects of Darzalex include infusion-related reactions, fatigue, pyrexia (fever), cough, nausea, back pain, upper respiratory tract infection, anaemia, neutropenia (low counts of infection-fighting white blood cells) and thrombocytopenia (low levels of blood platelets).

As part of the conditional marketing authorisation, the applicant for Darzalex must provide results from two Phase III studies of Darzalex used in combination with standard treatments for this disease (lenalidomide/dexamethasone and bortezomib/dexamethasone). Both studies are ongoing and the data will be provided by the applicant by the second half of 2017. Until availability of full data, the CHMP will review the benefits and risks of Darzalex annually to determine whether the conditional marketing authorisation can be maintained.

Because multiple myeloma is rare, Darzalex received an orphan designation from the Committee for Orphan Medicinal Products (COMP) in 2013. 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 for scientific advice.

The applicant received scientific advice from the CHMP on quality and clinical aspects of the application.

The opinion adopted by the CHMP at its March 2016 meeting is an intermediary step on Darzalex'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 Darzalex is Janssen-Cilag International N.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 EMA can be found on its website: www.ema.europa.eu

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