EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 May 2014
EMA/307827/2014
Press Office

Press release

European Medicines Agency recommends approval of Gazyvaro for chronic lymphocytic leukaemia

Medicine represents new treatment option for patients with rare life-threatening disease who cannot use standard therapy

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorisation for Gazyvaro (obinutuzumab) in combination with the cancer medicine chlorambucil for the treatment of adults with previously untreated chronic lymphocytic leukaemia.

Gazyvaro has an orphan designation. It is to be used in patients with additional medical conditions who cannot be treated with full dose fludarabine-based therapy.

Chronic lymphocytic leukaemia is a rare type of cancer which affects certain white blood cells called B-lymphocytes. It is a long-term debilitating and life-threatening disease as patients can develop severe infections. Chronic lymphocytic leukaemia accounts for approximately 30% of adult leukaemias. In the European Union (EU), more than 62,000 people were diagnosed with leukaemia in 2012 and over 41,000 people died from the disease.

Chronic lymphocytic leukaemia remains an incurable disease. Treatments currently available generally induce remission, however the disease returns in nearly all patients.

Gazyvaro is a monoclonal antibody that targets B-lymphocytes, thereby helping the body's immune system to kill the cancer cells.

The main study on which Gazyvaro's recommendation is based is a phase III trial including 781 previously untreated patients with chronic lymphocytic leukaemia and coexisting medical conditions. The study showed that patients treated with Gazyvaro in combination with chlorambucil lived significantly longer without their disease getting worse compared to patients treated with chlorambucil alone (26.7 months versus 11.1 months) or rituximab plus chlorambucil (26.7 months versus 15.2 months). In addition, the risk of disease progression or death was reduced by 86% when Gazyvaro was given with chlorambucil.

The safety profile of Gazyvaro was in accordance with what would be expected for a monoclonal antibody in this class. Infusion-related reactions, neutropenia and infections were among the most

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common adverse events reported. Some rare but serious adverse events were reported; however, the toxicity profile of Gazyvaro was considered acceptable in view of its benefits.

The applicant for Gazyvaro, Roche, received scientific advice from the CHMP during the development of the medicine. The advice pertained to quality, non-clinical and clinical aspects of the dossier.

The CHMP opinion on Gazyvaro 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. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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