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Media and Public Relations

Press release

New treatment for rare white blood cell cancer

Treatment of follicular lymphoma to be added to Gazyvaro's approved uses

The European Medicines Agency (EMA) has recommended extending the authorised indication of Gazyvaro (obinutuzumab) to treat patients with follicular lymphoma. The medicine is to be used in combination with bendamustine in patients who were previously treated with chemotherapy.

Gazyvaro was first authorised in the European Union (EU) in July 2014 for use in combination with chlorambucil in patients with previously untreated chronic lymphocytic leukaemia.

Follicular lymphoma and chronic lymphocytic leukaemia are both rare types of cancer that affect certain white blood cells that fight infection, called B-lymphocytes. In follicular lymphoma, the body produces abnormal B cells that build up in lymph nodes.

While effective treatments exist for follicular lymphoma, the disease often comes back and becomes increasingly aggressive and resistant to existing treatment options. Patients whose disease has become aggressive often die after one to two years.

The active substance in Gazyvaro is a monoclonal antibody that targets B-lymphocytes and triggers the death of cancer cells through the activation of the immune system.

The recommendation from EMA's Committee for Medicinal Products for Human Use (CHMP) is based on the results of a phase III trial that compared the effects of Gazyvaro given in combination with bendamustine and followed by Gazyvaro as a maintenance treatment, with the effects of bendamustine alone, in 321 patients with follicular lymphoma who did not respond to or whose disease progressed with chemotherapy. In this study, patients treated with Gazyvaro in combination with bendamustine lived longer without their disease progressing compared to patients treated with bendamustine alone (on average about 29 months compared to 14 months).

The most common side effects reported with the combination of Gazyvaro and bendamustine were consistent with the known safety profiles of the individual medicines.

Because follicular lymphoma is rare, Gazyvaro was designated as an orphan medicine in 2015. 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 the designation gives medicine developers access to incentives, such as fee reductions for marketing authorisation applications and for scientific advice.

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The applicant received scientific advice from the CHMP on the design of the phase III trial supporting the application.

The opinion adopted by the CHMP at its April 2016 meeting is an intermediary step on Gazyvaro's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on EU-wide marketing authorisations. Once the extension of indication has been granted, a decision about price and reimbursement will take place at the level of each Member State considering 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 Gazyvaro is Roche. More information on the medicine is available here.
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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