13 November 2026

EMA recommends extending Gazyvaro's use to systemic lupus erythematosus

Gazyvaro reduces disease activity and use of corticosteroids

EMA has recommended extending the use of Gazyvaro (obinutuzumab) in the European Union to treat adults with moderate to severe, active systemic lupus erythematosus (SLE). The medicine will be used as an add-on treatment in patients who test positive for certain antibodies and whose disease remains active despite standard therapy.

SLE is an autoimmune disease that predominantly affects women. It occurs when the immune system attacks the body's own tissues, causing inflammation that can damage organs. Some patients continue to have active disease despite standard treatment and remain at risk of permanent organ damage and cardiovascular disease. Long-term corticosteroid use can also cause serious side effects, including infections and osteoporosis. Additional treatment options are therefore needed for these patients.

Gazyvaro contains obinutuzumab, a monoclonal antibody which attaches to a protein called CD20 on B cells, a type of immune cell involved in the inflammation and tissue damage seen in SLE. By attaching to CD20, obinutuzumab causes B cells to die, reducing their numbers and helping to reduce inflammation.

EMA's recommendation is based on a randomised, double-blind study involving 303 adults with active SLE despite standard treatment. Patients received either Gazyvaro or placebo, both in addition to standard treatment. The primary endpoint was the proportion of patients who responded after 52 weeks based on a measure called the SLE Responder Index (SRI4). A response means a reduction in disease activity without the disease getting worse or new tissues or organs becoming affected. A response was achieved by 76.7% of patients receiving Gazyvaro, compared with 53.5% of those receiving placebo. The study also showed that patients treated with Gazyvaro were able to reduce their corticosteroid use while maintaining disease control and experienced fewer disease flares.

The most frequently reported side effects of Gazyvaro in patients with SLE included upper respiratory tract infections and urinary tract infections.

Gazyvaro has been authorised in the EU since July 2014 and is already used to treat chronic lymphocytic leukaemia, follicular lymphoma and certain forms of lupus nephritis.

The opinion adopted by the CHMP is an intermediary step on Gazyvaro's path to patient access for this new indication. The opinion will now be sent to the European Commission for the adoption of a decision extending the medicine's EU-wide marketing authorisation. Decisions about price and reimbursement

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2026. Reproduction is authorised provided the source is acknowledged.

for the new indication will take place at the level of each Member State, taking into account the potential role or use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with related documents, is available on the Agency's website at: www.ema.europa.eu.
2. The applicant for Gazyvaro is Roche Registration GmbH.

Contact

Media enquiries

Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu

All other enquiries

please submit your request via the online form

Follow us on Bluesky