Obinutuzumab (Gazyvaro®) in combination with bendamustine for the treatment of relapsed/refractory follicular lymphoma (FL)

Grössmann N

Record Status
This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors’ conclusions
Currently, obinutuzumab is approved as combination therapy with chlorambucil for the treatment of patients with untreated chronic lymphocytic leukaemia (CLL) both in Europe and the US. Recently (February 2016), the US Food and Drug Administration (FDA) approved obinutuzumab for the treatment of patients with follicular lymphoma (FL), who did not respond or progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen; also the European Medicines Agency (EMA) adopted a positive opinion for this indication. The FDA approval was based on the results of a phase III study, GADOLIN, which is available in abstract form only. Although the study shows a significant improvement in PFS, the lack of mature OS data, in addition to the fact that there was no difference in overall response (OR) highlights the need for long-term data. Furthermore, a long-term safety profile as well as further quality of life (QoL) data will be necessary to exclude any risks of late side effects. In addition, any original article presenting the study will need to identify potential advantages and disadvantages for specific subgroups.

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Address for correspondence
Ludwig Boltzmann Institut fuer Health Technology Assessment (LBI-HTA), Garnisongasse 7 rechte Stiege Mezzanin
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