Ofatumumab (Arzerra®) as maintenance therapy in patients with relapsed chronic lymphocytic leukaemia (CLL)

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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, ofatumumab is approved for two indications for chronic lymphocytic leukaemia (CLL) in Europe and the US (1st line treatment & refractory CLL). Recently (January 2016), the FDA approved ofatumumab for maintenance treatment of adult patients with relapsed CLL in partial or complete remission after at least two previous treatments. The FDA approval was based on the results of the PROLONG trial, a randomised, open-label phase III study. Although the study shows a significant improvement in PFS, the lack of OS gain should be further investigated. The potential risk of the development of resistance as well as the high number of AEs should be taken into account. Therefore, long-term data will be required. More data will also be required to identify the clinical benefit for patients of specific cytogenetic subgroups.

Project page URL
http://hta.lbg.ac.at/page/horizon-scanning-in-der-onkologie

Final publication URL
http://eprints.hta.lbg.ac.at/1085/1/DSD_HSO_Nr.57.pdf

Additional data URL
http://eprints.hta.lbg.ac.at/1085/

Indexing Status
Subject indexing assigned by CRD

MeSH
Humans; Adult; Antibodies, Monoclonal; Antigens, CD20; Leukemia, Lymphocytic, Chronic, B-Cell; Neoplasm Recurrence, Local

Language Published
English

Country of organisation
Austria

English summary
An English language summary is available.

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