

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

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Ofatumumab (Arzerra®) is a human monoclonal antibody which binds specifically to CD20 on the surface of B cells. Thereby, ofatumumab triggers complement-dependent cell lysis and antibody-dependent cell-mediated cytotoxicity of CD20 overexpressing B cells.

Currently, ofatumumab is approved for two indications for chronic lymphocytic leukaemia (CLL) both 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. 474 previously treated patients were randomised to either observation or ofatumumab treatment. The randomisation was stratified by clinical response at entry, number of previous treatments and type of the most recent previous treatment. The primary outcome of the study was progression-free survival (PFS). Results showed a significant increase in PFS in patients who received ofatumumab; those patients gained 14.2 months in median PFS compared to the observation arm. In contrast, no statistically significant difference between the two study arms could be detected in overall survival (OS) (HR 0.85,  $p = 0.4877$ ). Safety data showed that treatment related adverse events (AEs) were more frequent in patients of the ofatumumab group. The most common grade  $\geq 3$  AEs were neutropenia and infections.

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.

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