

Obinutuzumab (Gazyva®) for previously untreated patients with chronic lymphocytic leukaemia (CLL)

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Chronic lymphocytic leukaemia (CLL) is the most common adult leukaemia, accounting for approximately 25 to 30 percent of all leukaemias. Obinutuzumab is a type II, glyco-engineered, humanised anti-CD20 monoclonal antibody that binds selectively to the extracellular domain of the human CD20 antigen. Obinutuzumab is not yet licensed in Europe, but the FDA licensed obinutuzumab in November 2013 for the treatment of previously untreated CLL patients. It is the first drug approved with "breakthrough therapy designation" by the FDA. A three arm, open-label, multicentre phase III study examined the efficacy and safety of obinutuzumab in combination with chlorambucil and chlorambucil alone (stage 1a), rituximab in combination with chlorambucil and chlorambucil alone (stage 1b) as well as obinutuzumab in combination with chlorambucil and rituximab in combination with chlorambucil (stage 2) in patients with CLL. 781 patients were randomly assigned and were stratified by Binet stage at baseline and geographic region. The primary outcome was progression free survival (PFS). For patients treated with obinutuzumab-chlorambucil or rituximab-chlorambucil median PFS improved significantly compared with chlorambucil monotherapy by 15.6 months respectively 5.2 months. In terms of safety, neutropenia, infusion-related reactions, infections and thrombocytopenia occurred more frequently in the obinutuzumab-chlorambucil group. The phase III study compared different treatment strategies for CLL and also included untreated elderly patients with coexisting conditions. Obinutuzumab is a therapy option for patients with CLL, but comorbidity and functional status – both influencing patient selection – should be assessed prior to treatment initiation. The challenge in the era of anti-CD20 antibodies is to identify the optimal combination and sequence of treatments in order to achieve best quality of life and long-term control of CLL.

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