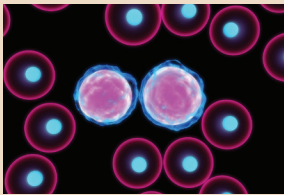


# Managing Infusion-Related Reactions for Patients With Chronic Lymphocytic Leukemia Receiving Obinutuzumab

Keith Dawson, DNP, MS, RN, Mollie Moran, MSN, CNP, AOCNP®, Kathleen Guindon, DM, OL, MS, RN, and Hui Wan, MD, PhD



© Sebastian Kaulitzki/Thinkstock

**Background:** In patients with previously untreated chronic lymphocytic leukemia (CLL) and comorbidities, treatment with the glycoengineered, type II anti-CD20 monoclonal antibody obinutuzumab (Gazyva®) (GA101) plus chlorambucil (Leukeran®) was associated with superior outcomes to rituximab (Rituxan®) plus chlorambucil, with a similar safety profile. However, a higher occurrence of infusion-related reactions (IRRs) was reported with obinutuzumab. These reactions typically require additional management.

**Objectives:** The focus of this article is to provide oncology nurses and physicians with advice for obinutuzumab IRR management based on clinical trial data and nursing experience.

**Methods:** The authors reviewed the published management strategies for IRRs with obinutuzumab that were identified during the phase III CLL11 trial and an expanded access phase IIb study (ML28979). Practical advice for obinutuzumab IRR management was developed based on available clinical trial information and nursing experience.

**Findings:** IRRs with obinutuzumab are generally manageable. Most IRRs (all grades), and all grade 3–4 IRRs, occurred during the first infusion. Therefore, IRR management could be improved substantially with extra vigilance at this early stage.

Keith Dawson, DNP, MS, RN, is a senior medical science director of U.S. medical affairs in hematology at Genentech, Inc., in San Francisco, CA; Mollie Moran, MSN, CNP, AOCNP®, is an oncology nurse practitioner at the Ohio State University Comprehensive Cancer Center—Arthur G. James Cancer Hospital and Richard J. Solove Research Institute in Columbus; Kathleen Guindon, DM, OL, MS, RN, is a senior medical science liaison of U.S. medical affairs in hematology at Genentech, Inc.; and Hui Wan, MD, PhD, is an international medical director of hematology at F. Hoffmann-La Roche Ltd. in Basel, Switzerland. The authors take full responsibility for the content of the article. Dawson, Guindon, and Wan received stock from F. Hoffmann-La Roche Ltd., and Moran has previously consulted for Genentech, Inc., and F. Hoffmann-La Roche Ltd. Editorial support was provided by Laura White, PhD, at Gardiner-Caldwell Communications (an Ashfield Company, part of UDG Healthcare plc.) through support from F. Hoffmann-La Roche Ltd. The content of this article has been reviewed by independent peer reviewers to ensure that it is balanced, objective, and free from commercial bias. No financial relationships relevant to the content of this article have been disclosed by the independent peer reviewers or editorial staff. Mention of specific products and opinions related to those products do not indicate or imply endorsement by the *Clinical Journal of Oncology Nursing* or the Oncology Nursing Society. Dawson can be reached at dawson.keith@gene.com, with copy to editor at CJONEditor@ons.org. (Submitted March 2015. Revision submitted June 2015. Accepted for publication July 1, 2015.)

Key words: obinutuzumab; rituximab; infusion-related reaction; premedication; slow infusion; split dose

Digital Object Identifier: 10.1188/16.CJON.E41-E48

Treatment regimens containing the anti-CD20 monoclonal antibody rituximab (Rituxan®) have improved clinical outcomes in chronic lymphocytic leukemia (CLL) versus chemotherapy alone (Byrd et al., 2005; Foà et al., 2014; Goede et al., 2014; Hallek et al., 2010; Hillmen et al., 2014; Tam et al., 2008). Consequently, rituximab plus chlorambucil (Leukeran®) (R-Clb) is a current standard-of-care regimen for treatment-naïve, comorbid CLL (Hagemeister, 2010; Keating, 2010). However, CLL remains incurable using standard approaches (Rioufol & Salles, 2014); therefore, new therapies are needed to prolong CLL remission.

Obinutuzumab (Gazyva®) (GA101) is a novel, humanized, anti-CD20 monoclonal antibody (Abraham & Stegner, 2014) approved by the U.S. Food and Drug Administration in November 2013 for use with Clb regimens in patients with treatment-naïve CLL (Lee et al., 2014). The glycoengineered, type II antibody obinutuzumab enhances induction of antibody-dependent, cell-mediated cytotoxicity and direct cell death when compared to the type I antibody rituximab (Glennie, French, Cragg, & Taylor, 2007; Morschhauser et al., 2009, 2010; Mössner et al., 2010; Niederfellner et al., 2011). Obinutuzumab plus chlorambucil (G-Clb) has increased