This material is protected by U.S. copyright law. Unauthorized reproduction is prohibited. To purchase quantity reprints, please e-mail reprints@ons.org or to request permission to reproduce multiple copies, please e-mail pubpermissions@ons.org.



Sandra A. Mitchell, CRNP, MScN, AOCN®
Associate Editor

Downloaded on 09 15 2019. Single-user license only. Copyright 2019 by the Oncology Nursing Society. For permission to post online, reprint, adapt, or reuse, please email pubpermissions@ons.org

# PHARMACY CORNER

## Radioimmunotherapy Agent Approved for Non-Hodgkin's Lymphoma

The U.S. Food and Drug Administration has granted approval for the first radioimmunotherapy agent, Zevalin™ (ibritumomab tiuxetan, IDEC Pharmaceuticals, San Diego, CA). Zevalin, as part of the Zevalin therapeutic regimen, is indicated for patients with relapsed or refractory low-grade, follicular, or transformed B cell non-Hodgkin's lymphoma (NHL), including patients with Rituxan® (rituximab, IDEC Pharmaceuticals) refractory follicular NHL.

Radioimmunotherapy is a promising new area of cancer treatment that combines the targeting power of monoclonal antibodies with the cell-damaging ability of localized radiation. Radioimmunotherapy agents are made by linking monoclonal antibodies, which are engineered to recognize and attach to substances on the surface of certain cells, to radioactive isotopes. These radiation-carrying antibodies circulate until they locate and bind to the surface of specific cells to deliver their cytotoxic radiation directly to malignant cells. Zevalin binds to both malignant and normal B cells. Normal B cells generally are replenished within six to nine months following therapy. Lymphoma tumors are very sensitive to radiation, but targeting external beam radiation to cancerous immune system cells throughout the body is difficult. Zevalin combines a monoclonal antibody with the cancer-killing ability of radiation. Zevalin is linked to the radioisotope yttrium-90 that targets the CD20 antigen.

The Zevalin therapeutic regimen consists of Rituxan, followed by indium-111 Zevalin. Seven to nine days later, a second infusion of Rituxan is administered, followed by yttrium-90 Zevalin. The Zevalin therapeutic regimen consists of two low doses of Rituxan (250 mg/m$^2$), an imaging dose of Zevalin, two or three whole body scans to assess the efficacy of biodistribution, and a therapeutic dose of Zevalin, all delivered on an outpatient basis over eight days. The recommended dose is 0.4 mCi/kg for patients with platelet counts greater than 150,000 and 0.3 mCi/kg for patients with platelet counts between 100,000–149,000. For all patients, the maximum dose is 32 mCi. Zevalin is not recommended for patients with platelet counts below 100,000.

The effectiveness of the Zevalin therapeutic regimen in a relapsed or refractory patient population was based on overall response rates in two studies. The first study was conducted in 54 patients with relapsed follicular lymphoma who no longer responded adequately to Rituxan; 74% showed an overall response rate to treatment with Zevalin with 15% of patients achieving a complete remission to therapy according to the International Workshop Response Criteria (IWRC).

The second study, a phase III, randomized, controlled trial, which supported accelerated approval, was conducted in 143 patients with relapsed or refractory, low-grade or follicular NHL or transformed B cell NHL. The 73 patients who received the Zevalin therapeutic regimen showed an overall response rate of 80%, compared to 56% in 70 patients who received Rituxan alone, according to IWRC. Thirty percent of patients receiving Zevalin achieved a complete remission and 4% achieved an unconfirmed complete remission to therapy, compared to 16% of patients receiving Rituxan who achieved a complete remission and 4% who achieved an unconfirmed complete remission, according to IWRC.

In safety data based on 349 patients, the most serious adverse reactions of the Zevalin therapeutic regimen included severe infusion reactions (e.g., hypotension, angioedema, hypoxia, bronchospasm) and severe and prolonged cytopenias, including thrombocytopenia (61% of patients with platelet counts less than 50,000 cells/mm$_3$) and neutropenia (57% of patients with absolute neutrophil counts less than 1,000 cells/mm$_3$) in patients with a platelet cell count greater than 150,000/mm$_3$ prior to treatment. Severe infections (predominately bacterial in origin) and hemorrhage, including fatal cerebral hemorrhage, have occurred in a minority of patients in clinical studies. Also seen were myeloid malignancies and dyscrasias (e.g., myelodysplastic syndrome). The most common toxicities reported were neutropenia, thrombocytopenia, anemia, gastrointestinal symptoms (e.g., nausea, vomiting, abdominal pain, diarrhea), increased cough, dyspnea, dizziness, arthralgia, anorexia, and ecchymosis. Hematologic toxicity often was severe and prolonged, whereas most nonhematologic toxicity was mild in severity. The effects of the Zevalin therapeutic regimen on survival are not known.

Zevalin should be used only by healthcare professionals qualified by training and experience in the safe use of radionuclides and monoclonal antibodies. Deaths have occurred within 24 hours of rituximab infusions. These fatalities were associated with an infusion reaction symptom complex that included hypoxia, pulmonary infiltrates, acute respiratory distress syndrome, myocardial infarction, ventricular fibrillation, or cardiogenic shock. Yttrium-90 Zevalin administration results in severe and prolonged cytopenias in most patients.

For more information, contact IDEC Pharmaceuticals at 877-878-4332 or visit the Zevalin Web site at www.zevalin.com.

## New Therapy Approved for Hormone Receptor Positive Breast Cancer

The U.S Food and Drug Administration has announced the approval of Faslodex® Injection (fulvestrant, AstraZeneca Pharmaceuticals, Wilmington, DE), indicated for the treatment of hormone receptor positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy. Faslodex is administered to patients in a monthly, 250 mg intramuscular injection.


*Description of products does not indicate or imply endorsement by the* Oncology Nursing Forum *or the Oncology Nursing Society.*

Digital Object Identifier: 10.1188/02.ONF.999-1001