

media fact sheet

TREANDA® (BENDAMUSTINE HYDROCHLORIDE) FOR INJECTION

What is TREANDA?

In March 2008, the U.S. Food and Drug Administration approved TREANDA® (bendamustine hydrochloride) for Injection, a novel chemotherapy, for the treatment of chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established. TREANDA received its second approval in October 2008 for the treatment of indolent B-cell non-Hodgkin's lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

How does TREANDA work?

TREANDA has a unique chemical structure that is synthesized to combine an alkylating group and a purine-like benzimidazole component. Though the exact mechanism of action of TREANDA remains unknown, TREANDA may act in two distinct ways to kill cancer cells. Preclinical studies suggest that TREANDA may lead to cell death by a process known as apoptosis (programmed cell death) as well as by an alternate cell death pathway which disrupts normal cell division known as mitotic catastrophe (a non-apoptotic pathway).

How common are the diseases for which TREANDA is approved to treat?

There are approximately 245,225 people living with, or in remission from, leukemia in the United States. The American Cancer Society (ACS) estimated 15,000 new CLL cases in 2010 and approximately 4,400 deaths due to CLL.

In the United States, there are approximately 452,723 people living with, or in remission from, non-Hodgkin's lymphoma (NHL), the seventh most common cancer. The ACS estimated 65,540 new NHL cases in 2010 about 40% of which were the indolent (or slow growing) form and 20,210 deaths due to NHL.

What is important to know about the safety of TREANDA?

The following serious adverse reactions have been associated with TREANDA: myelosuppression, infections, infusion reactions and anaphylaxis, tumor lysis syndrome, skin reactions including SJS/TEN, other malignancies, and extravasation. Some of these reactions have been fatal, including myelosuppression, infections, and SJS/TEN (when TREANDA was administered concomitantly with allopurinol and other medications known to cause SJS/TEN). Patients should be monitored closely for these reactions and treated promptly if any occur. Adverse reactions may require interventions such as decreasing the dose of TREANDA, or withholding or delaying treatment. Myelosuppression is frequently severe and should be expected when treating patients with TREANDA.

TREANDA is contraindicated in patients with a known hypersensitivity to bendamustine or mannitol. Women should be advised to avoid becoming pregnant while using TREANDA.

The most common non-hematologic adverse reactions associated with TREANDA (frequency $\geq 15\%$) are nausea, fatigue, vomiting, diarrhea, pyrexia, constipation, anorexia, cough, headache, weight decreased, dyspnea, rash, and stomatitis. The most common hematologic abnormalities associated with TREANDA (frequency $\geq 15\%$) are lymphopenia, anemia, leukopenia, thrombocytopenia, and neutropenia.

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What has been the clinical development history of TREANDA?

Based upon the extensive clinical studies of TREANDA in hematologic and solid tumors conducted in Germany, a clinical development program was initiated in support of the approved indications.

Key studies:

- A Phase 3 clinical trial supporting the approval in CLL evaluating the safety and efficacy of TREANDA, compared to chlorambucil in patients who were not previously treated for their disease, met both primary endpoints of overall response rate and progression-free survival. Chlorambucil, a chemotherapy drug, is an FDA-approved therapy for patients with CLL.
- A pivotal trial of patients with indolent B-cell NHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen supported approval for this indication. The study demonstrated that patients had high durable responses to TREANDA. The safety of TREANDA is supported by the pivotal study and a supporting monotherapy study.

What are the disease areas in which TREANDA is being studied?

Bendamustine hydrochloride, the active ingredient in TREANDA is being studied in a number of therapeutic areas. For further information on clinical trials with TREANDA, please view the Cephalon pipeline located at <http://www.cephalon.com/our-science/pipeline.shtml>.

How is TREANDA administered?

TREANDA has a convenient intravenous dosing schedule that can be administered in an outpatient setting.

For CLL, the recommended dose is 100 mg/m² administered over 30 minutes on Days 1 and 2 of a 28-day cycle for up to 6 cycles.

For NHL, the recommended dose is 120 mg/m² administered over 60 minutes on Days 1 and 2 of a 21-day cycle for up to 8 cycles.

Who markets TREANDA in the United States?

Cephalon, Inc. (Nasdaq: CEPH), Frazer, PA, an international biopharmaceutical company, holds exclusive rights to market and develop TREANDA in the United States.

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