

fact sheet

TREANDA® (bendamustine hydrochloride) for Injection

What is TREANDA?	TREANDA® (bendamustine hydrochloride) for Injection, a novel chemotherapy, was first approved by the U.S. Food and Drug Administration for the treatment of chronic lymphocytic leukemia (CLL) in March 2008. TREANDA received its second approval in October 2008 for the treatment of patients with 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?	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).
What are the disease areas in which TREANDA is being studied?	In worldwide clinical trials, bendamustine hydrochloride, the active ingredient in TREANDA, has been or is being evaluated for safety and efficacy using various regimens in the following areas: <ul style="list-style-type: none">• Chronic lymphocytic leukemia• Non-Hodgkin's lymphoma• Multiple myeloma• Breast cancer• Hodgkin's lymphoma
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: <ul style="list-style-type: none">• 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.• The FDA approval is supported by 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. 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.• Extensive clinical study of TREANDA in hematologic and solid tumors in Germany has shown that TREANDA is well tolerated in patients when used as a monotherapy or in combination with other commonly-used therapies. The most serious adverse events in clinical trials with TREANDA have been myelosuppression, infections, infusion reactions and anaphylaxis, tumor lysis syndrome, skin reactions and other malignancies. Patients receiving TREANDA rarely experienced hair loss.

<p>How is TREANDA administered?</p>	<p>TREANDA has a convenient intravenous dosing schedule that can be administered in an outpatient setting.</p> <p>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.</p> <p>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.</p>
<p>Who will market TREANDA in the United States?</p>	<p>Cephalon, Inc. (Nasdaq: CEPH), Frazer, PA, an international biopharmaceutical company, holds exclusive rights to market and develop TREANDA in the United States and is marketed by Cephalon Oncology.</p>

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