

fact sheet

TREANDA® (bendamustine HCl) for Injection

What is TREANDA?	TREANDA® (bendamustine HCl) for Injection, approved by the U.S. Food and Drug Administration in March 2008 is a novel chemotherapy with alkylating properties for the treatment of patients with chronic lymphocytic leukemia (CLL). The efficacy of TREANDA relative to first-line therapies other than chlorambucil has not been established.
How does TREANDA work?	<p>Preclinical data demonstrate that TREANDA can lead to cell death via several pathways.</p> <p>TREANDA damages the DNA in cancer cells, which leads to programmed cell death (a normal process of cell self-destruction known as apoptosis) and a disruption of normal cell division (mitotic checkpoint inhibition) which leads to an alternate cell death pathway (mitotic catastrophe).</p> <p>The exact mechanism of action of TREANDA remains unknown.</p>
In what disease areas is TREANDA being studied?	<p>In worldwide clinical trials, bendamustine HCl, the active ingredient in TREANDA, has been or is being evaluated for safety and efficacy in the treatment of many tumors and different regimens including:</p> <ul style="list-style-type: none">• Chronic Lymphocytic Leukemia• Non-Hodgkin's Lymphoma• Multiple myeloma• Small cell lung cancer• Breast cancer• Hodgkin's lymphoma <p>TREANDA is only approved for use in the United States as a treatment for chronic lymphocytic leukemia.</p>

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<p>What has been the clinical development history of TREANDA?</p>	<p>Based upon the extensive clinical studies of TREANDA in hematologic and solid tumors conducted in Germany, a clinical development program was initiated in the United States. Major milestones were met in 2007 when Cephalon submitted two new drug applications (NDAs) for TREANDA. In September 2007 the company submitted an NDA for TREANDA for the treatment of patients with CLL, for which the FDA also has granted orphan drug designation and priority review. In December 2007, Cephalon submitted an NDA to the FDA for TREANDA for the treatment of patients with indolent (slow-growing) non-Hodgkin's lymphoma (NHL) who have progressed during or following treatment with rituximab or a rituximab-containing regimen; an FDA review decision is expected by October 31, 2008.</p> <p>Key studies:</p> <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 and demonstrated a manageable and predictable tolerability profile. Chlorambucil, a chemotherapy drug, is an FDA-approved therapy for patients with CLL. • The TREANDA NDA for relapsed indolent NHL is supported by three studies in patients with NHL, including two single-agent studies and one in combination with rituximab. In these studies, patients treated with TREANDA had a high rate of response and a manageable and predictable tolerability profile. • 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 single agent or in combination with other commonly-used therapies. <p>While adverse events are expected with this type of therapy, those seen in clinical trials with TREANDA are generally predictable and manageable. The most common adverse events were hematologic (e.g., myelosuppression) and non-hematologic such as fever, fatigue and gastrointestinal (e.g., nausea, vomiting), however patients rarely experienced hair loss.</p>
<p>Who will market TREANDA in the United States?</p>	<p>Cephalon, Inc. (Nasdaq: CEPH), Frazer, PA, an international biopharmaceutical company, owns all rights to the investigational agent TREANDA in the United States and it will be marketed by Cephalon Oncology.</p>
<p>What is Cephalon Oncology?</p>	<p>Cephalon Oncology is a strategic business unit focused on the development and commercialization of oncology products and resources for patients and healthcare providers. The Cephalon Oncology portfolio includes a number of promising investigational and marketed compounds. In addition to TREANDA, the Cephalon Oncology therapeutic portfolio in the United States includes TRISENOX® (arsenic trioxide) injection, a product approved in the United States for the treatment of patients with relapsed or refractory acute promyelocytic leukemia, and CEP-701, an oral small molecule inhibitor of tyrosine kinases including FLT-3, TRK and JAK-2, in phase 3 development for acute myeloid leukemia.</p> <p>For more information about Cephalon Oncology, visit www.CephalonOncology.com.</p>