

Eltrombopag for Thrombocytopenia Due to Prior Treatment or Disease and Those Due to Idiopathic Thrombocytopenia Purpura (ITP)

A Phase II Trial of Eltrombopag for Patients with Chronic Lymphocytic Leukemia (CLL) and Thrombocytopenia

Objective:

- To determine the overall response rate of eltrombopag in patients with CLL and thrombocytopenia
- To determine time-to-response, time to CLL progression, to assess tolerability and toxicities of eltrombopag and to assess pharmacokinetics of the drug and thrombopoietin levels in CLL patients

Eligibility Criteria:

- Diagnosis of CLL or SLL; no Richter's, MDS or CML
- Age 18 or greater
- Must be platelet (PLT) transfusion-dependent to maintain PLTS at or above 20K/ μ l, or average of two PLT counts taken within two weeks of screening equal or greater than 50K/ μ l (non-transfused) with no single count greater than 55K/ μ l
- ITP patients must have failed at least 1 prior treatment for ITP with no concurrent treatment for ITP, except for stable doses of corticosteroids or cyclosporine for two weeks prior to enrollment with a plan for dose taper if responding to eltrombopag
- No chemotherapy treatment for CLL within the last three weeks
- No treatment with thrombomimetic agents in the past three months
- ECOG performance status of 2 or less
- Adequate liver and renal function
- No active infection or significant medical illness
- No pregnant or breast-feeding females
- Must be willing to use adequate contraceptive precautions



Procedures:

- All patients will be registered at MD Anderson
- Oral eltrombopag will be given daily and dose adjustments may occur every two weeks
- Routine blood tests are done at MD Anderson screening to determine eligibility
- May be performed by the referring physician or at his/her office:
 - Blood tests, physical exam, side effects and bruising or bleeding will be performed at each visit
 - Visits will be weekly for one month, biweekly for two more months, and then monthly
 - Formal response evaluation will occur monthly and include review of PLT transfusion history and blood counts
- If the disease improves, a bone marrow biopsy, physical and lab testing will occur at MD Anderson
- Eltrombopag treatment will continue until loss of PLT response or treatment for CLL/SLL is necessary

Benefits for Patients:

- May help to control thrombocytopenia or ITP
- Future patients may benefit from what is learned

Protocol # 2010-0123

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Schedule an appointment or make referral online at

<https://my.mdanderson.org> or call (713) 563-2000.

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For information on related articles or references for this study,

visit <http://physicianrelations.org>

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