

Unique Protocol ID: 13131

Secondary IDs: I3S-MC-JABA

Brief Title: A Study of LY2787206 in Cancer and Anemia

Official Title: A Phase 1 Safety Study of LY2787106 in Patients With Cancer and Anemia

Study Type: Interventional

Sponsor: Eli Lilly and Company

Collaborators: none

Brief Summary: This study will evaluate the safety LY2787106 in patient with cancer and anemia. It will also evaluate when LY2787106 can improve anemia.

Overall Status: Recruiting

Study Start Date: October 2009

Study Completion Date: July 2011 [Anticipated]

Study Design:

Primary Purpose: Supportive Care

Study Phase: Phase 1

Interventional Model: Single Group Assignment

Number of Arms: 1

Masking: Open Label

Allocation: N/A

Control: Uncontrolled

Endpoint Classification: Safety Study

Enrollment: 50 Anticipated

Primary Outcome Measure:

Measure: Adverse Events/Serious Adverse Events

Timeframe: throughout study

Secondary Outcome Measure:

Measure: Hemoglobin

Timeframe: throughout study

Condition(s): Anemia

Keywords:

Cancer related Anemia

Arms	Assigned Interventions
Experimental: LY2787106	Drug: LY2787106  Dose Escalation, intravenous, day one of up to three 21 day cycles

Eligibility Criteria:

Inclusion Criteria:

- Have histological or cytological evidence of non-myeloid cancer (solid tumors, lymphomas or multiple myeloma) that is metastatic and/or incurable
- Have been treated with at least one systemic (oral, IV or SQ) anti-cancer therapy or regimen
- Have a hemoglobin  $\leq 10$  g/dL
- Have given written informed consent prior to any study-specific procedures
- Have adequate organ function including:
  - Hematologic: Absolute neutrophil count (ANC)  $\geq 1.5 \times 10^9/L$  and platelets  $\geq 75 \times 10^9/L$ . Platelet transfusions are not allowed within 14 days of enrollment to reach  $75 \times 10^9/L$
  - Hepatic: Bilirubin  $\leq 1.5$  times upper limits of normal (ULN), alanine transaminase (ALT), and aspartate transaminase (AST)  $\leq 2.5$  times ULN
  - Renal: Serum creatinine  $\leq 1.5$  times ULN
- Have an Eastern Cooperative Oncology Group (ECOG) performance status of  $\leq 2$
- If female with child bearing potential: Have a negative serum pregnancy test
- Have an estimated life expectancy of  $\geq 12$  weeks

Exclusion Criteria:

- Have received treatment in the previous 21 days with, or have not recovered fully from, a drug that has not received regulatory approval for any indication

- Have received ESAs or red blood cell transfusions in the previous 28 days, or in the investigator's opinion, likely to need red blood cell transfusion more frequently than every 28 days
- Have received parenteral iron supplementation within the prior 14 days or requires oral iron supplementation
- Have a documented history of pure red cell aplasia, thalassemia major or sickle cell disease
- Have a history of cirrhosis or major organ transplantation
- Significant cardiac disease, such as:
  - NYHA CHF of Class III or IV
  - known ejection fraction (EF) < 40%
  - history of myocardial infarction (MI) in the past year
  - unstable angina
  - $\geq$ CTCAE v3.0 Grade 2 hypertension ( $\geq$ 150/100 mm Hg)
  - clinically significant cardiac arrhythmia ( $\geq$ CTCAE Grade 2)
  - QTc >470 msec, or
  - other clinically significant baseline ECG abnormality.
- Have received treatment in the previous 24 weeks for anemia caused by a chronic disease other than cancer, such as rheumatoid arthritis, systemic lupus erythematosus, or myelofibrosis
- Have a chronic disease (e.g. RA, SLE, etc) other than cancer that was treated with chemotherapy (e.g. methotrexate, cyclophosphamide, etc.) or biological agents (e.g. agents targeting TNFalpha, IL-6, etc.) in the previous 12 weeks
- Have evidence of hemolysis or clinically significant bleeding
- Have a clinically significant systemic infection within 14 days of enrollment
- Have a suspected or confirmed history of hemochromatosis
- Have other serious preexisting medical conditions (left to the discretion of the investigator)
- Have symptomatic central nervous system malignancy or metastasis (screening not required)
- Have acute or chronic leukemia
- Are a female who is pregnant or lactating
- Have a history of human immunodeficiency virus (HIV), hepatitis B, or hepatitis C (screening not required)
- Have received external beam radiotherapy to more than 25% of the bone marrow
- Have known clinically significant hypersensitivity to biologic agents
- Have received live vaccine(s) within 1 month of screening or with plans of doing that during the participation to the study

Minimum Age: over 18 years

Maximum Age: N/A

Gender: Both

Contact for Public Queries: Call 1-877-CTLILLY (1-877-285-4559) or 1-317-615-4559 Mon - Fri 9 AM - 5 PM Eastern time (UTC/GMT - 5 hours, EST)

Contact for Scientific Queries: Call 1-877-CTLILLY (1-877-285-4559) or 1-317-615-4559 Mon - Fri 9 AM - 5 PM Eastern time (UTC/GMT - 5 hours, EST)

Locations:

Lilly Clinical Trial Site  
Santa Monica, CA  
Recruiting

Lilly Clinical Trial Site  
Encinitas, CA  
Recruiting

Lilly Clinical Trial Site  
Albany, NY  
Recruiting

Lilly Clinical Trial Site  
Norfolk, VA  
Recruiting

Lilly Clinical Trial Site  
Kettering, OH  
Recruiting

Lilly Clinical Trial Site  
Indianapolis, IN  
Recruiting

Lilly Clinical Trial Site  
Vancouver, WA  
Recruiting

Lilly Clinical Trial Site  
Dallas, TX  
Recruiting

Lilly Clinical Trial Site  
Nashville, TN  
Recruiting