

Unique Protocol ID: 13008

Secondary ID: I3O-MC-JSBA

Brief Title: A Study of LY2801653 in Advanced Cancer

Official Title: A Phase 1 Study of LY2801653 in Patients With Advanced Cancer

Study Type: Interventional

Sponsor: Eli Lilly

Collaborators: none

Brief Summary: The purpose of this study is to determine a safe dose of LY2801653 to be given to patients with advanced cancer and to determine any side effects that may be associated with LY2801653 in this patient population. Efficacy measures will be used to assess the activity of LY2801653 in this patient population.

Overall Status: Recruiting

Study Start Date: October 2009

Study Completion Date: March 2012

Study Design:

Primary Purpose: Treatment

Study Phase: Phase 1

Interventional Model: Single Group Assignment

Number of Arms: 1

Masking: Open Label

Allocation: Non-Randomized

Control: Uncontrolled

Endpoint Classification: Safety Study

Enrollment: 105 [Anticipated]

Primary Outcome Measure:

Measure: To determine a recommended Phase 2 dose range and schedule of LY2801653 in patients with advanced cancer

Timeframe: throughout study

Secondary Outcome Measure:

Measure: To document any antitumor activity observed with LY2801653 in patients with advanced cancer

Timeframe: throughout study

Measure: To characterize the safety and toxicity profile of LY2801653 in patients with advanced cancer

Timeframe: throughout study

Measure: To estimate the area under the concentration / time curve (AUC) of LY2801653

Timeframe: Cycle 1, day 1; cycle 2, day1

Measure: To estimate the maximum plasma concentration (C_{max}) of LY2801653

Timeframe: Cycle 1, day 1; cycle 2, day1

Measure: To explore the pharmacodynamic (PD) effect of LY2801653 on circulating DNA

Timeframe: throughout study

Measure: To explore the pharmacodynamic (PD) effect of LY2801653 on CK-18 levels

Timeframe: throughout study

Measure: To explore the pharmacodynamic (PD) effect of LY2801653 on circulating tumor cells

Timeframe: throughout study

Condition(s): Cancer

Arms	Assigned Interventions
Experimental: A: LY2801653 This study consists of a dose escalation of LY2801653 followed by dose confirmation cohorts in specific tumor types.	Drug: LY2801653 LY2801653 given orally once daily during 28-day cycles

Eligibility Criteria:

Inclusion Criteria:

- Diagnosed with advanced and / or metastatic cancer during dose escalation
- Diagnosed with colorectal, gastric, or papillary renal cell carcinoma during dose confirmation
- Must be at least 18 years of age
- Adequate hematologic, renal, and liver functions
- ECOG status of 0 or 1
- Ability to swallow capsules

Exclusion Criteria:

- Have serious preexisting medical conditions that would preclude participation in the study
- Have a chronic underlying infection
- Have symptomatic central nervous system (CNS) malignancy or metastasis
- Have current acute or chronic leukemia
- Are pregnant or lactating
- Have hepatocellular cancer, liver cirrhosis with a Child-Pugh stage of B or higher, or have received a liver transplant
- Have a history of congestive heart failure with a New York Heart Association class greater than 2, unstable angina, recent myocardial infarction (within 6 months of study enrollment), transient ischemic attacks, stroke, or arterial or venous vascular disease
- Have a QTc interval greater than 470 msec

Minimum Age: 18

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
Philadelphia, PA
Recruiting

Lilly Clinical Trial Site
Washington, DC
Recruiting