

Unique Protocol ID: 11980

Secondary ID: H9V-JE-GFRC

Brief Title: A Study in Japanese Patients With Chronic Kidney Disease

Official Title: A Single-Dose, Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Subcutaneous LY2382770 in Japanese Patients With Chronic Kidney Disease

Study Type: Interventional

Sponsor: Eli Lilly and Company

Collaborators: N/A

Brief Summary: The main purpose of this study is to evaluate the safety and tolerability of single doses of LY2382770 administered by subcutaneous injection to subjects with Stage 2 to 4 chronic kidney disease (CKD).

Overall Status: Recruiting

Study Start Date: March 2010

Study Completion Date: September 2010

Study Design:

Primary Purpose: Treatment

Study Phase: Phase 1

Interventional Model: Parallel Assignment

Number of Arms: 4

Masking: Double Blind (Subject, Investigator)

Allocation: Randomized

Control: Placebo Control

Endpoint Classification: Safety Study

Enrollment: 15 [Anticipated]

Primary Outcome Measure:

Measure: Clinically Significant Effects

Timeframe: 3 months

Secondary Outcome Measure:

Measure: Pharmacokinetics – Area Under the Curve (AUC)

Timeframe: Predose, 4, 24, 72 hours and 5, 7, 14, 21, 28, 42, 56 days after single injection

Measure: Pharmacokinetics – concentration maximum (C<sub>max</sub>)

Timeframe: Predose, 4, 24, 72 hours and 5, 7, 14, 21, 28, 42, 56 days after single injection

Measure: Change in urine Type IV collagen

Timeframe: Predose, 7, 14, 28, 56 days after single injection

Measure: Change in urine connective tissue growth factor (CTGF) profiles

Timeframe: Predose, 7, 14, 28, 56 days after single injection

Measure: Change in urine transforming growth factor (TGF)- $\beta$ 1 profiles

Timeframe: Predose, 7, 14, 28, 56 days after single injection

Measure: Change in urine creatinine

Timeframe: Predose, 7, 14, 28, 56 days after single injection

Measure: Change in urine albumin profiles

Timeframe: Predose, 7, 14, 28, 56 days after single injection

Condition(s): Chronic Kidney Disease

Keywords:

chronic kidney disease

CKD

TGF-beta

Arms	Assigned Interventions
Experimental: 20 mg LY2382770	Drug: LY2382770 Administered by subcutaneous injection, single dose
Experimental: 60 mg LY2382770	Drug: LY2382770 Administered by subcutaneous injection, single dose
Experimental: 120 mg LY2382770	Drug: LY2382770 Administered by subcutaneous injection, single dose
Placebo Comparator: Placebo	Drug: Placebo Administered by subcutaneous injection, single dose

#### Eligibility Criteria:

##### Inclusion Criteria:

- Ambulatory men and women with stable chronic kidney disease (CKD) (as determined by the investigator) due to diabetes, hypertension, or focal segmental glomerulosclerosis (FSGS) who have an estimated glomerular filtration rate (eGFR) of 15 to 89 mL/min/1.73 m<sup>2</sup>
- A physiological status that is not expected to jeopardize successful completion of the study
- If receiving an angiotensin-converting enzyme (ACE) inhibitor, an angiotensin II receptor blocker (ARB), or both drugs concurrently, the dose(s) must be stable for at least 2 months prior to randomization
- Urine albumin/Creatinine ratio is more than 30mg/g
- Clinical laboratory test results that are consistent with the severity of the subject's CKD or results with acceptable deviations that are judged to be not clinically significant by the investigator

##### Exclusion Criteria:

- History of autoimmune disease, or having known current or quiescent chronic inflammatory or autoimmune disease, such as lupus nephritis
- Positive for both antinuclear antibody (ANA) and double-strand DNA (dsDNA) antibody (only ANA positive samples will be automatically tested for dsDNA antibody) at screening
- Receiving dialysis (hemodialysis or peritoneal dialysis)
- Hemoglobin is less than 10g/dL
- Glycosylated hemoglobin is more than 10%
- A current organ transplant

Minimum Age: 20 years

Maximum Age: 75 years

Gender: Both

Contact for Public Queries: There may be multiple sites in this clinical trial. 1-877-CTLILLY (1-877-285-4559) or (1-317-615-4559)

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

Osaka, Japan

Recruiting