

Unique Protocol ID: 13299

Secondary ID: I2R-JE-BIAH

Brief Title: A Study for Patients With Type 2 Diabetes

Official Title: A Multiple Dose Study to Evaluate the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of LY2605541 in Japanese Patients With Type 2 Diabetes Mellitus

Study Type: Interventional

Sponsor: Eli Lilly and Company

Collaborators: N/A

Brief Summary: To assess the PK of LY2605541 after multiple, daily subcutaneous doses in patients with type 2 diabetes mellitus.

Overall Status: Completed

Study Start Date: April 2010

Study Completion Date: August 2010 [Actual]

Study Design:

Primary Purpose: Treatment

Study Phase: Phase 1

Interventional Model: Single Group Assignment

Number of Arms: 3

Masking: Open Label

Allocation: Non-randomized

Control: Uncontrolled

Endpoint Classification: Pharmacokinetics Study

Enrollment: 18 [Anticipated]

Primary Outcome Measure:

Measure: Pharmacokinetics, maximum observed drug concentration (C<sub>max</sub>)

Timeframe: days 1, 7 and 14

Measure: Pharmacokinetics, area under the curve (AUC)

Timeframe: days 1, 7 and 14

Measure: Pharmacokinetics, time of maximum observed drug concentration (t<sub>max</sub>)

Timeframe: days 1, 7 and 14

Secondary Outcome Measure:

Measure: Clinically significant effects

Timeframe: 10 weeks

Measure: Pharmacodynamics, change in blood glucose

Timeframe: days 1, 7 and 14

Measure: Pharmacodynamics, change in C-peptide

Timeframe: baseline, days 1, 2, 7, 8, 14, 15, 17, 19, 21, 23 and 25

Measure: Pharmacodynamics, change from baseline to 15 days endpoint in HbA<sub>1c</sub>

Timeframe: baseline, day 15

Condition(s): Diabetes Mellitus, Type 2

Arms	Assigned Interventions
Experimental: 0.025 mg/kg LY2605541	Drug: LY2605541 subcutaneous doses for 14 days
Experimental: 0.075 mg/kg LY2605541	Drug: LY2605541 subcutaneous doses for 14 days
Experimental: 0.15 mg/kg LY2605541	Drug: LY2605541 subcutaneous doses for 14 days

## Eligibility Criteria:

### Inclusion Criteria:

- Type 2 diabetes mellitus
- Have been treated with a stable dose regimen of oral antidiabetic agents for at least 60 days prior to screening. Biguanides, phenylalanine derivative, alpha glucosidase inhibitors or dipeptidyl peptidase-4 inhibitors must be discontinued and sulfonylurea dose will be reduced to the country-specific minimum recommended dose from at least 2 weeks before the day of LY2605541 initial dose. Patients who used thiazolidines must have stopped it for 3 months prior to the day of LY2605541 initial dose
- HbA1c value between 6.5% and 10.0%, inclusive at screening and with a fasting blood glucose value of 200 mg/dL or less at screening
- Body Mass Index 18.5 to 35.0 kg/m<sup>2</sup>

### Exclusion Criteria:

- Have previously completed or withdrawn from this study or any other study investigating LY2605541, and received study drug
- Have had >1 episode of severe hypoglycaemia within 6 months of screening or are currently diagnosed as having hypoglycaemia unawareness
- Are pregnant or intend to become pregnant during the course of the study.
- Are women who are breastfeeding
- Have cardiac disease with functional status
- Have a history of renal transplantation, are currently receiving renal dialysis, or have impaired renal function measured as creatinine clearance <70 mL/min
- Have a malignancy other than basal cell or squamous cell skin cancer
- Have had a blood transfusion or severe blood loss within 3 months prior to screening, or have known hemoglobinopathy, hemolytic anemia, sickle cell anemia, or have a hemoglobin value <11 g/dL (males) or < 10 g/dL (females), or any other condition known to interfere with HbA1c methodology
- Irregular sleep/wake cycle

Minimum Age: 20 years

Maximum Age: 64 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

Tokyo, Japan

Completed