STUDY SYNOPSIS

Name of Sponsor/Company
AstraZeneca Pharmaceuticals (Philippines), Inc

Study Number
NCT01223456

Title
A descriptive study of the efficacy and safety of ONGLYZA (Saxagliptin) under conditions of actual use in the Philippines

Study period
Patient registration: 29 October 2010 to 15 November 2012
Patient treatment: 29 October 2012 to 15 December 2012

Phase of the Study IV

Objectives
The study is a three-year post marketing surveillance that aims to monitor the safety and efficacy of ONGLYZA in the management of diabetes mellitus type 2 under the conditions of actual use in the Philippines.

Primary Objective:

To document and monitor safety and tolerability of ONGLYZA in actual clinical practice.

Secondary Objectives:

- To determine the response to ONGLYZA based on glycemic and clinical improvement after at least 3 months of treatment.
- To determine the level of satisfaction among physicians who prescribe ONGLYZA based on the efficacy and tolerability

Study design

The study is an open-label, multi-center, prospective descriptive study, done under the conditions of actual use of ONGLYZA in clinical practice.

Number of subjects planned/enrolled

The study initially planned to include approximately 3,000 patients within the period of three years. Up to the end of 2012, investigators across 11 sites nationwide were able to enrol 820 patients. The sponsor decided to stop the patient recruitment in relation to the guidance given by the Philippine Food and Drug Administration on April 2013. A total of 594 patients out of the 820 enrolled were able to complete the study.

Study population

The target population are patients ≥18 years old, male and non-pregnant female, who have diabetes mellitus type 2 and are prescribed ONGLYZA by their attending physicians (refer to the approved prescribing information). Patients must be able to understand and give voluntary full, informed consent.

Treatments

The recommended dose of ONGLYZA is 2.5 mg or 5 mg once daily as monotherapy or as add-on combination therapy with metformin, a thiazolidinedione, or a sulfonylurea. The recommended starting doses of ONGLYZA and metformin, when used as initial combination therapy, are 2.5 mg or 5 mg ONGLYZA plus 500 mg metformin once daily. Patients with inadequate glycemic control on this starting dose should further have their metformin dose increased according to approved local label guidelines. ONGLYZA can be taken with or without food.

Analyses variables

- Treatment Response

Glycemic control: Mean absolute change from baseline in glycosylated hemoglobin A1c (Hb1Ac) three months post-treatment in all patients who have both baseline and 3 month post-treatment HbA1c

Clinical Endpoint: Doctor's clinical assessment of each individual patient's response to saxagliptin treatment based on glycemic control (HbA1c) and improvement of clinical symptoms.

- Safety

All adverse events observed during the treatment duration should be recorded and reported to AstraZeneca Philippines following SOP on Adverse Event Handling in the Philippines (SOP-330-PH ed 2.0).

Statistical methods

Descriptive analysis (mean, frequencies and percentages) will be done using Epi Info and STATA to describe and assess efficacy and safety data.

Results – Study Subjects

The 820 patients enrolled in the study all met the eligibility criteria. However, only 549 patients were able to complete the study, meaning with pre- and post treatment evaluation in the case report forms (CRF). One patient dropped out due to pregnancy.

Demographic Characteristics at Baseline

Parameter	Total
Patients enrolled	820
Patients with complete CRFs, n (%)	549 (66.95)
Mean Age (years), (Range)	58.61(25-100)
Males, n (%)	229 (41.7)
Females, n (%)	320 (58.3)
Mean Diabetes Duration (years), (range)	7.17 (0.25-50)

Results – Efficacy

Parameter	Total
HbA1c	
Mean HbA1c (%) at Baseline	6.91
Mean HbA1c (%) post treatment	5.52
Mean HbA1c (%) Difference	1.39
Clinical Response to Treatment	
YES, n (%)	510 (95.3)
NO, n (%)	25 (4.7)
Physician Satisfaction	
Satisfied, n (%)	500 (93.56)
Not Satisfied, n (%)	35 (6.54)

Results – Safety

Five patients (5) reported adverse events (AE) while on therapy. Of the five, one patient reported two AEs – pruritus and headache.

Type of Adverse Events Reported	Frequency
Headache	3
Bipedal Edema	1
Pruritus	1
Epigastric pain	1