

## STUDY REPORT SUMMARY

### ASTRAZENECA PHARMACEUTICALS

**FINISHED PRODUCT:** N/A

**ACTIVE INGREDIENT:** N/A

<b>Study No:</b> NIS-GTH-NEX-2009/1
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PREVALENCE OF GASTROESOPHAGEAL REFLUX DISEASE IN PATIENTS WITH UPPER GASTROINTESTINAL TRACT SYMPTOMS IN THAILAND
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**Developmental Phase:** NIS

**Study Completion Date:** 25 Feb 2011

**Date of Report:** 22 Sep 2011

#### OBJECTIVES:

To determine the prevalence of GERD in patients who suffer with upper gastrointestinal tract symptoms by using GerdQ Thai version and to evaluate response to various treatments.

#### METHODS:

This is a non- interventional hospital-based, prospective, epidemiological study conducted in 27 hospitals across Thailand between December, 2009 and February, 2011. Male or female aged of at least 18 years who have symptoms suggestive of upper gastrointestinal tract symptoms such as heartburn/ regurgitation, abdominal pain, bloating, belching and nausea / vomiting were eligible. Each patient was assessed for GERD using GerdQ Thai version. Patients who had been diagnosed as having GERD were treated based on clinical judgments of the attending physicians. Patients who had been treated for GERD and comeback to the same hospital 4-8 weeks after the last visit were assessed for their responses to the treatments using the GerdQ. Patients with GerdQ score of 8 or greater were diagnosed as having GERD.

#### RESULTS:

Data was collected from 27 hospitals across Thailand. A total of 4,183 patients diagnosed with clinical diagnosis of GERD were screened, 169 were excluded. Among a total of 4,014 patients with upper gastrointestinal tract symptoms who were enrolled, 1,958 patients had GerdQ score of 8 or greater. From this group, 1,497 patients made follow-up visits. The rate of follow-up was 76.5%. Of the 4,014 patients, 68.8% were female, mean age of 51.5±13.8 years, and 81.4% were non-smokers. About one third of them, 33.7%, were over-weight. Most of them had been with upper gastrointestinal symptoms for half a year. During the last 4 weeks prior to the hospital visit, the most common upper gastrointestinal tract symptoms was bloating, 87.3%, followed by abdominal pain, 80.9%, and belching, 66.8%. About one fifth of patients (22.0%) had 6 symptoms concurrently. The prevalence of GERD among patients who had upper gastrointestinal tract symptoms was 48.8% (95%CI: 47.2 to 50.3). At baseline, mean GerdQ Score was 7.3 (95%CI: 7.2 to 7.4). About one fifth, 21.7%, of them were classified as disrupting GERD (i.e., GerdQ Score ≥8 and Impact score ≥3). Treatment advice based on GerdQ Score was that 38.4% of patients require longer treatment, a higher dosage, or a more effective treatment. Over all, GerdQ score of patients was reduce at the follow-up visits, with the mean changes of 3.1 (95%CI: 2.9 to 3.2; p-value < 0.001).

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