STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: This non interventional trial was NOT designed to document a specific product
ACTIVE INGREDIENT:

Study No: NIS-GAT-NEX-2007/1
LIFE NIS

Developmental phase: marketed
Study Completion Date: 01/2008
Date of Report: 10/2008

OBJECTIVES:

Gastroesophageal reflux disease (GERD) is a chronic disease that causes a substantial reduction in the quality of life for persons suffering from it.

The goal of the „LIFE“ patient observational program was to demonstrate the restrictions that patients with GERD experience in everyday life and, using the GERD Impact Scale (GIS), to show to what degree its symptoms impair patient's lives, as well as to determine how well an effective acid suppression medication might improve the symptoms.

METHODS:

The „LIFE“ patient observational program is a prospective, open, multi-center, non-interventional study, i.e., a study without a comparative group. The observational program, in which 85 different centers participated, included 632 patients. The subjects were reflux patients who received therapy for newly-occurring, typical GERD symptoms. The first patient was included in the study on Jan. 5, 2007 and the last was included on Nov. 26, 2007. An inclusion visit (Visit 1), an intermediate visit after 2-3 weeks (Visit 2), and a final visit after 6-8 weeks (Visit 3) were documented.

An assessment of acid control was done using the questions in the GIS (GERD Impact Scale). The GIS asks the patients about their symptoms and their impact on the patients' daily life. The patients state how often they suffer from reflux symptoms and how they disturb their sleep, work, eating habits, and social life. They are also asked about whether they take

over-the-counter GERD-medications. One of four possible answers („daily“, „often“, „sometimes“, „never) is checked to describe how often symptoms occur.

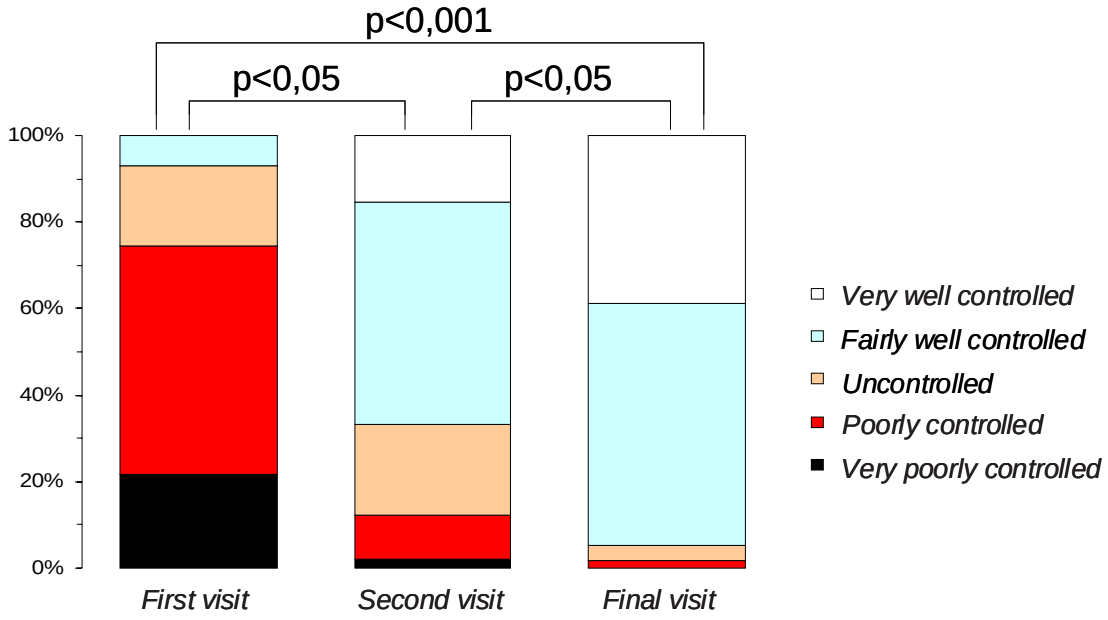
RESULTS:

More than 99% of the therapeutic medications used were proton pump inhibitors, whereby most of these were esomeprazole (95.1%) and only a few (< 1%) were H2-receptor antagonists.
It was possible to freely choose and combine the therapeutic management, which was initiated before participating in the user observation.

Results of the acid contoll measured with the GERD Impact Scale (GIS)

The moderate to very poor acid suppression ascertained for 92.6% (n=632) of the patients at baseline had significantly improved during the study (acid suppression improvement at the time of the intermediate visit vs. inclusion visit $p<0.05$; 67.1% vs. 7.5% very good/good; 12.2% vs. 73.0% poor/very poor; moderate 20.7% vs. 19.6% and at the time of the final visit vs. the inclusion visit $p<0.001$; 94.7% vs. 7.5% very good/good; 1.6% vs. 73.0% poor/very poor; moderate 3.8% vs. 19.6%).
Since 95% of the patients were treated with esomeprazole (n=601), the results of this patient group is shown in detail. At the intermediate visit, over two thirds of the patients (66.7% vs. 7.2% at the inclusion visit) (n=401 vs. 43) had very good/good acid suppression. The portion of the patients with poor/very poor acid suppression sank to 2.3% vs. 74.5% at the inclusion visit (n=74 vs. 448). By the final visit, further significant improvement of acid suppression could be achieved ($p<0.05$ vs. intermediate visit, $p<0.001$ vs. final visit): In total, 94.8% (n=570) of the patients treated with esomeprazole had very good to good acid suppression, 3.5% (n=21) had moderate acid suppression, and the portion of patients with poor acid suppression could be reduced to 1.7% (n=10) (very poor: 0.0%) (Figure 1).

Figure 1 Assessment of acid control for patients treated with esomeprazole using the Gerd Impact Scale



Safety and tolerance:

In the course of the study, adverse events were documented for a total of four patients treated with esomeprazole, whereby none of the adverse events were considered to be serious.