AstraZeneca

NIS REPORT SYNOPSIS

European Study in Patients with Osteoarthritis, Rheumatoid Arthritis, or Ankylosing Spondylitis at Gastrointestinal Risk: A Retrospective, Non-interventional Study of VIMOVO™ Prescribing Patterns

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: VIMOVO™

ACTIVE INGREDIENTS: naproxen and esomeprazole magnesium

Developmental Phase: NOT APPLICABLE

Study Completion Date: Last Patient Last Visit (last visit date for data included in this report): 17 March 2014

Date of Report: 12 June 2014

OBJECTIVES:

The study objectives were as follows:

- To describe the extent to which various factors influence the decision to prescribe VIMOVO to patients with osteoarthritis (OA), rheumatoid arthritis (RA), or ankylosing spondylitis (AS) who are at gastrointestinal (GI) risk, and to estimate the proportion of these patients for whom lower doses of naproxen or other non-steroidal anti-inflammatory drugs (NSAIDs) were considered not sufficient
- To describe the characteristics of patients prescribed VIMOVO, including demography, comorbidities, OA/RA/AS disease history (disease duration and treatment), and risk factors for GI and cardiovascular (CV) events
- To describe the characteristics of physicians prescribing VIMOVO, including specialty and practice setting

METHODS:

This was a multinational, multicentre, non-interventional, retrospective, descriptive study of generalist and/or specialist (rheumatologist and orthopaedist) decision-making with regard to VIMOVO prescriptions for patients with OA, RA or AS who are at GI risk. The sample size was planned to be 1500 to 2000 patients from approximately 250 sites across 5 European countries.

In the period immediately after launch, physicians were introduced to VIMOVO prescribing information. Therefore, patients treated with VIMOVO within the first 3 months after launch were not included in the cohort to ensure that physicians would have had time to be introduced to and become familiar with the prescribing information and the appropriate use of VIMOVO. The study cohort therefore included patients initiating VIMOVO during the 3 to 12 months following the launch of VIMOVO in each country.

Prior medical history, medication history and diagnosis were collected through patient medical records. A questionnaire was also used to collect prescriber characteristics in addition to factors considered when prescribing VIMOVO.

Data collection was initiated following a country-specific index date, approximately 6 months after product launch; based upon actual market uptake of VIMOVO, this may have varied to up to 12 months post launch. All study sites within a country were assigned the same index date and were not contacted prior to the index date. Initiation of site-specific activities (for example, ethics committee approval, investigator training, necessary consents, etc) for selection of patient records meeting study selection criteria commenced on or following the index date. For every patient included in the study, the VIMOVO prescription date was always before the index date.

RESULTS:

Physician Characteristics

The majority of physicians were categorised as “Primary Care” (79.2%), followed by “Specialist (rheumatologist)” (8.3%), “Hospital (rheumatologist)” (5.8%), “Other” (5.0%), and “Specialist (orthopaedic surgeon)” (1.7%). None of the participating physicians were categorised as “Hospital (orthopaedic surgeon)”.

Overall, the median number of years in practice was 21.5 years. The mean percentage of patients in the physician’s practice diagnosed with either OA, RA, or AS was 26.2%. Most of the patients in the practice were outpatients (overall mean value of 80.3%).

Patient Characteristics

Of the 1571 patients included in the analysis population, the mean age (standard deviation) was 65.3 (11.9) years. The majority of the patients were female (62.6%). The most common reason for VIMOVO use (patients could have more than one reason) was OA (83.8%), followed by RA (15.7%), AS (5.9%), and Other (5.2%). Demographics were similar across countries and physician specialties.

Overall, the most common comedication of special interest was acetylsalicylic acid (ASA; 22.9% of all patients), followed by oral corticosteroids (12.3%), selective serotonin reuptake inhibitors (SSRIs; 11.2%), and anticoagulants (4.6%). The most common comorbid conditions (in ≥10% of patients) were hypertension (44.9%), gastrointestinal disease (25.3%), obesity (22.0%), diabetes (14.5%), other relevant disease (12.3%), and respiratory disease (11.5%).

Overall, 44.4% of patients had any GI history prior to VIMOVO use. The most common GI conditions (in ≥10% of patients) prior to VIMOVO use were dyspepsia (18.3%), gastritis (12.5%), abdominal pain (11.0%), and heartburn (11.0%). Overall, 5.0% of patients had any GI history post VIMOVO use. Dyspepsia and abdominal pain were reported post VIMOVO use in 1.8% and 1.2% of patients, respectively. No other GI condition was reported post VIMOVO use in ≥1.0% of the analysis population.

Overall, 8.7% of patients had any CV history. The reason for VIMOVO use with the highest rate of cardiovascular history was Other (14.8%), followed by AS (10.8%), OA (9.0%), and RA (6.1%). Overall, 23.6% of patients had any other medical history (ie, not GI or cardiovascular). The most common other medical history (in ≥10% of patients) was osteoporosis (10.9%).

Of the 1571 patients included in the analysis population, the majority (78.0%) had prior NSAID use. The reason for VIMOVO use with the highest percentage of ongoing VIMOVO use was AS (71.0%), followed by RA (52.0%), Other (48.1%), and OA (40.6%). For patients whose VIMOVO use was not ongoing, the median duration of VIMOVO use was 31.0 days.

Factors Influencing the Physician's Decision to Prescribe VIMOVO

"Treatment with lower doses of naproxen (<1000 mg total daily dose) or of other NSAIDs was not considered sufficient" was rated as contributing at least "a little bit" (ie, a score ≥1 on the Likert 5-point scale) to the physician's decision to prescribe VIMOVO for 82.2% of patients. Similar rates were seen across reason for VIMOVO use. In addition, this factor was the most frequently rated at least "a little bit" in Finland and Spain (100% and 98.0%, respectively) and in "Hospital (rheumatologist)" and "Specialist (orthopaedic surgeon)" settings (99.3% and 88.9%, respectively).

Overall, the VIMOVO prescribing factors most frequently rated as contributing at least "a little bit" (ie, a score ≥1 on the Likert 5-point scale) were "Patient had high gastrointestinal risk and gastroprotection was considered necessary" (95.5%) and "Label side effect profile of VIMOVO more desirable as compared to that of other NSAIDs" (94.4%). Similar rates were seen for these factors across reason for VIMOVO use.

The VIMOVO prescribing factor least frequently rated as contributing at least "a little bit" was "Patient request" (44.2% overall) regardless of reason for VIMOVO use, country, and most physician specialties. "Specialist (orthopaedic surgeon)" and "Specialist (rheumatologist)" had fewer ratings of at least "a little bit" for "Patient was not compliant with gastroprotection" (22.2% and 77.8%, respectively) compared to "Patient request" (33.3% and 86.3%, respectively).

Overall, the VIMOVO prescribing factors most frequently rated as contributing "most of all" (ie, a score of 4 on the Likert 5-point scale) were "Label side effect profile of VIMOVO more desirable as compared to that of other NSAIDs" (36.2%) and "Patient had high gastrointestinal risk and gastroprotection was considered necessary" (35.7%). These 2 factors were most frequently rated "most of all" regardless of reason for VIMOVO use. "Treatment with lower doses of naproxen (<1000 mg total daily dose) or of other NSAIDs was not

considered sufficient" was also frequently rated "most of all" in Spain (35.5%), Finland (33.3%), Germany (26.7%), and Switzerland (24.8%) and by "Specialist (rheumatologist)" (30.1%).

The VIMOVO prescribing factor least frequently rated "most of all" was "Patient request" (2.7% overall) regardless of reason for VIMOVO use, country, or physician specialty.

Factors Influencing the Physician's Decision to Prescribe NSAID

Overall, the NSAID prescribing factor least frequently rated as contributing at least "a little bit" (ie, a score ≥1 on the Likert 5-point scale) was "Available over-the-counter" (58.3%) regardless of country. Each of the other NSAID prescribing factors were frequently rated at least "a little bit" (93.3% to 100.0%). All NSAID prescribing factors, including "Available over-the-counter", were rated at least "a little bit" with a frequency of 100.0% by "Specialist (orthopaedic surgeon)".

Overall, the NSAID prescribing factor most frequently rated as contributing "most of all" (ie, a score of 4 on the Likert 5-point scale) was "Patient's underlying gastrointestinal risk level" (62.5%). This was the factor most frequently rated "most of all" in each country and physician specialty.

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