

FDA Approved VIMOVOTM for Arthritis Patients At Risk of Developing NSAID-Associated Gastric Ulcers

New treatment option for the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis offered pain relief with a built-in proton pump inhibitor (PPI)

For immediate release: April 30, 2010

Wilmington, DE (April 30, 2010) – AstraZeneca and POZEN Inc. today announced the U.S. Food and Drug Administration (FDA) has approved VIMOVOTM (naproxen and esomeprazole magnesium) delayed-release tablets for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.¹ VIMOVO, co-developed by POZEN Inc. and AstraZeneca, is a fixed-dose combination of enteric-coated naproxen, a pain-relieving non-steroidal anti-inflammatory drug (NSAID), and immediate-release esomeprazole, a proton pump inhibitor (PPI). The FDA approval was supported by data from a clinical development program, including results from the pivotal PN400-301 and PN400-302 studies, which showed patients taking VIMOVO experienced significantly fewer endoscopic gastric ulcers, compared to patients receiving enteric-coated naproxen.²

Twenty-seven million Americans are affected by osteoarthritis³, which is the most common form of arthritis.⁴ While many patients with osteoarthritis treat their symptoms with NSAIDs⁵, 50% of chronic NSAID users are at risk of gastrointestinal ulcers.⁵

"In a single pill, VIMOVO provides a proven pain reliever with a built-in PPI for arthritis patients at-risk for NSAID-associated gastric ulcers," said Howard Hutchinson, M.D., Chief Medical Officer, AstraZeneca. "The approval also demonstrates the commitment of

¹ Prescribing Information for VIMOVO. AstraZeneca Pharmaceuticals LP, Wilmington, DE.

² Goldstein, et al: PN 400 Significantly Reduces the Incidence of Gastric Ulcers Compared With Enteric-Coated Naproxen in Patients Requiring Chronic NSAID Therapy Regardless of Low-Dose Aspirin Use: Results from Two Prospective, Randomized Controlled Trials.

³ Helmick, C., Felson, D., Lawrence, R., Gabriel, S., et al. Estimates of the Prevalence of Arthritis and Other Rheumatic conditions in the United States. *Arthritis & Rheumatism* 58(1), 15-25. 2008.

⁴ Arthritis Foundation. Osteoarthritis: What is it? http://www.arthritis.org/disease-center.php?disease_id=32 Accessed April 16, 2010.

⁵ American College of Gastroenterology (ACG). "Understanding Ulcers, NSAIDs and GI Bleeding." <http://www.acg.gi.org/patients/gibleeding/index.asp#compl>. Accessed April 2009.

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AstraZeneca and POZEN to provide a new pain relief option that addresses the unmet medical needs of these patients.”

In the PN400-301 and 302 studies, the primary end point was the cumulative incidence of gastric ulcers through six months. In each of the trials, patients received either VIMOVO or enteric-coated naproxen 500 mg, twice daily, over a six-month treatment period. Endoscopies were performed at baseline and at one, three, and six months. Data from study PN400-301 showed a 4.1% incidence of gastric ulcers in patients taking VIMOVO, compared to 23.1% among patients taking enteric-coated naproxen ($p < 0.001$). Study PN400-302 showed a 7.1% incidence of gastric ulcers among patients taking VIMOVO, compared to 24.3% with enteric-coated naproxen ($p < 0.001$).²

The most commonly observed adverse events in the clinical trials (experienced by >5% of patients in the VIMOVO group) were erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain and nausea.¹

Important Safety Information about VIMOVO

Cardiovascular Risk

- **Naproxen, a component of VIMOVO, may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.**
- **VIMOVO is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.**

Gastrointestinal Risk

- **NSAIDs, including naproxen, a component of VIMOVO, cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal (GI) events.**

VIMOVO is contraindicated in patients with known hypersensitivity to any component of VIMOVO or substituted benzimidazoles; in patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs; in patients during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery; or in patients in the late stages of pregnancy.

Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals.

Treatment should be withdrawn when active and clinically significant bleeding from any source occurs.

As with all NSAIDs, VIMOVO can lead to the onset of new hypertension or worsening of pre-existing hypertension, either of which may contribute to the increased incidence of CV events. Blood pressure should be monitored closely.

Fluid retention and edema have been observed in some patients taking NSAIDs, including VIMOVO. NSAIDs should be used with caution in patients with fluid retention or heart failure.

NSAIDs, including VIMOVO, may diminish the antihypertensive effect of angiotensin converting enzyme (ACE) inhibitors and angiotensin II antagonists, beta-blockers, and in some patients can reduce the natriuretic effect of furosemide and thiazides.

VIMOVO can be administered with low-dose aspirin (≤ 325 mg/day) therapy. The concurrent use of aspirin and VIMOVO may increase the risk of serious adverse events.

VIMOVO is not recommended in patients with moderate or severe renal insufficiency. In addition, NSAIDs may cause renal toxicity.

VIMOVO is not recommended in patients with severe hepatic insufficiency. Consider dose reduction in mild/moderate hepatic insufficiency. If abnormal liver enzymes persist or worsen discontinue use immediately.

Serious skin adverse reactions such as exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, which can be fatal and can occur without warning. Discontinue VIMOVO at first appearance of skin rash or any other sign of hypersensitivity.

Symptomatic response to esomeprazole, a component of VIMOVO, does not preclude the presence of gastric malignancy.

Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole, of which VIMOVO contains an enantiomer.

Several studies and literature reports indicate that long-term proton pump inhibitor (PPI) therapy is associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine.

Esomeprazole, a component of VIMOVO, inhibits gastric acid secretion and may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (eg, ketoconazole, iron salts, and digoxin).

Concomitant use of VIMOVO and warfarin may result in increased risk of bleeding complications. Monitor for increases in INR and prothrombin time.

The most commonly observed adverse events in clinical trials (experienced by >5% patients in the VIMOVO group) were erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, and nausea.

Please see [Important Safety Information and Prescribing Information](#) for VIMOVO, including **Boxed Warnings**.

NOTES TO EDITORS

About VIMOVO

VIMOVO is a fixed-dose combination of delayed-release enteric-coated naproxen, a non-steroidal anti-inflammatory drug (NSAID), and immediate-release esomeprazole, a stomach acid-reducing proton pump inhibitor (PPI), approved for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. VIMOVO is not recommended for use in children younger than 18 years of age.¹

VIMOVO has been developed as a sequential-delivery tablet formulation combining an immediate-release esomeprazole magnesium layer and an enteric-coated naproxen core. As a result, esomeprazole is released first in the stomach, prior to the dissolution of naproxen in the small intestine. The enteric coating prevents naproxen release at pH levels below 5.5 providing protection against possible local gastric toxicity of naproxen.

AstraZeneca submitted a Marketing Authorization Application (MAA) to the European Medicines Association (EMA) for VIMOVO on October 15, 2009.

Upon the FDA's notification of approval of the New Drug Application for VIMOVO, a \$20 million milestone payment from AstraZeneca will be payable to POZEN.

About Osteoarthritis

Osteoarthritis is a degenerative joint disease caused by the breakdown and eventual loss of the cartilage of one or more joints.⁴ Osteoarthritis is the most common form of arthritis and the most common cause of chronic pain⁴, affecting 151 million individuals worldwide⁶ and 27 million Americans.³ A combination of factors can contribute to osteoarthritis, including being overweight, aging, joint injury or stress, heredity, and muscle weakness.⁷ Osteoarthritis commonly affects the hands, spine or large weight-bearing joints, such as the hips and knees.⁷

About Rheumatoid Arthritis

⁶ Global Burden of Osteoarthritis in the year 2000. (Symmons, Mathers, Pflieger, 2006), Global Burden of Disease 2004.

⁷ Mayo Clinic. Osteoarthritis: Causes. <http://www.mayoclinic.com/health/osteoarthritis/DS00019/DSECTION=causes>. Accessed February 2009.

Rheumatoid arthritis is a chronic disease, mainly characterized by inflammation of the lining, or synovium, of the joints. It can lead to long-term joint damage, resulting in chronic pain, loss of function and disability.⁸

About Ankylosing Spondylitis

Ankylosing spondylitis is a chronic inflammatory disease that primarily causes pain and inflammation of the joints between the vertebrae of the spine and the joints between the spine and pelvis (sacroiliac joints). Ankylosing spondylitis may also cause inflammation and pain in other parts of the body as well.⁹

ABOUT POZEN

POZEN Inc., headquartered in Chapel Hill, NC, is a pharmaceutical company committed to transforming medicine that transforms lives. Since its founding in 1996, POZEN has successfully created novel pharmacologic agents primarily for pain and pain-related conditions by combining existing drug therapies that result in superior patient outcomes. Moving forward, POZEN is poised to become a model 21st century pharmaceutical company dedicated to ensuring that they produce cost-effective, evidence-based medicines; take a fresh approach to sales, marketing and medical education; and deliver high-quality, affordable pharmaceuticals to their customers. The Company's common stock is traded on The NASDAQ Stock Market under the symbol "POZN." For more detailed company information, including copies of this and other press releases, please visit: www.pozen.com.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines. As a leader in gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease medicines, AstraZeneca generated global revenues of \$32.8 billion in 2009. In the United States, AstraZeneca is a \$14.8 billion health care business.

For more information about AstraZeneca in the US or our AZ&Me™ Prescription Savings programs, please visit: www.astrazeneca-us.com or call 1-800-AZandMe (292-6363).

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⁸ Mayo Clinic. Rheumatoid Arthritis. Definition. <http://www.mayoclinic.com/health/rheumatoid-arthritis/DS00020>. Accessed October 2009.

⁹ Mayo Clinic. Ankylosing Spondylitis. Definition. <http://www.mayoclinic.com/health/ankylosing-spondylitis/DS00483>. Accessed September 2009.

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