

# news release

2009-06-30

# ASTRAZENECA DEVELOPMENT PARTNER, POZEN, INC., SUBMITS NEW DRUG APPLICATION FOR PN400 VIMOVO Proposed as trade name

Wilmington, Del. (30 June 2009) – AstraZeneca today announced that its development partner, Pozen, Inc., has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for VIMOVO (PN400) (enteric coated naproxen /esomeprazole magnesium) tablets, a product under investigation for the treatment of the signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS) in patients who are at risk of developing NSAID-associated ulcers. PN400 is a fixed-dose combination of enteric coated naproxen and immediate release esomeprazole. The proposed trade name is VIMOVO, pending regulatory approval. Upon the FDA's notification of acceptance of the NDA filing for PN400, a \$10 million milestone payment from AstraZeneca will be payable to POZEN.

If approved, PN400 would offer a new arthritis treatment option for patients at risk of gastric ulcers, associated with non-steroidal anti-inflammatory drugs (NSAID). Nearly 27 million US residents and 140 million people worldwide suffer from osteoarthritis. The risk factors for NSAID-associated gastric ulcers include age (>/= 50 years), a documented history of gastric ulcers, or concomitant use of low-dose aspirin.

The NDA submission is based on data from a comprehensive clinical trials programme. The PN400 301/302 studies fully met their primary objective, showing subjects taking PN400 experienced significantly fewer endoscopically confirmed gastric ulcers compared to subjects receiving enteric coated (EC) naproxen. The primary endpoint was the cumulative incidence of gastric ulcers through six months. In each of the trials, approximately 400 subjects received either PN400 or EC naproxen 500mg, twice daily, over a six-month treatment period. Subjects underwent upper endoscopies at baseline and at one, three, and six months.

# **NOTES TO EDITORS**

### About VIMOVO (naproxen sodium/esomeprazole magnesium)

VIMOVO is an investigational product under co-development by AstraZeneca and POZEN, Inc. that combines the pain reliever naproxen (an NSAID) with esomeprazole, a proton pump inhibitor (PPI). VIMOVO is under investigation for the treatment of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in patients who are at risk of developing NSAID-associated gastric ulcers.





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#### **About Osteoarthritis**

Osteoarthritis (OA) is a degenerative joint disease caused by the breakdown and eventual loss of the cartilage of one or more joints. Osteoarthritis is the most common form of arthritis and the most common cause of chronic pain, affecting nearly 140 million individuals worldwide, and impacting approximately 18% of women and 9.6% of men aged 60 and above. A combination of factors can contribute to osteoarthritis, including being overweight, aging, joint injury or stress, heredity and muscle weakness. Osteoarthritis commonly affects the hands, feet, spine or large weight-bearing joints, such as the hips and knees.

# **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.

#### About AstraZeneca

AstraZeneca is a major international healthcare business engaged in the research, development, manufacturing and marketing of meaningful prescription medicines and supplier for healthcare services. AstraZeneca is one of the world's leading pharmaceutical companies with healthcare sales of US\$ 31.6 billion and is a leader in gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infectious disease medicines. For more information about AstraZeneca, please visit: www.astrazeneca.com or www.astrazeneca.se

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