



**Sumavel™ DosePro™ (sumatriptan injection) Approved by FDA
for Acute Migraine and Cluster Headache:
First Product Featuring Novel DosePro Needle-Free Delivery System**

SAN DIEGO, Calif., (July 16, 2009): Zogenix, Inc. (“Zogenix”), a privately held pharmaceutical company, today announced that it has received approval from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for Sumavel DosePro (sumatriptan injection) needle-free delivery system to treat acute migraine, with or without aura, and cluster headache. Sumavel DosePro is a first-of-its-kind needle-free delivery system for subcutaneous sumatriptan, a treatment that provides migraine relief within 10 minutes for some patients.

“In my 28 years treating migraine patients, a consistent challenge has been delivering fast relief in a patient acceptable form,” said Roger K. Cady, M.D., director of the Headache Care Center in Springfield, Mo. “Sumavel DosePro will be a welcome treatment option because it combines key benefits – the rapid efficacy of subcutaneous sumatriptan and a simple to use needle-free delivery system.”

Triptans, the most commonly prescribed class of drugs for the treatment of migraine, are a \$3.3 billion market in the U.S. (*Source: Wolters Kluwer Health, Source® Pharmaceutical Audit Suite (PHAST). Based on AWP for U.S. retail prescriptions of drugs in the triptan market, May 2008 —April 2009.*) According to the National Headache Foundation, acute migraines affect nearly 30 million Americans. Tablets are a treatment option for some migraine sufferers, but not all patients are satisfied with tablet therapy. Fast-acting, non-oral options are needed particularly for those who experience migraine episodes associated with sudden onset, waking, nausea or vomiting.

The FDA approval of Sumavel DosePro is based on extensive efficacy and safety data from original filings for needle-based sumatriptan injection (IMITREX®), in addition to clinical studies conducted by Zogenix on bioequivalence, usability and safety specific to the Sumavel DosePro combination drug/needle-free delivery system.

“We are pleased to receive approval from the FDA for Sumavel DosePro, our first commercial product. We believe our DosePro technology represents a ground-breaking advancement in the self-administration of subcutaneous medications without a needle,” said Stephen Farr, Ph.D., president, chief operating officer and director of Zogenix. “We fully expect this FDA approval to catalyze DosePro licensing discussions in several other therapeutic areas.”

“During market research sessions with health care providers and migraine patients, ‘cool’ was one of the most common responses to Sumavel DosePro – that’s a very unusual description in this industry,” said Roger Hawley, chief executive officer and director of Zogenix. “We believe our novel DosePro delivery system could transform the future of subcutaneous drug delivery of pharmaceuticals. This first approval was made possible by years of dedication and shared entrepreneurial spirit of our Zogenix team, our business partners and our investors.”

Zogenix plans to launch Sumavel DosePro with its own sales force and a co-promotion partner, and will make the product commercially available as soon as possible.

About Sumavel DosePro

Sumavel DosePro (sumatriptan injection) needle-free delivery system is indicated for the acute treatment of migraine attacks, with or without aura, and the acute treatment of cluster headache episodes.

Sumavel DosePro should only be used where a clear diagnosis of migraine or cluster headache has been established. Sumavel DosePro is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine and should not be administered intravenously. For a given attack, if a patient does not respond to the first dose of Sumavel DosePro, the diagnosis of migraine or cluster headache should be reconsidered before administration of a second dose.

Important Safety Information

Sumavel DosePro is contraindicated in patients with ischemic heart disease or those with symptoms consistent with ischemic heart disease. It should not be administered to patients with cerebrovascular syndromes, peripheral vascular disease or in patients with uncontrolled hypertension. Very rarely, serious cardiac adverse events have been reported when taking sumatriptan, including patients with no findings of cardiovascular disease. Considering the extent of use of sumatriptan in patients with migraine, the incidence of these events is extremely low.

Sumavel DosePro should not be used within 24 hours of other ergotamine-containing or ergot-type medications or other 5-HT₁ agonists and is not generally recommended for use with selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors SNRIs or MAO inhibitors. Sumavel DosePro should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

The most common adverse events observed in controlled clinical trials with sumatriptan injection were injection site reactions, atypical sensations (such as feelings of tingling, warm/hot sensations), dizziness and flushing. Most side effects lasted for only a short time. In clinical trials comparing the safety and tolerability of Sumavel DosePro to sumatriptan injection, most injection site reactions resolved spontaneously, with no apparent difference between Sumavel DosePro and sumatriptan needle injection.

About DosePro technology

The DosePro technology is an easy-to-use, pre-filled drug delivery system designed to enable self-administration of single doses of liquid drug formulations, subcutaneously, without a needle. The DosePro technology has undergone more than ten years of design, process engineering, clinical evaluation and development work. DosePro is protected by more than 80 patents, issued and applied for, worldwide. Approximately 9,000 injections have been delivered in clinical trials in healthy volunteers using the DosePro needle-free drug delivery system.

About Zogenix

Zogenix, Inc., with offices in Emeryville and San Diego, Calif., is a privately held pharmaceutical company focused on the development and commercialization of medicines to treat neuroscience disorders and pain. The company's initial focus is the commercialization of Sumavel DosePro. Zogenix submitted a New Drug Application with the U.S. Food and Drug Administration for Sumavel DosePro in December 2007, and received FDA approval in July 2009. The company's pipeline also includes ZX002, a novel oral controlled-release formulation of hydrocodone without acetaminophen for the treatment of chronic pain, expected to enter Phase 3 clinical trials in 2009. Zogenix also plans to license the patented DosePro needle-free drug delivery system to other companies. For additional information, visit www.zogenix.com.

Zogenix™, Sumavel™ and DosePro™ are trademarks of Zogenix, Inc. IMITREX® is a registered trademark of GlaxoSmithKline.

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