



**SUMAVEL™ DosePro™ Available in the United States  
to Treat Acute Migraine and Cluster Headaches**

*– Innovative Needle-Free Delivery System Provides Fast Migraine Relief –*

**SAN DIEGO, Calif. and DEERFIELD, Ill., January 13, 2010** — Zogenix, Inc. (“Zogenix”), a privately held pharmaceutical company, and Astellas Pharma US, Inc. (“Astellas”) announced today the U.S. commercial launch of SUMAVEL™ DosePro™ (sumatriptan injection) needle-free delivery system. In July 2009, the U.S. Food and Drug Administration approved SUMAVEL DosePro for the acute treatment of migraine, with or without aura, and the acute treatment of cluster headaches. SUMAVEL DosePro delivers subcutaneous sumatriptan, a treatment that provides migraine relief starting within 10 minutes for some patients\*, in a first-of-its-kind needle-free delivery system. SUMAVEL DosePro is expected to be available at most retail pharmacy outlets this month.

“Migraines can be disabling, with profound implications on quality of life,” said Roger K. Cady, M.D., vice president of the National Headache Foundation board of directors and director of the Headache Care Center in Springfield, Mo. “One of the most common complaints of my migraine patients is that they would like to achieve faster relief. The availability of SUMAVEL DosePro makes it possible for patients to benefit from the fast relief of a subcutaneous formulation in a simple to use, needle-free delivery system.”

Sumavel DosePro offers other practical benefits. Approximately 30 percent of patients report vomiting as a symptom of migraine attacks, and the vast majority of attacks are also accompanied by nausea (*Lipton RB, Stewart WF, Diamond S, Diamond ML, Reed M. Prevalence and burden of migraine in the United States: data from the American Migraine Study II. Headache. 2001*). During these episodes, oral therapies may be an impractical treatment option. Further, while most forms of triptans can be effective when taken early in a migraine attack, patients who experience rapid onset of migraines, or those that occur upon waking may not always achieve the fast relief they would like from tablet and nasal forms. Quickly absorbed subcutaneous sumatriptan may offer an alternative for these patients, although until now, it was only available in a needle-based system. New SUMAVEL DosePro delivers sumatriptan subcutaneously (under the skin) without a needle, which can offer fast relief in a patient-friendly delivery system.

“We are extremely pleased to announce the introduction of SUMAVEL DosePro, which represents the first needle-free subcutaneous sumatriptan available to treat acute migraines,” said Stephen Farr, Ph.D., president, chief operating officer and director of Zogenix. “Given its unique attributes, SUMAVEL DosePro offers a new, fast-acting, non-oral option for patients who suffer from migraine. We believe SUMAVEL DosePro has the potential to not only replace needle-based injectable forms of sumatriptan, but also tablet and nasal triptan forms for many migraine episodes.”

Zogenix and Astellas have an exclusive co-promotion agreement to market SUMAVEL DosePro needle-free delivery system in the United States. Zogenix is focusing its sales activities primarily on the neurology market while Astellas is focusing principally on primary care physicians.

\*In two well-controlled clinical trials (N=1104) with patients experiencing moderate or severe pain and one or more migraine symptoms, the efficacy of subcutaneous sumatriptan vs. placebo was evaluated. In these clinical trials, 16 percent of patients achieved relief within 10 minutes vs. four percent for placebo; 70 percent of patients achieved relief at one hour vs. 22 percent for placebo ( $P<.001$ ); and 82 percent of patients achieved relief at two hours vs. 39 percent for placebo ( $P<.05$ ) [SUMAVEL DosePro prescribing information].

### **About SUMAVEL DosePro**

SUMAVEL DosePro (sumatriptan injection) 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 uncontrolled hypertension, in patients with history, symptoms or signs of ischemic heart disease, coronary artery vasospasm, cerebrovascular or peripheral vascular disease including ischemic bowel disease and in patients with other significant underlying cardiovascular diseases or known hypersensitivity to sumatriptan. SUMAVEL DosePro should not be given to patients in whom unrecognized coronary artery disease is predicted by the presence of risk factors without a prior cardiovascular evaluation. Serious cardiovascular events, including death, 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. Cerebrovascular events, some fatal, have been reported in patients treated with sumatriptan. In a number of cases, it appears possible that the cerebrovascular events were primary, sumatriptan having been administered in the incorrect belief the symptoms experienced

were a consequence of migraine when they were not. It is important to advise patients not to administer SUMAVEL DosePro if a headache being experienced is atypical.

SUMAVEL DosePro should not be used within 24 hours of other ergotamine-containing or ergot-type medications or other 5-HT<sub>1</sub> agonists and is not generally recommended for use with MAO-A inhibitors. The development of a potentially life-threatening serotonin syndrome may occur with triptans, including treatment with SUMAVEL DosePro, particularly during combined use with selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). SUMAVEL DosePro should be used during pregnancy only if the potential benefit justifies the potential risk.

In controlled clinical trials with sumatriptan injection, the most common adverse reactions were injection site reactions, tingling, warm/hot sensation, burning sensation, feeling of heaviness, pressure sensation, feeling of tightness, numbness, feeling strange, tight feeling in head, flushing, tightness in chest, discomfort in nasal cavity/sinuses, jaw discomfort, dizziness/vertigo, drowsiness/sedation and headache.

For full prescribing information, go to [www.SUMAVELDosePro.com/\[insert new url to PI\]](http://www.SUMAVELDosePro.com/[insert new url to PI])

### **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, which received U.S. Food and Drug Administration 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, preparing to enter Phase 3 clinical trials. Zogenix also plans to license the patented DosePro needle-free drug delivery system to other companies. For additional information, please visit [www.zogenix.com](http://www.zogenix.com).

### **About Astellas**

Astellas Pharma US, Inc., located in Deerfield, Illinois, is a U.S. affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global category leader in focused areas by combining outstanding R&D and marketing capabilities. In

the US, Astellas markets products in the areas of Anti-Infectives, Cardiovascular, Dermatology, Immunology, Neuroscience, and Urology. For more information about Astellas Pharma US, Inc., please visit our Web site at [www.us.astellas.com](http://www.us.astellas.com).

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