



## **Zogenix and Astellas Enter Exclusive Co-Promotion Agreement in the US for Newly Approved Sumavel™ DosePro™**

*— Novel Product Recently Approved by the FDA  
for Treatment of Acute Migraine and Cluster Headache —*

**SAN DIEGO, CA, and DEERFIELD, IL (August 3, 2009):** Zogenix, Inc. (“Zogenix”), a privately held pharmaceutical company and Astellas Pharma US, Inc. (“Astellas”), announced today their exclusive co-promotion agreement for Sumavel DosePro (sumatriptan injection) needle-free delivery system. Sumavel DosePro received FDA approval in July 2009 and 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.

“Partnering with Astellas is a significant milestone for Zogenix which will allow us to bring this cutting edge treatment to a broader number of people suffering from migraines,” said Roger Hawley, CEO and director of Zogenix, Inc. “It was essential that we found the right partner for the introduction of our first product, Sumavel DosePro. Astellas will bring significant sales and marketing experience to our promotional efforts and help ensure the successful launch of Sumavel DosePro.”

According to the National Headache Foundation, acute migraines affect nearly 30 million Americans, primarily women between the ages of 25 and 40, who are treated by primary care physicians and neurologists. Tablets are a treatment option for some of these 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.

“Part of Astellas’ corporate strategy is to continue establishing successful partnerships, so we are especially pleased to bring Sumavel DosePro to market with Zogenix,” said Seigo Kashii, president and CEO of Astellas. “We believe this innovative product will have a broad appeal which complements our current primary care efforts and enriches our local portfolio. We look forward to our collaboration with Zogenix to further meet the needs of patients.”

Sumavel DosePro is expected to be commercially available in January 2010. Under the terms of the agreement, the companies will collaborate on the promotion and marketing of Sumavel DosePro with Zogenix focusing their sales activities primarily on the neurology market while Astellas will focus mostly on primary care physicians. Zogenix will have responsibility for manufacturing and distribution of the product. Product sales will be booked by Zogenix and Astellas will be compensated based on sales performance within their prescriber audience.

### **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-HT<sub>1</sub> 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.

### **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](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 Immunology, Urology, Anti-Infectives, Cardiovascular and Dermatology. For more information about Astellas Pharma US, Inc., please visit our website at [www.us.astellas.com](http://www.us.astellas.com).

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