

ZOGENIX

Zogenix and Desitin Filing for European Regulatory Approval of SUMAVEL DosePro

October 28, 2009

- European Pivotal Trial Confirms Bioequivalence -

SAN DIEGO, CA and Hamburg, Germany - (October 28, 2009): Zogenix, Inc. ("Zogenix"), a privately held pharmaceutical company, and Desitin Pharmaceuticals GmbH ("Desitin"), a privately held, mid-sized German pharmaceutical company, today announced that Desitin has filed for European regulatory approval of SUMAVEL DosePro (sumatriptan injection) needle-free delivery system. The announcement follows successful completion of a European pivotal bioequivalence trial comparing needle-free SUMAVEL DosePro to a traditional needle-based autoinjector, Imigran®-Inject, the European brand of Imitrex STATdose System®. In March 2008, Zogenix and Desitin entered into a license agreement granting exclusive rights in the European Union to Desitin Pharmaceuticals GmbH ("Desitin") to develop and commercialize SUMAVEL DosePro.

SUMAVEL DosePro was recently approved by the U.S. FDA to treat acute migraine, with or without aura, and cluster headache, and will be launched by Zogenix in the U.S. in January 2010. 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 clinical trials, the drug was shown to be absorbed rapidly, resulting in peak plasma concentrations within approximately 12 minutes. This rate of absorption of subcutaneous sumatriptan has been shown to correlate with rapid and complete relief of migraine symptoms, including migraine relief within 10 minutes for some patients and within 30 minutes for almost 50% of patients. Overall safety profiles were comparable for SUMAVEL DosePro and Imitrex STATdose System®.

"This filing demonstrates Desitin's ability to move this product candidate through development and into the European regulatory approval process," commented Dr. Martin Zentgraf, Desitin's General Manager. "Subject to regulatory approval, we look forward to launching it with our CNS-focused sales representatives and partner companies in the major European countries, bringing this important product candidate to the market for the benefit of patients."

"SUMAVEL DosePro is a unique new product which we believe has broad global appeal," said Roger Hawley, chief executive officer and director of Zogenix. "With FDA approval and commercial manufacturing in place, Desitin's achievement of this milestone in Europe with SUMAVEL DosePro will attract the attention of other companies who may be interested in our technology for delivery of their drugs in other therapeutic areas, including biologics."

About Migraine

Migraine is considered the most common neurological condition in the developed world. It is typically characterized by severe, recurring head pain, usually located on one side of the head and one or more of the following associated symptoms: nausea; vomiting; and increased sensitivity to light, sound and/or smell. Oral and nasal treatment options are available but often do not work quickly enough for patients who experience migraine episodes associated with sudden onset, waking, nausea or vomiting. While needle-based treatment options are associated with faster onset of relief, some patients are deterred from use due to needle-aversion and complicated delivery systems.

About SUMAVEL DosePro

Zogenix plans to launch SUMAVEL DosePro in the US in January 2010, with their US co-promotion partner, Astellas.

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 sensitivity 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-HT₁ 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.

MOST COMMON ADVERSE REACTIONS

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.

Please see full prescribing information [click here](#).

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 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, 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, visit www.zogenix.com.

About Desitin

Desitin Pharmaceuticals GmbH, based in Hamburg, Germany is an independent, private, fully integrated, German pharmaceutical company focused on the development, manufacturing and distribution of products for the treatment of central nervous system disorders. Desitin, with turnover in 2008/2009 of over \$110 million, is one of the leading European companies in the field of epilepsy with additional expertise in Parkinson's disease and psychiatric disorders. With their pharmaceutical and clinical development capabilities, the company develops innovative products such as controlled-release and high-dose antiepileptics. Desitin's sales infrastructure offers comprehensive coverage in Germany, Switzerland, Northern and Eastern Europe. The company also has strategic partnerships with other companies covering nearly all of the remaining countries in Europe. For additional information, visit www.desitinpharma.com.

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