

ZOGENIX

Zogenix Demonstrates Increased Overall Patient Satisfaction With SUMAVEL(R) DosePro(R) Over Multiple Migraine Attacks

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Phase 4 Clinical Data Presented at AAN Annual Meeting

SAN DIEGO, Apr 13, 2011 (GlobeNewswire via COMTEX) -- Zogenix, Inc. (Nasdaq:ZGNX) today reported clinical data from its Phase 4 open-label, multicenter study of SUMAVEL(R) DosePro (R) (sumatriptan injection) Needle-free Delivery System. The clinical data were presented in two poster presentations at the 63rd Annual Meeting of the American Academy of Neurology (AAN) in Honolulu, Hawaii.

Stephen J. Farr, Ph.D., President and Chief Operating Officer of Zogenix, said, "The clinical findings of this Phase 4 study indicate that patients showed a greater Overall Satisfaction with subcutaneous sumatriptan delivered by SUMAVEL DosePro than their current triptan therapy, which was predominantly oral dosage forms. SUMAVEL DosePro improves upon traditional needle-based sumatriptan injection therapy by providing convenience and ease of use in a needle-free delivery system, and may be a useful therapeutic option when rapid onset of efficacy is important in relieving migraine pain and symptoms."

John F. Rothrock, M.D., Director of the University of Alabama School of Medicine Headache Treatment and Research Program, and co-author of the Phase 4 study, stated, "Migraine patients typically experience migraine attacks that vary widely in severity of headache and associated symptomatology, and consequently they require multiple treatment options for treating these attacks. Results of this study showed an increased rate of Overall Satisfaction and lasting relief from migraine symptoms. Coupled with the ease of use and rapid onset of action, needle-free SUMAVEL DosePro should be viewed as an attractive addition to the toolbox of migraine therapeutics for patients treating their migraines of moderate to severe intensity."

The first poster presentation reported on treatment satisfaction, measured using the validated Patient Perception of Migraine Questionnaire, Revised (PPMQ-R). Among over 200 current triptan users (any drug or dosage form) self-administering SUMAVEL DosePro to treat multiple migraine attacks, PPMQ-R Overall Satisfaction increased significantly ($p=0.0007$) from baseline to the end of treatment. The results also demonstrated a significant improvement ($p<0.0001$) in the PPMQ-R Total score, which is a composite of subscale scores for 17 questions relating to efficacy, functionality, and ease of use. Patients reported enhanced confidence in treating repeated migraine attacks after trying SUMAVEL DosePro.

The second poster presentation reported on the efficacy and tolerability of SUMAVEL DosePro among current triptan users over multiple migraine attacks. The results confirmed that SUMAVEL DosePro is safe and well tolerated by migraine patients, and demonstrated that it provided rapid, sustained relief from migraine pain, as well as associated symptoms such as nausea, photophobia, and phonophobia. Using SUMAVEL DosePro, one-third of the 669 treated migraine episodes had pain relieved in 15 minutes, with 70 percent achieving pain relief within 30 minutes. Pain freedom was achieved in 61 percent of the treated attacks within two hours. These incidences of pain relief and pain-free response for needle-free SUMAVEL DosePro are consistent with those demonstrated by previous double-blind, placebo-controlled clinical studies of injectable sumatriptan.

Zogenix and its co-promotion partner, Astellas Pharma US, Inc., launched SUMAVEL DosePro in the United States in January 2010 for the acute treatment of migraine and cluster headache. SUMAVEL DosePro offers fast-acting, easy-to-use, needle-free subcutaneous administration of sumatriptan in a pre-filled, single-use delivery system. The combination of these unique product attributes allows physicians to prescribe SUMAVEL DosePro to address important unmet needs of many migraine sufferers.

About the Phase 4 Study

Zogenix completed a Phase 4 open-label, multicenter study in the United States to evaluate treatment Overall Satisfaction, treatment confidence, patient preference, and treatment tolerability for SUMAVEL DosePro in adult patients diagnosed with migraine and currently treated with triptans. More than 200 patients, who were predominantly taking oral triptan therapy, tried SUMAVEL DosePro to treat at least one and up to four migraines over a 60-day period, with the primary endpoint being the change in Overall Satisfaction. The study utilized the Patient Perception of Migraine Questionnaire-Revised, or PPMQ-R, to evaluate patient satisfaction with migraine treatment through analysis of efficacy, functionality, ease of use and tolerability/side effects.

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-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.

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 http://www.zogenix.com/docs/SV0018.0709A_SDP_PI.pdf

For more information about SUMAVEL DosePro, please visit www.SUMAVELDosePro.com.

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 10 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. (Nasdaq:ZGNX), with offices in San Diego and Emeryville, California, is a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Zogenix's first commercial product, SUMAVEL(R) DosePro(TM) (sumatriptan injection) Needle-free Delivery System, was launched in January 2010 for the acute treatment of migraine and cluster headache. Zogenix's lead investigational product candidate, ZX002, is a novel, oral, single-entity controlled-release formulation of hydrocodone currently in Phase 3 clinical trials for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy.

For additional information, please visit www.zogenix.com.

SUMAVEL(R) and DosePro (R) are registered trademarks of Zogenix, Inc.

Forward Looking Statements

Zogenix cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed" and similar expressions are intended to identify forward-looking statements. These statements are based on the company's current beliefs and expectations. These forward-looking statements include statements regarding the attributes of SUMAVEL DosePro and its usefulness as a therapeutic option in relieving migraine pain and symptoms. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: the market potential for migraine treatments, and Zogenix's ability to compete within that market; inadequate therapeutic efficacy or unexpected adverse side effects relating to SUMAVEL DosePro that could delay or prevent commercialization, or that could result in recalls or product liability claims; Zogenix's dependence on its collaboration with Astellas Pharma US, Inc. to promote SUMAVEL DosePro; and other risks described in the company's prior press releases and filings with the Securities and Exchange Commission.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Zogenix undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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