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News Release

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Zogenix Announces FDA Approval of 4 mg SUMAVEL(R) DosePro(R) (sumatriptan injection) Needle-Free Delivery System

SAN DIEGO, Dec. 10, 2013 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of central nervous system (CNS) disorders and pain, announced today that the U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) for a 4 mg dose of SUMAVEL DosePro (sumatriptan injection) Needle-free Delivery System. SUMAVEL DosePro has been available in a 6 mg dose for the treatment of acute migraine and cluster headache. The 4 mg dose of SUMAVEL DosePro can be used to help migraine sufferers who require management of side effects. The 4 mg dose of SUMAVEL DosePro is expected to be available approximately June 2014.

SUMAVEL DosePro is the first and only needle-free delivery system for subcutaneous sumatriptan for the treatment of acute migraine and cluster headache. Clinical data has shown that the current 6 mg dose of SUMAVEL DosePro can provide migraine pain relief within 10 minutes for some patients (16% of patients versus 4% for placebo). The product was launched in January 2010, reaching over 225,000 total prescriptions at the end of the third quarter 2013.[1]

"Having a lower dose option of SUMAVEL DosePro will allow physicians to use another tool in the management of migraine and cluster headache," said Roger K. Cady, M.D., director of the Headache Care Center in Springfield, Mo. Cady continued, "The well-established efficacy of sumatriptan injection with the benefit of increasing patient satisfaction using needle-free technology, supports the goal of optimizing migraine treatment."[2]

Roger L. Hawley, chief executive officer of Zogenix, said, "We are pleased to be able to provide treatment solutions to help patients better manage their migraine and cluster headache attacks. We continue to improve our product and educational resources based on the feedback we receive from headache specialists who are experts in the treatment of migraine."

According to the National Headache Foundation, acute migraine attacks affect nearly 30 million Americans, primarily women between the ages of 25 and 40, who are treated by primary care physicians, neurologists and headache specialists. 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 attacks associated with sudden onset, waking, nausea or vomiting. The U.S. Headache Consortium endorses migraine treatment guidelines which support a "toolbox" approach to providing treatment options for improved outcomes.

About SUMAVEL DosePro

INDICATION and IMPORTANT LIMITATIONS

Sumavel DosePro (sumatriptan injection) is a serotonin (5-$HT_{1B/1D}$) receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults and the acute treatment of cluster headache in adults.

Limitations of Use

SUMAVEL DosePro is intended for use only if a clear diagnosis of migraine or cluster headache has been established. If a patient has no response to the first migraine attack treated with SUMAVEL DosePro, reconsider the diagnosis of migraine before SUMAVEL DosePro is administered to treat any subsequent attacks. SUMAVEL DosePro is not indicated for the prevention of migraine attacks.

Dosage and Administration

The maximum single recommended dose of Sumavel DosePro for the acute treatment of migraine or cluster headache is 6 mg given subcutaneously. SUMAVEL DosePro is intended for subcutaneous use only. SUMAVEL DosePro is intended for use as an acute treatment of migraine or an acute treatment of cluster headache. For the treatment of cluster headache, the

efficacy of a lower dose has not been established. The maximum cumulative dose of SUMAVEL DosePro in a 24-hour period is 12 mg, with doses separated by at least 1 hour. SUMAVEL DosePro is intended to be administered only to the abdomen or thigh.

IMPORTANT SAFETY INFORMATION

SUMAVEL DosePro is contraindicated in patients with ischemic coronary artery disease (CAD) (angina pectoris, history of myocardial infarction, or documented silent ischemia) or coronary artery vasospasm, including Prinzmetal's angina; Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders; history of stroke or transient ischemic attack (TIA); hemiplegic or basilar migraine; peripheral vascular disease; ischemic bowel disease; uncontrolled hypertension; recent (within 24 hours) use of another 5-HT_1 agonist (e.g., another triptan) or of an ergotamine-containing medication; current or recent (past 2 weeks) use of monoamine oxidase-A inhibitor; and known hypersensitivity to sumatriptan.

There have been rare reports of serious cardiac adverse reactions, including acute myocardial infarction, occurring within a few hours following administration of SUMAVEL DosePro. Some of these reactions occurred in patients with no known CAD. SUMAVEL DosePro may cause coronary artery vasospasm (Prinzmetal's angina), even in patients without a history of CAD. 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.

Warnings and Precautions

Discontinue use of SUMAVEL DosePro if the following occur: arrhythmias; cerebral hemorrhage, subarachnoid hemorrhage, and stroke; gastrointestinal ischemia and infarction events, peripheral vasospastic reactions; serotonin syndrome; and/or anaphylactic/anaphylactoid reactions. Perform cardiac evaluation in patients with multiple cardiovascular risk factors, including myocardial ischemia/infarction and Prinzmetal's angina. While generally not associated with myocardial ischemia; evaluate for CAD in patients at high risk with the following symptoms: chest/throat/neck/jaw pain, tightness, pressure, or heaviness. In the event of a headache associated with medication overuse, detoxification may be necessary. In the event of an increase in blood pressure, monitor blood pressure. Use with caution in patients with epilepsy or a lowered seizure threshold.

Adverse Reactions

In controlled clinical trials with sumatriptan injection, the most common adverse reactions were injection site reactions, tingling, dizziness/vertigo, warm/hot sensation, burning sensation, feeling of heaviness, pressure sensation, flushing, feeling of tightness, and numbness.

For full prescribing information, please click here: http://www.zogenix.com/downloads/SV0468.1113_SDP_PI.pdf

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

About Zogenix

Zogenix, Inc. (Nasdaq:ZGNX), with offices in San Diego and Emeryville, California, is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with central nervous system disorders and pain-related conditions who need innovative treatment alternatives to help them return to normal daily functioning. Zogenix recently received FDA approval for Zohydro ER (hydrocodone bitartrate) extended-release capsules, the first extended-release oral formulation of hydrocodone without acetaminophen. Zogenix developed and commercialized the first needle-free subcutaneous injection, SUMAVEL® DosePro® (sumatriptan injection) for migraine and cluster headache. The development pipeline for Zogenix includes a once-monthly subcutaneous injection for schizophrenia.

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," "plans," "expects," "will," "potential" 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 and the potential of the 4 mg dose of SUMAVEL DosePro to provide a new management alternative for migraine sufferers. 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, including with the 4 mg dose of SUMAVEL DosePro; Zogenix's ability to successfully execute its sales and marketing strategy for the commercialization of SUMAVEL DosePro; unexpected adverse side effects relating to SUMAVEL DosePro that could result in recalls or product liability claims; Zogenix's reliance on Mallinckrodt to co-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 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.

[1] *Source Healthcare Analytics, Source® PHAST Prescription Monthly, January 2010 –June 2013*

[2] *Cady, R. K., Aurora, S. K., Brandes, J. L., Rothrock, J. F., Myers, J. A., Fox, A. W. and Farr, S. J. (2011), Satisfaction With and Confidence in Needle-Free Subcutaneous Sumatriptan in Patients Currently Treated with Triptans. Headache: The Journal of Head and Face Pain. doi: 10.1111/j.1526-4610.2011.01972.x*

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