Zogenix Closes Sale of SUMAVEL(R) DosePro(R) Migraine Therapy to Endo International

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SAN DIEGO, May 19, 2014 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of pain-related and central nervous system (CNS) disorders, announced today the closing of its previously announced sale of its SUMAVEL® DosePro® Needle-free Delivery System (sumatriptan injection) product line to Endo International plc (Nasdaq:ENDP) for $85 million in cash and milestone payments of up to $20 million.

The SUMAVEL DosePro New Drug Application has been transferred to Endo, who now owns worldwide rights to the product. The commercial transition of SUMAVEL DosePro from Zogenix to Endo will begin immediately, with Endo taking responsibility for the product line. Endo will purchase the finished goods inventory and support the manufacturing operations managed by Zogenix with a working capital loan.

Roger Hawley, Chief Executive Officer of Zogenix, said, "We are pleased to complete this transaction and look forward to collaborating with Endo to ensure a smooth transition and to support the ongoing success of SUMAVEL DosePro."

In conjunction with the closing of the sale, Zogenix repaid its outstanding debt of approximately $40 million to HealthCare Royalty Partners and the related financing agreement was terminated.

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) is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with pain-related conditions and CNS disorders who need innovative treatment alternatives to help them return to normal daily functioning.

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 ongoing success of SUMAVEL DosePro and the potential receipt of milestone payments from Endo. 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 press release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: the ability of Endo to achieve the pre-determined sales and manufacturing milestones; Zogenix's dependence on third-party suppliers to ensure continued adequate supply of SUMAVEL DosePro to affiliates of Endo; and other risks detailed in Zogenix's prior press releases as well as in public periodic 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 press 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.

SUMAVEL® DosePro® is a registered trademark of Endo International plc.

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CONTACT: Investors
Zack Kubow, The Ruth Group
646.536.7020, zkubow@theruthgroup.com

Media
Aaron Estrada, The Ruth Group
646.536.7028, aestrada@theruthgroup.com

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