

# ZOGENIX

## Zogenix and Valeant Pharmaceuticals Enter Exclusive Co-Promotion Agreement for Migranal(R) Nasal Spray

June 27, 2013

### Zogenix Sales Force to Begin Promoting Migranal(R) to Its Customer Base of Neurologists and Headache Specialists

SAN DIEGO, June 27, 2013 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain, announced today an exclusive co-promotion agreement for Migranal® (dihydroergotamine mesylate, USP) Nasal Spray in the United States.

Under the terms of the agreement, Zogenix's sales force will begin selling Migranal Nasal Spray to its customer base of prescribers, which is primarily composed of neurologists, headache specialists and related nurse practitioners and physician assistants in late July 2013. The initial term of the agreement will be through December 31, 2015, and can be extended by mutual agreement of the parties. Valeant will record all product revenues and Zogenix will be compensated in the form of a quarterly service fee that is calculated as a percentage of net sales over a baseline amount.

Migranal Nasal Spray is indicated for the acute treatment of migraine headaches with or without aura. It is complementary to Zogenix's commercialized migraine product, SUMAVEL® DosePro® Needle-free Delivery System (sumatriptan injection), which is indicated for the acute treatment of migraine attacks, with or without aura, and cluster headache. Because the active ingredients in Migranal Nasal Spray and SUMAVEL DosePro are from different classes of migraine prescription medications, Migranal may allow patients to get relief from attacks if they have not responded to triptans, the most widely prescribed class of migraine treatments.

Roger L. Hawley, chief executive officer of Zogenix, stated, "We are pleased to enter a co-promotion agreement with Valeant for Migranal Nasal Spray. We view Migranal as complementary to SUMAVEL DosePro and supportive of the migraine treatment guidelines, which encourage the use of a toolbox of treatment options to address the variety in migraine attacks. We believe that our sales force is well positioned to expand adoption of Migranal with neurologists and headache specialists that prescribe SUMAVEL DosePro, providing more patients with this treatment option. We believe this agreement fits well with our vision to be the leading specialty migraine company and help drive our commercial operations towards profitability."

#### 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.

Do not use Sumavel DosePro and any ergotamine-containing or ergot-type medication within 24 hours of each other; do not use SUMAVEL DosePro and another 5-HT<sub>1</sub> agonist (e.g. triptan) within 24 hours of each other (with the exception of a single dose of another sumatriptan product, provided the doses are separated by at least 1 hour). SUMAVEL DosePro 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, please click here: [http://www.zogenix.com/downloads/SV0468.0611\\_SDP\\_PI.pdf](http://www.zogenix.com/downloads/SV0468.0611_SDP_PI.pdf)

For more information about SUMAVEL DosePro, please visit [www.SUMAVELDosePro.com](http://www.SUMAVELDosePro.com).

#### MIGRANAL IMPORTANT SAFETY INFORMATION

Serious and/or life-threatening peripheral ischemia has been associated with the coadministration of dihydroergotamine with potent CYP3A4 inhibitors including protease inhibitors and macrolide antibiotics. Because CYP3A4 inhibition elevates the serum levels of dihydroergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of these medications is contraindicated.

- Migranal Nasal Spray should not be given to patients with ischemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia), to patients who have clinical symptoms or findings consistent with coronary artery vasospasm, including Prinzmetal's variant angina.
- Migranal also should not be given to patients with uncontrolled hypertension, patients who have used 5-HT<sub>1</sub> agonists, ergotamine-containing or ergot-type medications or methysergide within the last 24 hours, or patients with hemiplegic or basilar migraine.
- Migranal Nasal Spray is also contraindicated in patients with known peripheral arterial disease, sepsis, following vascular surgery, and severely impaired hepatic or renal function.
- Migranal Nasal Spray should not be administered to pregnant women or nursing mothers.

Migranal® Nasal Spray should only be used where a clear diagnosis of migraine headache has been established.

Serious cardiac events, including some that have been fatal, have occurred following use of DHE 45 but are extremely rare. During clinical studies and the foreign postmarketing experience with Migranal Nasal Spray, there have been no fatalities due to cardiac events. The most commonly reported adverse events in clinical trials for Migranal Nasal Spray were rhinitis, altered sense of taste, application site reactions, dizziness, nausea and vomiting. Adverse events associated with discontinuation were rhinitis, dizziness, facial edema, cold sweats, accidental trauma, depression, elective surgery, somnolence, allergy, vomiting, hypotension, and paresthesia.

For more information on Migranal, visit <http://migranal.com/migranal-home>.

#### 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® DosePro® (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, Zohydro™ ER (hydrocodone bitartrate extended release capsules), is an oral, extended-release formulation of various strengths of hydrocodone, without acetaminophen, intended for administration every 12 hours for around the clock management of moderate to severe chronic pain. In May 2012, Zogenix submitted to the FDA a New Drug Application for Zohydro ER. Zogenix's second investigational product candidate, Relday™, is a proprietary, long-acting injectable formulation of risperidone for the treatment of schizophrenia; an investigational new drug application was submitted to the FDA in May 2012.

#### 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" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements regarding Migranal Nasal Spray's and SUMAVEL DosePro's usefulness as a therapeutic option in relieving migraine pain and symptoms, the potential for the co-promotion arrangement to increase sales of Migranal Nasal Spray and the potential for the co-promotion arrangement to help Zogenix achieve profitability. 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: Zogenix's ability to successfully sell Migranal Nasal Spray to Zogenix's customer base of prescribers; unexpected adverse side effects relating to Migranal Nasal Spray that could result in recalls or product liability claims; the potential early termination of the co-promote arrangement; 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.

SUMAVEL®, DosePro®, Relday™ and Zohydro™ ER are trademarks of Zogenix, Inc.

MIGRANAL® is a registered trademark of Valeant Pharmaceuticals International, Inc. or its affiliates.

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CONTACT: Zogenix Contacts:

Investors

Zack Kubow | The Ruth Group

646.536.7020 | [zkubow@theruthgroup.com](mailto:zkubow@theruthgroup.com)

Media

Caitlin Cox | The Ruth Group

646.536.7033 | [ccox@theruthgroup.com](mailto:ccox@theruthgroup.com)

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