



NEWS RELEASE

## FDA Approves ZOMIG® (zolmitriptan) Nasal Spray for Migraine in Pediatric Patients (Ages 12-17)

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HAYWARD, Calif., June 16, 2015 /PRNewswire/ -- Impax Specialty Pharma, a division of Impax Laboratories, Inc. (NASDAQ: IPXL), announced today that the U.S. Food and Drug Administration (FDA) has approved ZOMIG Nasal Spray for use in pediatric patients 12 years of age and older for the acute treatment of **migraine** with or without aura.

ZOMIG Nasal Spray is the first nasal-delivered prescription medicine approved for the treatment of acute migraine attacks in pediatric patients. Nasal sprays may offer an alternative method of administration when patients experience migraine-associated nausea, have difficulty taking oral formulations, or do not have liquids available.

ZOMIG Nasal Spray's approval came after the FDA's review of safety and efficacy data from pivotal clinical trials demonstrating that ZOMIG Nasal Spray 5 mg is significantly more effective than placebo in providing no headache pain, relief of headache, and other associated symptoms of migraine when treating migraine in pediatric patients. In clinical trials, the medication also had a safety profile similar to that demonstrated in adults. For full safety and efficacy information, please see the prescribing information.

The American Migraine Prevalence and Prevention (AMPP) Study estimated the 1-year prevalence of migraine among US children ages 12 to 19 at 6.3%, with prevalence among boys at 5.0% and among girls 7.7%.<sup>2</sup> "Until now, there have been few medications to treat pediatric patients with painful, debilitating attacks of migraine," said Dr. Alan M. Rapoport, Past President of the International Headache Society and Clinical Professor of Neurology at the David Geffen School of Medicine. "We are pleased that ZOMIG Nasal Spray has been approved by the FDA for use in patients ages 12 to 17."

"Treatment options have been limited for pediatric patients and we are pleased with FDA's decision and look

forward to bringing migraine relief to pediatric patients by making ZOMIG Nasal Spray available to this 'school age' patient population," said Fred Wilkinson, President and Chief Executive Officer of Impax Laboratories. "This expanded indication exemplifies our strategy to broaden the reach of our current product portfolio to address unmet needs in underserved therapeutic areas, thereby adding value for patients and shareholders alike."

The recommended starting dose for ZOMIG Nasal Sprays in pediatric patients 12 years of age and older is 2.5 mg. As the individual response to ZOMIG Nasal Spray may vary, the dose should be adjusted on an individual basis. The maximum recommended single dose of ZOMIG is 5 mg. The maximum daily dose should not exceed 10 mg in any 24 hour period.

## About ZOMIG Nasal Spray

ZOMIG Nasal Spray was first approved by the U.S. Food and Drug Administration (FDA) in September 2003 for the acute treatment of migraine attacks, with or without aura, in adults. In clinical trials, ZOMIG Nasal Spray provided relief in as soon as 15 minutes for some patients and the maximum effect was reached within 2–4 hours for most adult patients. At 2 hours, 69% of patients taking the 5mg dose had headache response (taking the patient from moderate to severe pain to mild or no pain) and 36% were pain free.<sup>1</sup>

## Indication

ZOMIG Nasal Spray is a serotonin (5-HT)<sub>1B/1D</sub> receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years and older.

### Limitations of Use:

Use ZOMIG only after clear diagnosis of migraine has been established. If a patient has no response to ZOMIG treatment for the first migraine attack, reconsider the diagnosis of migraine before ZOMIG is administered to treat any subsequent attacks. ZOMIG is not indicated for the prevention of migraine attacks. Safety and effectiveness of ZOMIG have not been established for cluster headache. ZOMIG Nasal Spray is not recommended in patients with moderate to severe hepatic impairment.

## Important Safety Information

- ZOMIG is contraindicated in patients with
  - History of coronary artery disease (CAD) or coronary artery vasospasm
  - Symptomatic Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders
  - History of stroke, transient ischemic attack, or hemiplegic or basilar migraine
  - Peripheral vascular disease
  - Ischemic bowel disease

- Uncontrolled hypertension
  - Recent (within 24 hours) use of another 5-HT<sub>1</sub> agonist (eg, another triptan), or an ergotamine-containing medication
  - Monoamine oxidase (MAO)-A inhibitor used in past 2 weeks
  - Known hypersensitivity to ZOMIG, ZOMIG-ZMT, or ZOMIG Nasal Spray. Anaphylaxis, anaphylactoid, and hypersensitivity reactions including angioedema have occurred in patients receiving zolmitriptan.
- Myocardial ischemia, myocardial infarction and Prinzmetal Angina: Perform cardiac evaluation in patients with multiple risk factors and, if satisfactory, administer first dose of ZOMIG in a medically supervised setting
  - Arrhythmias: Discontinue ZOMIG if these occur
  - Sensations of tightness, pain and pressure in the chest, throat, neck, and jaw commonly occur after treatment with 5-HT<sub>1</sub> agonists like ZOMIG and are usually non-cardiac in origin: Perform a cardiac evaluation if these patients are at cardiac risk
  - Cerebrovascular events, some fatal; non-coronary Gastrointestinal Ischemic Reactions and Peripheral Vasospastic Reactions; and increases in blood pressure (which have been very rarely associated with serious clinical events) have been reported with ZOMIG. Discontinue use of ZOMIG if any of these events occur
  - Overuse of acute migraine drugs may lead to exacerbation headache (medication overuse headache). Detoxification of patients, including withdrawal of the overused drugs, and treatment of withdrawal symptoms may be necessary
  - Serotonin syndrome may occur with triptans, including ZOMIG, particularly during co-administration with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and MAO inhibitors. Discontinue ZOMIG if serotonin syndrome is suspected
  - The most common adverse reactions in adults (=5% and > placebo; in any dosage strength) in clinical trials for ZOMIG Nasal Spray were: unusual taste, paresthesia, hyperesthesia, and dizziness
  - The most common adverse reaction in pediatrics (ages 12 and 17 years; =5% and > placebo; in either the 2.5 or 5 mg ZOMIG dose groups) in clinical trials for ZOMIG Nasal Spray was unusual taste.

For full Prescribing Information see [www.Zomig.com](http://www.Zomig.com).

## About Impax Laboratories, Inc.

Impax Laboratories, Inc. (Impax) is a specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of central nervous system disorder branded products. Impax markets its generic products through its Impax Generics division and markets its branded products through the Impax Specialty Pharma division. Additionally, where strategically appropriate, Impax develops marketing partnerships to fully leverage its technology platform and pursues partnership opportunities that offer alternative dosage form technologies, such as injectables, nasal sprays, inhalers, patches, creams, and ointments. For more information, please visit the Company's Web site at: [www.impaxlabs.com](http://www.impaxlabs.com).

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

To the extent any statements made in this news release contain information that is not historical; these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause the Company's future results, performance, or achievements to differ significantly from the results, performance, or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to: fluctuations in revenues and operating income; the Company's ability to promptly correct the issues raised in the warning letter and Form 483 observations received from the FDA; the Company's ability to successfully develop and commercialize pharmaceutical products in a timely manner; reductions or loss of business with any significant customer; the substantial portion of the Company's total revenues derived from sales of a limited number of products; the impact of consolidation of the Company's customer base; the impact of competition; the Company's ability to sustain profitability and positive cash flows; any delays or unanticipated expenses in connection with the operation of the Company's manufacturing facilities; the effect of foreign economic, political, legal, and other risks on the Company's operations abroad; the uncertainty of patent litigation and other legal proceedings; the increased government scrutiny on the Company's agreements with brand pharmaceutical companies; product development risks and the difficulty of predicting FDA filings and approvals; consumer acceptance and demand for new pharmaceutical products; the impact of market perceptions of the Company and the safety and quality of the Company's products; the Company's determinations to discontinue the manufacture and distribution of certain products; the Company's ability to achieve returns on its investments in research and development activities; changes to FDA approval requirements ; the Company's ability to successfully conduct clinical trials; the Company's reliance on third parties to conduct clinical trials and testing; the Company's lack of a license partner for commercialization of IPX066 outside of the United States; impact of illegal distribution and sale by third parties of counterfeits or stolen products; the availability of raw materials and impact of interruptions in the Company's supply chain; the Company's policies regarding returns, allowances and chargebacks; the use of controlled substances in the Company's products; the effect of current economic conditions on the Company's industry, business, results of operations and financial condition; disruptions or failures in the Company's information technology systems and network infrastructure caused by third party breaches or other events; the Company's reliance on alliance and collaboration agreements; the Company's reliance on licenses to proprietary technologies; the Company's dependence on certain employees; the Company's ability to comply with legal and regulatory requirements governing the healthcare industry; the regulatory environment; the effect of certain provisions in the Company's government contracts; the Company's ability to protect its intellectual property; exposure to product liability claims; risks relating to goodwill and intangibles; changes in tax regulations; the Company's ability to manage growth, including through potential acquisitions and investments; the integration of the acquired business of Tower Holdings, Inc. and Lineage Therapeutics Inc. by the Company being more difficult, time-consuming or costly than expected, operating costs, customer loss and business disruption (including, without limitation, difficulties in maintaining relationships with employees, customers, clients or suppliers) being greater than expected following the acquisition, the retention of certain key

employees of the acquired business being difficult, the Company's and the acquired business's expected or targeted future financial and operating performance and results, the combined company's capacity to bring new products to market, and the possibility that the Company may be unable to achieve expected synergies and operating efficiencies in connection with the acquisition within the expected time-frames or at all, the restrictions imposed by the Company's credit facility; uncertainties involved in the preparation of the Company's financial statements; the Company's ability to maintain an effective system of internal control over financial reporting; the effect of terrorist attacks on the Company's business; the location of the Company's manufacturing and research and development facilities near earthquake fault lines; expansion of social media platforms and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and the Company undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

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**[www.impaxlabs.com](http://www.impaxlabs.com)**

### References

ZOMIG Nasal Spray Prescribing Information. Updated June 2015.

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Neurology July 3, 2007 vol. 69 no. 1 16-25

To view the original version on PR Newswire, visit: **<http://www.prnewswire.com/news-releases/fda-approves-zomig-zolmitriptan-nasal-spray-for-migraine-in-pediatric-patients-ages-12-17-300099548.html>**

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