NEWS RELEASE

Impax Receives FDA Approval for Generic Version of Adderall XR® (mixed salts of a single-entity amphetamine product) Capsules, CII

2/17/2016

HAYWARD, Calif., Feb. 17, 2016 /PRNewswire/ -- Impax Laboratories, Inc. (NASDAQ: IPXL) today announced that the U.S. Food and Drug Administration (FDA) has approved its Abbreviated New Drug Application (ANDA) for dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate (mixed salts of a single-entity amphetamine product) extended-release capsules, CII, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg.

Logo - **http://photos.prnewswire.com/prnh/20150310/180590LOGO**

"With this approval, we are now in a position to provide our customers a continuity in supply of generic Adderall XR as we transition from our current inventory of the authorized generic version to supply from our ANDA product," said Fred Wilkinson, President and Chief Executive Officer of Impax. "We anticipate that we will complete this transition during the second quarter of 2016 and now have the opportunity to maximize the value from this important product."

Mr. Wilkinson concluded, "The approvals of our generic Adderall XR application and the mid-January approval of EMVERM™ (mebendazole) extend these key franchises, while also providing additional opportunities to pursue growth within these product segments."

According to IMS Health (NSP), U.S. brand and generic sales of mixed amphetamine sales capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg were approximately $1.8 billion for the 12 months ending in November 2015.

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and

amphetamine sulfate extended-release capsules, a CNS stimulant, are indicated for the treatment of attention deficit hyperactivity disorder (ADHD). The product has a boxed warning because amphetamines have a high potential for abuse. In addition, prolonged administration may lead to dependence and misuse of amphetamines may cause sudden death and serious cardiovascular adverse reactions. The drug must be dispensed with a patient Medication Guide that describes important information about its uses and risks.

IMPORTANT SAFETY INFORMATION

Contraindications

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules administration is contraindicated in patients with the following conditions:

- Advanced arteriosclerosis
- Symptomatic cardiovascular disease
- Moderate to severe hypertension
- Hyperthyroidism
- Known hypersensitivity or idiosyncrasy to the sympathomimetic amines (e.g., anaphylaxis, angioedema, serious skin rashes)
- Glaucoma
- Agitated states
- History of drug abuse
- During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive crises may result)

Warnings and Precautions

- Serious Cardiovascular Events: Sudden death has been reported with usual doses of CNS stimulants in children and adolescents with structural cardiac abnormalities or other serious heart problems; sudden death, stroke, and myocardial infarction have been reported in adults taking CNS stimulants at usual doses. Stimulant drugs should not be used in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious heart problems.
- Increase in Blood Pressure: Monitor blood pressure and pulse at appropriate intervals. Use with caution in patients for whom blood pressure increases may be problematic.
- Psychiatric Adverse Events: Stimulants may cause treatment-emergent psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychosis. Evaluate for bipolar disorder prior to stimulant use. Monitor for aggressive behavior.
- Long-Term Suppression of Growth: Monitor height and weight at appropriate intervals.

- Seizures: May lower the convulsive threshold. Discontinue in the presence of seizures.
- Peripheral Vasculopathy, Including Raynaud's Phenomenon: Stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Careful observation for digital changes is necessary during treatment with ADHD stimulants.
- Visual Disturbance: Difficulties with accommodation and blurring of vision have been reported with stimulant treatment.
- Tics: Stimulants may exacerbate tics. Evaluate for tics and Tourette's syndrome prior to stimulant administration.

Adverse Reactions

- Children (ages 6 to 12): Most common adverse reactions (= 5% and with a higher incidence than on placebo) were loss of appetite, insomnia, abdominal pain, emotional lability, vomiting, nervousness, nausea, and fever.
- Adolescents (ages 13 to 17): Most common adverse reactions (= 5% and with a higher incidence than on placebo) were loss of appetite, insomnia, abdominal pain, weight loss, and nervousness.
- Adults: Most common adverse reactions (= 5% and with a higher incidence than on placebo) were dry mouth, loss of appetite, insomnia, headache, weight loss, nausea, anxiety, agitation, dizziness, tachycardia, diarrhea, asthenia, and urinary tract infections.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call 1-800-FDA-1088. To report SUSPECTED ADVERSE REACTIONS contact Impax Laboratories, Inc. at 1-877-994-6729.

For the full prescribing information including Boxed Warnings and the Medication Guide click **here.**

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 its Impax Specialty Pharma division. Additionally, where strategically appropriate, Impax develops marketing partnerships to fully leverage its technology platforms 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**.

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 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 and indenture; the Company's level of indebtedness and liabilities and the potential impact on cash flow available for operations; 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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To view the original version on PR Newswire, visit:**http://www.prnewswire.com/news-releases/impax-receives-fda-approval-for-generic-version-of-adderall-xr-mixed-salts-of-a-single-entity-amphetamine-product-capsules-cii-300221210.html**

SOURCE Impax Laboratories, Inc.