NEWS RELEASE

Impax Receives Approval of EMVERM™ (mebendazole) Chewable Tablets, 100 mg

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EMVERM Provides a New Option for Patients with Pinworm, Whipworm, Roundworm and Hookworm in Single or Mixed Infections

HAYWARD, Calif., Jan. 15, 2016 /PRNewswire/ -- Impax Laboratories, Inc. (NASDAQ: IPXL) today announced that the United States Food and Drug Administration (FDA) has approved the Company's supplemental new drug application (sNDA) for EMVERM (mebendazole) 100 mg chewable tablets.

EMVERM is indicated for the treatment of Enterobius vermicularis (pinworm), Trichuris trichiura (whipworm), Ascaris lumbricoides (common roundworm), Ancylostoma duodenale (common hookworm), Necator americanus (American hookworm) in single or mixed infections. Pinworm is a highly contagious parasite that infects approximately 40 million people in the United States each year.1 Pinworm infection is three times more common than head lice.2 EMVERM is not for persons who have shown hypersensitivity to the drug.

"We are pleased to announce the approval of EMVERM, a new prescription product for the treatment of pinworm and certain worm infections," said Fred Wilkinson, President and Chief Executive Officer of Impax. "EMVERM is an important treatment option for pinworm as it offers a 95% clinical cure rate in a single 100 mg dose.3 We currently expect to initiate commercial distribution of EMVERM early in the second quarter of 2016."

"As part of our life cycle plan to enhance our anthelmintic franchise in addition to ALBENZA® (albendazole), with this approval, we can now offer an anthelmintic to treat the most common worm infections in the United States. Additionally, the approval of ENVERM further leverages the strategic benefits of the Tower Holdings acquisition4," Mr. Wilkinson concluded.

ALBENZA is indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval

forms of the pork tapeworm, Taenia solium. ALBENZA is also indicated for the treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, Echinococcus granulosus. ALBENZA is contraindicated in patients with known hypersensitivity to the benzimidazole class of compounds or any components of ALBENZA.

EMVERM (mebendazole) Important Safety Information

Mebendazole is contraindicated in persons who have shown hypersensitivity to the drug

Warnings: There is no evidence that mebendazole, even at high doses, is effective for hydatid disease. There have been rare reports of neutropenia and agranulocytosis when mebendazole was taken for prolonged periods and at dosages substantially above those recommended.

Precautions: Periodic assessment of organ system functions, including hematopoietic and hepatic, is advisable during prolonged therapy.

Information for Patients:

- Patients should be informed of the potential risk to the fetus in women taking mebendazole during pregnancy, especially during the first trimester (See Pregnancy below).
- Patients should also be informed that cleanliness is important to prevent reinfection and transmission of the infection.

Drug Interactions: Preliminary evidence suggests that cimetidine inhibits mebendazole metabolism and may result in an increase in plasma concentrations of mebendazole.

Pregnancy Category C: Mebendazole has shown embryotoxic and teratogenic activity in pregnant rats at single oral doses as low as 10 mg/kg (approximately equal to the human dose, based on mg/m2). In view of these findings the use of mebendazole is not recommended in pregnant women.

Nursing Mothers: It is not known whether mebendazole is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when mebendazole is administered to a nursing woman.

Pediatric Use: The drug has not been extensively studied in children under two years; therefore, in the treatment of children under two years the relative benefit/risk should be considered.

Adverse reactions:

Gastrointestinal: Transient symptoms of abdominal pain and diarrhea with expulsion of worms in cases of massive infection.

Hypersensitivity: Rash, urticaria and angioedema have been observed on rare occasions.

Central Nervous System: Very rare cases of convulsions have been reported.

Liver: There have been liver function test elevations [AST (SGOT), ALT (SGPT), and GGT] and rare reports of hepatitis when mebendazole was taken for prolonged periods and at dosages substantially above those recommended.

Hematologic: Neutropenia and agranulocytosis. (See WARNINGS above).

Overdosage: In the event of accidental overdosage, gastrointestinal complaints lasting up to a few hours may occur. Vomiting and purging should be induced. Activated charcoal may be given.

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 full Prescribing Information see **http://documents.impaxlabs.com/emverm/pi.pdf**.

ALBENZA (albendazole) Important Safety Information

Contraindications

ALBENZA is contraindicated in patients with known hypersensitivity to the benzimidazole class of compounds or any components of ALBENZA.

Warnings and Precautions

Fatalities have been reported due to bone marrow suppression; monitor blood counts in all patients at the beginning of each 28-day cycle of therapy, and every 2 weeks while on therapy Discontinue ALBENZA in all patients if clinically significant changes in blood counts occur.

Obtain pregnancy test in women of reproductive potential prior to therapy and avoid usage in pregnant women except in clinical circumstances were no alternative management is appropriate. Discontinue therapy if pregnancy occurs and apprise patient of potential hazard to the fetus.

Neurocysticercosis patients may experience cerebral hypertensive episodes, seizures or focal neurologic deficits after initiation of therapy; begin appropriate steroid and anticonvulsant therapy.

Cases of retinal involvement have been reported; examine the patient for the presence of retinal lesions before initiating therapy for neurocysticercosis.

Elevations of liver enzymes may occur. Monitor liver enzymes before the start of each treatment cycle and at least

every 2 weeks while on ALBENZA therapy and discontinue if clinically significant elevations occur.

Undiagnosed neurocysticercosis may be uncovered in patients treated with ALBENZA for other conditions. Patients with epidemiologic factors who are at risk for neurocysticercosis should be evaluated prior to initiation of therapy.

Adverse Reactions

Adverse reactions 1% or greater in hydatid disease: abnormal liver function tests, abdominal pain, nausea/vomiting, reversible alopecia, headache, dizziness/vertigo, fever.

Adverse reactions 1% or greater in neurocysticercosis: headache, nausea/vomiting, raised intracranial pressure, meningeal signs.

For full Prescribing Information see **www.Albenza.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**.

"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 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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References

1. Maguire JH. Intestinal nematodes (roundworms). In: Bennett JE, Dolin R, Blaser MJ, eds. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. 8th ed. Philadelphia, PA: Churchill Livingstone Elsevier; 2015:3199-3207.e2. and Weller PF, Nutman TB. Intestinal nematodes. In: Fauci AS, Kasper DL, Longo DL, et al, eds. Harrison's Principles of Internal Medicine. 17th ed. New York, NY: McGraw Hill; 2008:1319-1323.
2. Epidemiology & risk factors. Centers for Disease Control and Prevention website. **http://www.cdc.gov/parasites/lice/head/epi.html**. Updated September 24, 2013. Accessed November 17, 2015.
3. EMVERM Prescribing Information: p2/3/Table
4. In March 2015, Impax acquired Tower Holdings, Inc. and Lineage Therapeutics Inc., together with its subsidiaries, CorePharma LLC and Amedra Pharmaceuticals LLC.

To view the original version on PR Newswire, visit:**http://www.prnewswire.com/news-releases/impax-receives-approval-of-emverm-mebendazole-chewable-tablets-100-mg-300205033.html**

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