



NEWS RELEASE

Impax Receives Positive CHMP Opinion for NUMIENT™ (Levodopa and Carbidopa) Modified-Release Capsules for the Symptomatic Treatment of Adult Patients with Parkinson's disease

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AMSTERDAM, Sept. 25, 2015 /PRNewswire/ -- **Impax Laboratories, Inc. (NASDAQ: IPXL)** today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion recommending that NUMIENT (IPX066), a modified-release oral capsule formulation of levodopa-carbidopa, be granted approval for the symptomatic treatment of adult patients with Parkinson's disease. The European Commission (EC) will now consider the CHMP positive opinion in its decision of whether to grant marketing authorization for NUMIENT in Europe. The review of this application is being conducted under the centralized licensing procedure as a therapeutic innovation, and the final decision will be applicable in all 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway.

"The positive opinion from the CHMP recommending the approval of NUMIENT is a significant step forward to providing a new treatment option to patients in Europe suffering from Parkinson's disease," said Fred Wilkinson, President and Chief Executive Officer of Impax. "We are committed to realizing the full potential of this important franchise and we look forward to the European Commission's decision in the coming months."

"We continue to have discussions with potential partners to help commercialize NUMIENT in Europe. If approved, we will work quickly to bring NUMIENT to patients," concluded Mr. Wilkinson.

The CHMP's positive opinion is based on results from three Phase 3 controlled clinical studies which assessed the safety and efficacy of NUMIENT in patients with early (levodopa-naive) and advanced Parkinson's disease in the U.S. and in Europe. Refer to the "Summary of the Three Phase 3 Controlled Clinical Studies" for additional information.

About Parkinson's disease

Parkinson's disease is a chronic neurodegenerative movement disorder affecting approximately 7 to 10 million people globally[1]. There is currently no known cure for Parkinson's disease.

About NUMIENT

If approved in Europe, NUMIENT will be indicated for the symptomatic treatment of adult patients with Parkinson's disease. NUMIENT is not for use in patients with hypersensitivity to the active drug substances or excipients in NUMIENT, narrow-angle glaucoma, phaeochromocytoma, a previous history of neuroleptic malignant syndrome (NMS) and/or non-traumatic rhabdomyolysis, or in patients using nonselective monoamine oxidase inhibitors (MAO) inhibitors, which must be discontinued 2 weeks prior to starting to use NUMIENT.

Summary of the Three Phase 3 Controlled Clinical Studies

In APEX-PD, a trial that enrolled and randomized 381 levodopa-naive patients, the study met its primary efficacy endpoint of mean change from baseline in the sum of Unified Parkinson's Disease Rating Scale (UPDRS) Part II (activities of daily living) score and UPDRS Part III (motor examination) score for NUMIENT versus placebo at end of study.

In ADVANCE-PD, a trial of 393 randomized patients with advanced Parkinson's disease having "off" time, the results showed treatment with IPX066 (NUMIENT) reduced the percentage of "off" time (36.9% to 23.8%) from baseline versus immediate-release levodopa-carbidopa (36.0% to 29.8%) during waking hours to end of study, representing almost 1.2 hours of additional "off" time improvement. IPX066 (NUMIENT) also increased "on" time without troublesome dyskinesia during waking hours by 1.9 hours compared with an increase of 0.8 hours following treatment with immediate-release levodopa-carbidopa. Less "off" time was primarily related to more "on" time without troublesome dyskinesia.

In ASCEND-PD, a trial of 91 randomized patients with advanced Parkinson's disease having "off" time, compared IPX066 versus levodopa-carbidopa plus entacapone (LCE). Patients entered the study with a baseline "off" time of 36.1% (5.9 hours), and at the end of the randomized IPX066 treatment phase, patients had "off" time of 24.0% (3.8 hours) during waking hours compared to 32.5% (5.2 hours) for LCE ($p < 0.0001$), representing 1.4 hours of additional "off" time improvement.

Summary of the NUMIENT Safety Profile

The most frequently reported adverse reactions in the 978 patients exposed to NUMIENT during the entire clinical program were nausea, occurring in approximately 12% of all patients; dizziness, headache, and dyskinesia, each occurring in approximately 8% of all patients; and insomnia, occurring in approximately 6% of all patients. Serious events of gastrointestinal haemorrhage (uncommon) and of allergic oedema (uncommon) were reported in the clinical studies with NUMIENT.

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.

References

[1] Parkinson's Disease Foundation website http://www.pdf.org/en/parkinson_statistics

Company Contacts:

Mark Donohue

Investor Relations and Corporate Communications

(215) 558-4526

www.impaxlabs.com

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SOURCE Impax Laboratories, Inc.