Imprimis Pharmaceuticals Enters into License Agreement for Patented Urology Formulation

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SAN DIEGO, Oct. 29, 2014 /PRNewswire/ -- Imprimis Pharmaceuticals, Inc. (Nasdaq: IMMY) today announced that it has entered into a license agreement, under which Imprimis acquired the US rights to commercially compound a patented combination of alkalized lidocaine and heparin from Urigen Pharmaceuticals, Inc. Physicians in the US and abroad have been prescribing and instilling this compounded drug formulation in different dosages to treat individual patients suffering from interstitial cystitis, also known as painful bladder syndrome (IC/PBS). Compounded alkalized lidocaine and heparin instillation procedures have been reimbursable by private healthcare providers and to Medicare beneficiaries under CPT Code 51700.

Urigen's patented formulation first became available in 2011 as a compounded drug. Since then, there have been more than 125,000 instillation procedures completed in the US. In 2014, the number of prescriptions written for individual patients for Urigen's compounded alkalized lidocaine and heparin formulation is estimated to exceed 110,000, generating approximately $6.5M in annual prescription sales. To date, sales of this formulation have been generated without a dedicated national sales and marketing strategy.

According to the RAND IC Epidemiology Study (2009), the largest IC epidemiology study ever undertaken, and the BACH study (2009), the total addressable market for this debilitating chronic disease is estimated to be more than ten million women and men in the US.

Under the terms of the agreement, Imprimis shall pay Urigen tiered royalties based on net product sales with a minimum annual payment per unit for each prescription dispensed. The license does not require any cash payment by Imprimis upon execution. The license is non-exclusive for a period of six months, at which time Imprimis has the sole right to convert to an exclusive license. Once converted to an exclusive license, Imprimis is obligated to make certain annual minimum payments. The license is for the US market only and covers certain US patent rights that extend through 2026. The agreement contains provisions for the parties to remain long-term partners throughout the product lifecycle.

"The acquisition of the license to compound Urigen's alkalized lidocaine and heparin formulation is an important milestone for our company and a win for the millions of women and men in the US suffering from IC/PBS, a chronic and debilitating disease," stated Mark L. Baum, CEO of Imprimis. "We intend to build a dedicated national education and awareness program around IC/PBS and this important patented formulation. Similar to the *Go Dropless* ™ campaign we launched earlier this year for our Dropless Cataract Surgery™ program in ophthalmology, we intend to create national awareness for this urology formulation through a*Defeat IC* ™ campaign, which we expect to begin in early 2015. The *Defeat IC* ™ campaign will be aimed at physicians who treat the millions of patients in the US who present with IC/PBS symptoms. We appreciate the work that has been done thus far with the Urigen team to ready ourselves for the launch of our *Defeat IC* ™ campaign, and we look forward to continued collaboration with the Urigen team."

Compounded alkalized lidocaine and heparin may only be prescribed pursuant to a physician prescription for an individually identified patient consistent with federal and state laws governing compounded drug formulations.

ABOUT INTERSTITIAL CYSTITIS / PAINFUL BLADDER SYNDROME

IC/PBS is a chronic disease state characterized by bladder pressure, bladder pain, and in some patients, lesions in the bladder, commonly referred to as Hunner's lesions. Patients suffer from increased urinary urgency and frequency. IC/PBS symptoms are often misdiagnosed as urinary tract infections in women and chronic prostatitis in men, or other medical conditions. Patients are commonly prescribed antibiotics for the IC/PBS symptoms which often do not address the condition.

CLINICAL STUDY SUMMARY OF ALKALIZED LIDOCAINE AND HEPARIN

Two published journal articles describe the safety and efficacy of Urigen's alkalized lidocaine and heparin instillation in patients with IC/PBS. The article, Parsons, et al. 2012. *International Society for Sexual Medicine*, was a multicenter prospective, double-blind, placebo-controlled trial, and showed a statistically significant improvement in the reduction of pain (p=0.0363) and micturition urgency (p=0.0328) in patients with IC/PBS. The second published article, Parsons, 2005. *Journal of Urology*, studied the effect of two instillations (Group 1 = 1% Lidocaine; Group 2 = 2% Lidocaine) in IC/PBS patients in relieving urgency and frequency of micturition as well as pain. All patients in the study saw marked improvement in all three symptoms with a statistically significant response rate in Group 2 over Group 1.

ABOUT IMPRIMIS PHARMACEUTICALS

San Diego-based Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY) is a specialty pharmaceutical company dedicated to delivering high quality and innovative medicines to physicians and patients at accessible prices. Imprimis is pioneering a new commercial pathway using compounding pharmacies for the formulation and distribution of its proprietary drug therapies, which include formulations in ophthalmology and urology. For more information about Imprimis, please visit the company's corporate website at www.ImprimisPharma.com; ophthalmology business website at www.GoDropless.com; and urology business websites at www.DefeatIC.com and www.PainfulBladderSyndrome.com.

SAFE HARBOR

This press release contains forward-looking statements within the meaning of the US Private Securities Litigation Reform Act of 1995. Any statements in this release that are not historical facts may be considered such "forward-looking statements." Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ from those predicted include risks and uncertainties related to Imprimis' ability to make commercially available its compounded formulations and technologies in a timely manner or at all; physician interest in prescribing its formulations; risks related to its compounding pharmacy operations; its ability to enter into other strategic alliances, including arrangements with pharmacies, physicians and healthcare organizations for the development and distribution of its formulations; its ability to obtain intellectual property protection for its assets; its ability to accurately estimate its expenses and cash burn, and raise additional funds when necessary; risks related to research and development activities; the projected size of the potential market for its technologies and formulations; unexpected new data, safety and technical issues; regulatory and market developments impacting compounding pharmacies, outsourcing facilities and the pharmaceutical industry; competition; and market conditions. These and additional risks and uncertainties are more fully described in Imprimis' filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Such documents may be read free of charge on the SEC's web site at www.sec.gov. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Except as required by law, Imprimis undertakes no obligation to update any forward looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

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