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Imprimis Pharmaceuticals Reports Results of Independent Third Party Potency Analysis of its Compounded Pyrimethamine and Leucovorin Capsules

December 11, 2015

SAN DIEGO, Dec. 11, 2015 /PRNewswire/ -- Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY), a specialty pharmaceutical company focused on the development and commercialization of proprietary compounded drug therapies, today released the results of a third party potency analysis of its customizable compounded formulation of pyrimethamine and leucovorin for physicians to consider prescribing as a lower cost alternative to Daraprim® for toxoplasmosis and other types of infections. An independent third party laboratory tested the potency of the active pharmaceutical ingredients (API) of its pyrimethamine and leucovorin formulation using [U.S. Pharmacopeia](#) (USP) methods described in the monograph for each API. The USP standard, recognized by the FDA, is used in the U.S. and internationally in order to set the standards for the identity, strength, purity and other important qualities of active drug ingredients. The subject report on assays from a random sampling of Imprimis' pyrimethamine and leucovorin capsules found that the concentration of purported 12.5 mg of pyrimethamine was 100.1% potency with 12.509 mg of the active drug found, and the purported 2.5 mg of leucovorin tested had 100.5% potency with a concentration of 2.512 mg of active drug found. The sample met USP potency requirements.



Upon a physician prescription for a patient's specific condition, Imprimis will customize various quantities and dosages of its pyrimethamine and leucovorin formulation, making this formulation available as a personalized medicine, and the cost will remain \$0.99 per capsule. If you would like to learn more about this formulation, or if you are a physician and would like to order it, please visit www.ImprimisCares.com.

Mark L. Baum, CEO of Imprimis stated, "As a part of the process of familiarizing our newest customers with the value we are presenting to the market with one of our oral dosage formulations of pyrimethamine and leucovorin, I am happy to make public, independent potency testing results of a random sampling of this formulation. These excellent results speak to the quality of our process, the skill of our team and the value we bring in our service of patients."

Baum continued, "I am confident, that as a national leader in pharmaceutical compounding, our commitment to quality, for sterile and non-sterile dosage forms, is second to none. All raw materials we use are made at FDA-registered and inspected manufacturing facilities that must comply with current good manufacturing practices (cGMP). We only purchase active drug ingredients that have the USP monograph claim. All of our FDA approved raw materials come with certificates of analysis connected to the USP monograph. Federal and state oversight is a part of every aspect of our drug supply chain from raw material acquisition to production, testing and dispensing. We meet and/or exceed all quality standards for the formulations we dispense and we are committed to transparency to our customers when it comes to the batch and lot testing we do, including providing the actual sterility test results for each order we dispense for a sterile compounded drug."

Imprimis' finished compounded drug formulations do not have an FDA-approval label for recommended use. Imprimis finished compounded formulations are not FDA approved and may only be prescribed pursuant to a physician prescription for an individually identified patient consistent with federal and state laws governing compounded drug formulations.

Daraprim® is a registered trademark of Turing Pharmaceuticals LLC. Imprimis is not affiliated with Turing Pharmaceuticals LLC nor Daraprim®. Daraprim® is an FDA-approved drug. Please consult with your physician regarding which prescription options are most suitable for your specific needs.

ABOUT IMPRIMIS PHARMACEUTICALS

San Diego-based Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY) is a national leader in the development, production and dispensing of novel compounded pharmaceuticals. The company's business primarily consists of four therapeutic segments including ophthalmology, urology, sinus and integrative medicine. Imprimis dispenses compounded pharmaceuticals in all 50 states from four facilities located in California, Texas, New Jersey and Pennsylvania. For more information about Imprimis, please visit the corporate website at www.ImprimisPharma.com.

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This press release contains forward-looking statements within the meaning of the U.S. 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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