Imprimis' Dropless Therapy Shows Significant Advantages in a Large Peer-Reviewed Study

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SAN DIEGO, Oct. 25, 2016 /PRNewswire/ -- Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY), today announced the release of data from a peer-reviewed study of patients receiving Imprimis' proprietary Dropless Therapy® following cataract surgery. The study evaluated 1,541 eyes from 922 patients and demonstrated that in nearly 92% of cases (n=1413/1541), supplemental medication was not required after surgery. The study retrospectively reviewed a case series of patients receiving cataract surgery and eligible for a transzonular injection of compounded Tri-Moxi-Vanc (3.0 mg triamcinolone acetonide, 0.2 mg moxifloxacin, 2.0 mg vancomycin).

"I have performed over 5,000 cataract surgeries since Imprimis' Tri-Moxi-Vanc (TMV) was first introduced and, with the exception of steroid responsive and advanced glaucoma patients, I exclusively use TMV as a prophylactic alternative for my patients undergoing cataract surgery. As a result, I have had the opportunity to retrospectively compile and analyze the largest case series to date evaluating the clinical benefits of TMV," said Sydney Tyson, M.D., SurgiCenter of Vineland, Vineland, New Jersey. "Although eye drops have been the current standard of care, there is a paradigm shift occurring as more surgeons are moving to single-use intraocular injections."

"Clinical outcomes after injection of a compounded pharmaceutical for prophylaxis after cataract surgery: a large-scale review" was a retrospective analysis of the medical records of 922 patients who underwent cataract surgery followed by an injection of TMV from November 2013 through December 2014. The primary analysis consisted of 1,541 surgical cases performed at a single-specialty ambulatory center (SurgiCenter of Vineland, Vineland, New Jersey). The study protocol was approved by the Wills Eye Hospital Institutional Review Board (Philadelphia, Pennsylvania, USA). Cases were evaluated preoperatively and at postoperative Days 1, 14-21, and 90 for visual acuity, intraocular pressure (IOP), and presence of endophthalmitis, inflammation and cystoid macular edema (CME).

The primary findings of the study included:

- No major intraoperative complications associated with the transzonular injection technique
- No cases of postoperative endophthalmitis
- Mean visual acuity was significantly increased at all postoperative visits (P<0.0001), including the day after surgery
- Rates of infection and inflammation reported appear similar to reported rates with alternative prophylactic therapies such as topical drops
- Rate of breakthrough inflammation at Days 14-21 was 9.2% (n = 132/1429)
- Rate of visually significant postoperative cystoid macular edema was 2.0% (n = 28/1429)
- Rate of clinically significant postoperative IOP increase was low: 0.9% (n = 13/1425) of cases had an increase of at least 10 mmHg in IOP at Days 14-21 or 90
- Only four of these cases had an IOP over 30 mmHg

The paper is available online now to subscribers and will be published in the January 2017 print issue of *Current Opinion in Ophthalmology.* The authors are Sydney L. Tyson, MD, MPH, Robert Bailey, MD, Janika San Roman, MPH, CCRP, Tingting Zhan, PhD, Lisa A. Hark, PhD, RD and Julia A. Haller, MD. The authors received no financial support from Imprimis for the study. Dr. Tyson is a consultant for the company.

About Imprimis' Dropless Therapy

Imprimis' Dropless Therapy compounded antibiotic and steroid formulations are available in single, injectable intraocular doses administered by physicians following ocular surgery. Dropless Therapy may substantially reduce or eliminate the need for patient-administered eye drops following surgery, thereby potentially eliminating patient non-compliance and dosing errors associated with post-operative care regimens. Dropless Therapy can simplify the post-operative care process, provide safeguards against bacterial infection and inflammation, and may decrease overall costs. The sterile ophthalmic compounded formulations use the company's patent-pending SSP Technology®, which allows for active pharmaceutical ingredients that ordinarily do not mix well to solubilize into a predictable, well-distributed, micronized particle suspension. The drug formulations are optimized for isotonicity and pH most compatible for ophthalmic use, either as injectable or topical therapies. Every batch is tested for sterility prior to dispensing and a complimentary copy of the test report is included with each prescription. More information is available at www.GoDropless.com.

About Imprimis Pharmaceuticals

Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY) is a pharmaceutical company dedicated to producing and dispensing high quality innovative compounded medications in all 50 states. The company's unique business model drives patient access and affordability to many critical medicines. Headquartered in San Diego, California, Imprimis owns and operates three dispensing facilities located in California New Jersey and Pennsylvania. For more information about Imprimis, please visit the corporate website at www.ImprimisRx.com.

Forward-Looking Statements

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 our ability to make commercially available our compounded formulations and technologies in a timely manner or at all; physician interest in prescribing our formulations; risks related to our compounding pharmacy operations; our ability to enter into other strategic alliances, including arrangements with pharmacies, physicians and healthcare organizations for the development and distribution of our formulations; our ability to obtain intellectual property protection for our assets; our ability to accurately estimate our 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 our 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.

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

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/imprimis-dropless-therapy-shows-significant-advantages-in-a-large-peer-reviewed-study-300350350.html

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