Imprimis Pharmaceuticals' Subsidiary Melt Pharmaceuticals Initiates Clinical Development Program for its Patented Non-Opioid and Non-Invasive MK Melt™ Conscious Sedation Drug Candidate

October 23, 2018

SAN DIEGO, Oct. 23, 2018 (GLOBE NEWSWIRE) -- Melt Pharmaceuticals, a subsidiary of Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY), today announced that following the presentation of clinical data on the MKO Melt® (midazolam/ketamine/ondansetron) from a 611-patient IRB approved prospective, controlled, randomized, three arm comparator study at the American Academy of Ophthalmology meeting this month, additional studies on Melt's drug candidates will soon begin. Both new studies, along with an upcoming Pre-IND meeting with FDA, which is scheduled for this coming January, will inform the clinical development programs Melt expects to begin during 2019.

Pharmacokinetics and Pharmacodynamics of the MK Melt (Sublingual Midazolam and Ketamine)

The objective of this study is to establish the pharmacokinetics and pharmacodynamics of midazolam and ketamine following administration of the patented MK Melt in up to twenty-five healthy volunteers under an IRB approved protocol with informed consent. These measurements will identify the time course of effects of the MK Melt in relation to the concentrations of its component drugs in the body.

The study will define a window of sedation for the MK Melt in the volunteers, which will provide vital information for physicians and anesthesiologists related to the duration and quality of sedation. Included in the study will be monitoring of vital signs, blood levels, evaluation of the level of volunteers' sedation over time, and satisfaction questionnaires completed by volunteers and study personnel both during and at the conclusion of the study, which will provide vigorous assessments of the sedation achieved with the MK Melt. By establishing the time course of its anesthesia effects, this study should provide data that will allow anesthesiologists to optimize the timing of administration and dosing of the MK Melt for different sedation procedures.

This study is expected to be completed during the fourth quarter of 2018.

Pharmacodynamics of the MKO Melt (Sublingual Midazolam, Ketamine, and Ondansetron) During Oral Surgery & Dental Procedures

This multicenter clinical study is designed to evaluate the safety and efficacy of the MKO Melt for conscious sedation during dental surgery. There are eight participating sites with investigators that include leading oral maxillofacial surgeons, internationally acclaimed pioneers in dental procedures, and faculty members in dental medicine education from leading teaching institutions. This study anticipates at least 100 participants to be recruited and that the inclusion criteria will provide for a wide range of population groups at each participating center.

In this study, the MKO Melt for conscious/moderate sedation will be assessed across a breadth of medical dentistry indications including oral and maxillofacial surgery, dental specialties such as periodontics and endodontics, as well as general dentistry. The participating investigators plan to administer the MKO Melt to patients under an IRB approved protocol with informed consent during the patients' scheduled dental procedures.

The objective of this study is to evaluate the MKO Melt for management of pain/discomfort and anxiety during dental procedures and surgery. We anticipate that the multiple measures of sedation and satisfaction in this protocol provide a robust study design and will allow for definitive conclusions to be drawn.

This study is expected to be completed in the second or third quarter of 2019.

About Imprimis Pharmaceuticals

Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY) is a commercial-stage pharmaceutical company based in San Diego, California. In addition to owning the nation's leading ophthalmology pharmaceutical compounding business, ImprimisRx, the Company holds large equity positions in Eton Pharmaceuticals, Surface Pharmaceuticals and Melt Pharmaceuticals, companies originally founded as subsidiaries of Imprimis. The Company also owns royalty rights in certain 505(b)(2) drug candidates being developed by Eton, Surface and Melt. For more information about Imprimis, please visit the Investor Relations section of the corporate website by clicking here.

About Melt Pharmaceuticals

Melt Pharmaceuticals, Inc., is a development stage pharmaceutical company focused on the development and commercialization of patented non-opioid and non-intravenous (or non-IV) sedation and anesthesia therapeutics for human medical procedures in hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval through the U.S. Food and Drug Administration's 505(b)(2) regulatory pathway for these proprietary technologies. Melt's core technology is a series of combination non-opioid sedation drug formulations that may replace or supplement current sedation modalities for more than 100 million medical procedures in the United States. Melt is presently a subsidiary of Imprimis Pharmaceuticals, Inc.

Melt Pharmaceuticals' vision is to be the leading provider of non-opioid, non-intravenous conscious sedation and analgesia pharmaceuticals used for human medical procedures in hospital, outpatient, and in-office settings.

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.

No Imprimis compounded formulation is FDA-approved. Other than drugs compounded at a registered outsourcing facility, all Imprimis compounded formulations require a prescription for an individually identified patient consistent with federal and state laws.

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