Imprimis Pharmaceuticals, Inc. Receives Institutional Review Board (IRB) Approval for its Phase III Clinical Trial Protocol; Phase III Clinical Trial to Begin in 3Q 2013

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SAN DIEGO, July 22, 2013 /PRNewswire/ -- Imprimis Pharmaceuticals, Inc. (NASDAQ:IMMY), which is focused on the commercialization of compounded drug formulations utilizing the FDA 505(b)(2) development pathway, today announced it has received IRB approval for its Phase III clinical trial protocol of its lead product candidate, Impracor ™. Imprimis has engaged Agility Clinical, Inc., a Carlsbad, CA-based consulting and contract research organization (CRO), to conduct the study at 20 - 30 US sites. The IRB-approved Phase III trial is a randomized, multicenter, double-blind, parallel-group study to assess the efficacy and safety of Impracor (ketoprofen 10% cream) compared with placebo in the treatment of acute pain (flare) associated with osteoarthritis (OA) of the knee.

As previously announced, Imprimis designed the Phase III study with the assistance of key opinion leaders, and also relied upon feedback from the U.S. Food and Drug Administration (FDA) following a Type C meeting between Imprimis and FDA officials in April 2013.

"This is an important and critical step forward for Imprimis as we prepare to start enrollment of our Phase III clinical trial in the third quarter of this year," said Imprimis CEO Mark L. Baum. "The IRB approval of this protocol in many ways represents the culmination of a year of hard work, and marks the initiation of our Impracor Phase III study. With Agility as our clinical operations team, we have an experienced partner that will help us bring forward a new alternative therapy in the space of anti-inflammatory, pain-relieving drugs, to improve patient health and quality of life. We are delighted to be working with Dr. Neil Singla of Lotus Clinical Research, who has an excellent track record in conducting successful trials in the pain sector."

"We are excited that the Imprimis Phase III protocol was approved by an independent central ethics committee, Schulman Associates Institutional Review Board, Inc.," said Imprimis Chief Medical Officer Dr. Joachim Schupp. "This is an important milestone to commence our Phase III study in the third quarter of this year. The primary role of an IRB is to safeguard the rights, safety and welfare of participants in research. Agility Clinical and Lotus Clinical Research were instrumental in the final protocol and informed consent preparation."

"Helping innovative companies bring new treatments to patients is an important part of Agility's mission," said Ellen Morgan, CEO of Agility Clinical. "We are excited to be working with Imprimis and Lotus Clinical Research on this study. If approved, Impracor will provide patients suffering from osteoarthritis of the knee with an alternative to systemic NSAIDs for the management of their pain."

"We appreciate the opportunity to work with Imprimis Pharmaceuticals, Inc. and Agility Clinical on this important clinical trial," said Dr. Neil Singla, Owner of Lotus Clinical Research. "All parties have worked diligently over the past several months to design a robust protocol that will answer many critical regulatory and therapeutic questions concerning Impracor."

Imprimis has commenced the investigational site selection for training, qualification and study initiation.

About Imprimis Pharmaceuticals, Inc.

Imprimis Pharmaceuticals, Inc. (NASDAQ:IMMY) is a specialty pharmaceutical company focused on the commercial development of compounded drug formulations. Through its exclusive strategic relationship with Professional Compounding Centers of America (PCCA), the largest compounding pharmacy organization in North America, Imprimis expects to use its proprietary Accudel drug delivery technologies, as well as proprietary drug formulations for new indications and market data obtained through PCCA, to identify and pursue pharmaceutical development opportunities where there is a significant unmet medical need utilizing the FDA 505(b)(2) regulatory pathway. Imprimis' most near term drug candidate, Impracor, is a Phase III product candidate that utilizes the Accudel topical cream formulation to deliver the active drug ketoprofen, a non-steroidal anti-inflammatory drug (NSAID), through the skin directly into the underlying tissues where the drug exerts its localized anti-inflammatory and analgesic effects. For more information, visit http://imprimispharma.com/.

About Agility Clinical, Inc.

Agility Clinical, Inc. was founded in 2012 with an experienced executive management team whose mission is to help small and virtual pre-clinical and clinical stage companies develop drugs and devices, particularly in the orphan drug category. In addition to consulting, Agility provides customized full clinical trial services including project management, clinical operations, data management, biostatistics, medical, regulatory, and scientific affairs, medical writing and electronic source records (ESR). The Agility team has a true appreciation for the challenges virtual companies face in obtaining

the expertise they need. Agility has established operations in Carlsbad, CA. For more information, please visit www.agility-clinical.com.

About Lotus Clinical Research, LLC

Established in 2001, Lotus Clinical Research, LLC operates a 40 bed Phase I-3 privately owned research unit located on the 675–bed Huntington Hospital campus in Pasadena, California. We have a significant therapeutic expertise in research studies involving acute pain, chronic pain and opioid induced constipation. In addition to functioning as a research site, we provide analgesic protocol optimization services to industry sponsors which consist of: training tools for research subjects, educational materials for analgesic investigators/study staff, site identification/selection and protocol writing.

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 preliminary expectations and are subject to risks and uncertainties which may cause Imprimis' 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 uncertainties inherent in pre-clinical studies and clinical trials, unexpected new data, safety and technical issues, 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 filed with the SEC. 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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