



Flamel Technologies Doses First Patient in REST-ON Phase III Trial of FT218 for Excessive Daytime Sleepiness & Cataplexy

Lyon, France – December 16, 2016 - Flamel Technologies SA (NASDAQ: FLML) today announced that the first patient has been dosed in its Rest-On Phase III clinical trial of FT218, a once-nightly formulation of sodium oxybate utilizing the Company's proprietary Micropump® technology, for the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy.

Mike Anderson, Flamel's Chief Executive Officer, remarked, "This is an exciting milestone for Flamel. FT218 is our most important asset and has the potential to provide a number of benefits to narcoleptic patients, who suffer from debilitating quality of life issues. We are seeing significant interest in this trial from both physicians and patients alike, and are excited to continue the screening and enrollment process as more sites are initiated throughout Europe, Canada and the U.S."

REST-ON is a 264 patient, double-blind, randomized, placebo controlled Phase III clinical trial to assess the efficacy and safety of a once nightly formulation of sodium oxybate for extended-release oral suspension for the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. The study will be conducted across 50 – 60 clinical sites throughout the U.S., Europe and Canada.

About Sodium Oxybate

Sodium Oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid (GABA). It has been described as a therapeutic agent with high medical value; in Europe and the United States it is currently approved in a twice nightly formulation indicated for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy at doses up to 9g/night.

About Micropump®

Micropump® is a microparticulate system that allows the development of modified and/or controlled release of solid, oral dosage formulations of drugs. Micropump allows the achievement of extremely precise pharmacokinetic profiles of single or combination of drugs, in a variety of formats (such as tablets, capsules, sachet, or liquids (LiquiTime®)), while preserving the targeted release rate over the shelf-life of the product.

About Flamel Technologies

Flamel Technologies SA (NASDAQ: FLML) is a specialty pharmaceutical company utilizing its core competencies in formulation development and drug delivery to develop safer and more efficacious pharmaceutical products, addressing unmet medical needs and/or reducing overall healthcare costs. Flamel currently markets three branded, sterile injectable products in the United States, Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection), and Akovaz™

(ephedrine sulfate injection). The Company also develops products utilizing its proprietary drug delivery platforms, Micropump® (oral sustained release microparticles platform), along with its tangent technologies, LiquiTime® (a Micropump-derivative platform for liquid oral products) and Trigger Lock™ (a Micropump-derivative platform for abuse-resistant opioids). Additionally, the Company has developed a long acting injectable platform, Medusa™, a hydrogel depot technology, particularly suited to the development of subcutaneously administered formulations. Applications of Flamel's drug delivery products include sodium oxybate (Micropump®), currently being studied in a Phase III trial to assess the safety and efficacy of a once nightly dose for treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy, and extended-release of liquid medicines (LiquiTime®) through a license arrangement with Elan Pharma International Limited for the U.S. Over-the-Counter market. Additionally, the Company's Trigger Lock™ technology is currently being studied with hydromorphone, and several proof of concept studies of exenatide utilizing the Medusa™ technology were completed in 2016. In February 2016, Flamel acquired FSC Pediatrics, a company that markets three pediatric pharmaceutical products - Cefaclor for oral suspension, Karbinal™ ER, and AcipHex® Sprinkle™ (rabeprazole sodium). FSC also received 510(k) clearance from the FDA in October 2014 for Flexichamber™, a collapsible holding chamber used in the administration of aerosolized medication using pressurized Metered Dose Inhalers (pMDIs) for the treatment of asthma. The Company is headquartered in Lyon, France and has operations in Dublin, Ireland and in St. Louis, Missouri. Additional information may be found at www.flamel.com.

Safe Harbor

This release may include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements herein that are not clearly historical in nature are forward-looking, and the words "anticipate," "assume," "believe," "expect," "estimate," "plan," "will," "may," and the negative of these and similar expressions generally identify forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond Flamel's control and could cause actual results to differ materially from the results contemplated in such forward-looking statements. These risks, uncertainties and contingencies include the risks relating to: our dependence on a small number of products and customers for the majority of our revenues; the possibility that our Bloxiverz®, Vazculep® and Akovaz™ products, which are not patent protected, could face substantial competition resulting in a loss of market share or forcing us to reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for the pipeline product we are evaluating for potential application to the FDA pursuant to our "unapproved-to-approved" strategy, or that competitors could complete the development of such product and apply for FDA approval of such product before us; our dependence on the performance of third parties in partnerships or strategic alliances for the commercialization of some of our products; the possibility that our products may not reach the commercial market or gain market acceptance; our need to invest substantial sums in research and development in order to remain competitive; our dependence on certain



single providers for development of several of our drug delivery platforms and products; our dependence on a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products; the possibility that our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do; the challenges in protecting the intellectual property underlying our drug delivery platforms and other products; our dependence on key personnel to execute our business plan; the amount of additional costs we will incur to comply with U.S. securities laws as a result of our ceasing to qualify as a foreign private issuer; and the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2015, all of which filings are also available on the Company's website. Flamel undertakes no obligation to update its forward-looking statements as a result of new information, future events or otherwise, except as required by law.

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