Flamel Technologies Reaches Agreement with FDA on Protocol for Phase III Pivotal Trial of FT218

Lyon, France – October 6, 2016 – Flamel Technologies (NASDAQ: FLML) today announced that its Irish subsidiary, Flamel Ireland Holdings, has reached agreement with the U.S. Food and Drug Administration (FDA) for the design and planned analysis of a Phase III clinical trial of FT218, a once nightly formulation of sodium oxybate utilizing the Company's proprietary drug delivery platform, Micropump®. The agreement was reached through the Special Protocol Assessment (SPA) process.

A SPA is an acknowledgement by FDA that the design and planned analysis of the Company's pivotal clinical trial of FT218 adequately addresses the objectives necessary to support a regulatory submission. The Phase III trial, titled "A Double-blind, Randomized, Placebo Controlled, Two Arm Multi-center Study to Assess the Efficacy and Safety of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy," recently commenced patient enrollment in Canada, with sites in Europe and the U.S. to be initiated near-term.

Mike Anderson, Chief Executive Officer of Flamel, remarked, "We are thrilled to announce that we have come to a much anticipated agreement with FDA on our SPA for a pivotal study of FT218, Micropump® sodium oxybate. This is a major milestone for the trial, as we move forward with site initiation in Europe and subsequently, the United States. We believe our once nightly formulation of sodium oxybate has the potential to offer significant improvements over the current standard of care, in addition to meaningful improvement in overall quality of life for patients suffering from narcolepsy."

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 previously Unapproved Marketed Drugs ("UMDs") 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. Current applications of Flamel's drug delivery products include sodium oxybate (Micropump®), extended-release of liquid medicines such as ibuprofen and guaifenesin (LiquiTime®, through a license arrangement with Elan Pharma International Limited for the U.S. Over-the-Counter market) and a current study of the delivery of exenatide utilizing the Medusa™ technology. In February 2016, Flamel acquired FSC Pediatrics, a company that markets three pediatric pharmaceutical products - Cefaclor for oral suspension, indicated for infection, Karbinal™ ER, indicated for allergic rhinitis and AcipHex® Sprinkle™ (rabeprazole sodium) indicated for the treatment of gastroesophageal disease (GERD). FSC also received 510(k) clearance from the FDA in October 2014 for Flexichamber™, a collapsible holding chamber for 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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