



Flamel Technologies Files Special Protocol Assessment for Once Nightly Sodium Oxybate

Lyon, France – March 31, 2016 - Flamel Technologies (NASDAQ: FLML) today announced that it has filed a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA) for the pivotal Phase III study of its once nightly Micropump™ based sodium oxybate product. The SPA will provide the FDA an opportunity to review and comment on the company's planned study design, and once accepted, offers general acknowledgement by the FDA that the trial's design, clinical endpoints and statistical analyses are acceptable and support the scientific and regulatory requirements associated with the product.

Mike Anderson, Flamel's Chief Executive Officer, commented, "We are excited to announce the filing of our SPA for sodium oxybate. This is a key milestone as we pursue the development of a once nightly version of sodium oxybate for the treatment of narcolepsy."

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 two previously Unapproved Marketed Drugs ("UMDs") in the United States, Bloxiverz® (neostigmine methylsulfate injection) and Vazculep® (phenylephrine hydrochloride injection), and in September 2015 announced that the NDA for its third UMD filing was accepted by the FDA and assigned a PDUFA date of April 30, 2016. 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 Charlotte, North Carolina-based 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 the USA in both St. Louis, Missouri and Charlotte, North Carolina. 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® and Vazculep® 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 two pipeline products 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 products and apply for FDA approval of such products 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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