Flamel Technologies Provides Update on Corporate Progress

Clinical Programs Continue to Move Forward
Outlines Full Year 2016 Revenue Guidance

Lyon, France – January 8, 2016 - Flamel Technologies (NASDAQ: FLML) today announced an update on the Company's corporate progress as it relates to a number of initiatives, including ongoing clinical programs and 2016 revenue guidance.

Highlights include:

- ***Micropump™ sodium oxybate on track to begin Phase 3 pivotal trial***
- ***Recent independent study confirms the robust abuse-deterrent capabilities of Trigger Lock™***
- ***Two LiquiTime™ products to move into pivotal studies in 2016***
- ***Positive interim results of a first-in-man clinical trial with Medusa™***
- ***2016 revenues expected to be in the range of $100 to $120 million, including the launch of Éclat #3***
- ***Strong cash flow and liquidity to continue in 2016***

Mike Anderson, Chief Executive Officer of Flamel, remarked, "The Company has made excellent progress during 2015 at advancing its proprietary pipeline, using Flamel's best-in-class drug delivery platforms to create patent protected products that are expected to offer substantial benefits to healthcare consumers. We continued to generate significant operating profit and cash flow with Bloxiverz® and Vazculep®, enabling us to invest in our pipeline."

Micropump Sodium Oxybate (FT218)

The Company, after consultation with the FDA, will be submitting a Special Protocol Assessment (SPA) for once-nightly Micropump sodium oxybate in the first quarter of 2016 and upon approval will commence patient recruitment in the second quarter. SPAs serve as a way to reduce the risks associated with clinical studies, as the acceptance represents general agreement by the FDA of a pivotal trial's design, endpoints and analyses.

The pivotal trial of Flamel's Micropump technology applied to sodium oxybate for the treatment of narcolepsy is expected to run through early 2017. It is expected to be a placebo-controlled efficacy study of approximately 200-300 patients and will be conducted at between 50 and 60 clinical sites in North America and Europe.

Mr. Anderson continued, "For the past several months, we have had numerous contacts with potential investigators in order to accelerate enrollment procedures once the SPA is approved. We expect to file for Investigational Medicinal Product Dossier (IMPD) approval in the EU in conjunction with the SPA in the US. Any additional studies, such as pivotal pharmacokinetic (PK) studies, needed for a New Drug Application (NDA) approval will be run simultaneously, and the target for trial completion remains mid-2017. Ultimately, we believe we will be able to demonstrate improved efficacy, improved safety and improved patient satisfaction over the standard of care, JAZZ's Xyrem®, a twice nightly sodium oxybate formulation, which is expected to generate at least $950 million in revenues in 2015. Micropump sodium oxybate is our most

important development project and our entire organization is dedicated to moving it forward efficiently and completely."

Trigger Lock Hydromorphone (FT227)

In the second quarter of 2015, Flamel announced positive results from two pilot PK studies in healthy volunteers of FT227, an abuse-deterrent, extended-release, oral hydromorphone product using its proprietary Trigger Lock drug delivery platform. In addition, a recently completed independent study has confirmed the robust abuse-deterrent capabilities of FT227, duplicating the Company's previous internal work. The independent study of FT227 demonstrated better resistance in extraction/recovery studies in different media and under several different conditions than both Exalgo and Oxycontin, and was shown to resist both chemical and physical manipulation in concert with the FDA's 2015 Guidance. Flamel has requested a meeting with FDA in the first quarter of 2016 to discuss continued development of FT227 and expects to initiate licensing discussions for the technology in early 2016.

LiquiTime

In October 2015, Flamel licensed its LiquiTime technology for the Over-the-Counter (OTC) market to Perrigo. Included with the licensing arrangement were LiquiTime ibuprofen and guaifenesin, and a minimum of five additional products. Flamel plans to move the first two LiquiTime products, ibuprofen and guaifenesin, into pivotal testing in 2016. Ultimately, LiquiTime ibuprofen and guaifenesin will be filed for OTC approval via the 505(b)2 pathway.

Flamel expects commercialization of a minimum of seven OTC LiquiTime products with royalties in the mid-single digits and a minimum of $50 million in product launch and milestone payments.

Mr. Anderson commented, "The licensing of LiquiTime technology to Perrigo for the U.S. OTC market was strong validation of our technology, and we expect to see meaningful revenues from these products following their launch. Even though the remaining five products have not been finally identified, the U.S. cough/cold market is estimated to be $6.5 billion, representing a significant financial opportunity for the Company. Additionally, the Company is pursuing licensing options for OTC use of LiquiTime in Europe. Furthermore, we are engaged in several feasibility studies for additional LiquiTime prescription products, which we plan to identify in 2016. The use of LiquiTime for the Rx market is a meaningful opportunity for the Company."

Medusa Exenatide (FT228)

In December 2015, Flamel announced positive results of a Phase 1a study using its propriety Medusa technology applied to exenatide, a GLP1 analog used to treat patients suffering from Type 2 Diabetes Mellitus. Flamel's once weekly subcutaneous injection formulation of exenatide achieved all safety and pharmacokinetic (PK) assessment objectives. As such, the Company plans on moving into a multiple dose Phase 1b study with diabetic patients in early 2016. At the conclusion of the study, the Company will assess next steps. The Company does not anticipate moving beyond the Phase 1b trials on its own.

Marketed Products Revenue Outlook & Corporate Initiatives

Mr. Anderson continued, "We expect 2015 revenue to be at the lower end of our 2015 guidance of $170 to $185 million, and are providing product revenue guidance for 2016 in the range of $100 to $120 million in 2016. The year over year decline in revenue is primarily attributed to the declining Bloxiverz business that we anticipate will be impacted by the launch of a third FDA approved neostigmine methylsulfate. We remain excited about the expected FDA approval and launch of Éclat #3 by midyear. We fully expect that our UMD

products will continue to produce meaningful cash flow in the coming years, allowing for the autonomous development of Flamel's proprietary product pipeline."

The Company's full year 2016 revenue guidance is based on the following assumptions:

- On December 28, 2015, the FDA announced approval of a generic version of neostigmine to be marketed by West-Ward Pharmaceuticals, creating a market of three approved providers. While Flamel garnered a majority share of the neostigmine market of between 55 – 60% throughout 2015, expectations for market share in 2016 are in the range of 30 – 40% of a total market estimated to be approximately 4.5 million vials per year, with a reduction in net-price in the range of 20 – 30%. The decrease in total market size from approximately 5 million vials per year to 4.5 million vials per year is a result of Merck's December 2015 approval of Bridion® (sugammadex), a neostigmine alternative, which is expected to reduce the overall neostigmine market by approximately 10%.

- Vazculep, which is marketed in three vial sizes, 1mL, 5mL and 10mL, continues to increase its share of the phenylephrine market. Flamel supplies 100% of the 5mL and 10mL vials, and currently holds a combined share of 40% for all three vial sizes. The Company expects the entrance of a generic phenylephrine to the market in mid-2016, which would likely impact its share and pricing.

- The Company's third UMD (Éclat #3) is expected to receive FDA approval on its PDUFA date of April 30, 2016. Following launch of Éclat #3 in mid-year 2016, Flamel expects its market share to be in the range of 20 – 30%, and to increase substantially in 2017. Flamel closely monitors market conditions as it relates to its portfolio of UMD products, and while the market size of its third UMD was initially estimated in the range of $70 – 80 million, recent developments have made this asset more attractive than initially anticipated with the potential to earn an attractive return on investment for shareholders.

- During 2016, the Company expects to increase its R&D expenditures to a range of $35-50 million. The increase over 2015 is a result of additional investments for the sodium oxybate trial, the LiquiTime trials, and other projects.

Mr. Anderson concluded, "We will continue to pursue a number of other initiatives to increase shareholder value in 2016. Among the initiatives are the development of at least one additional UMD, the pursuit of inorganic growth through potential acquisitions, and the optimization of our effective tax rate. Our strong cash flow, substantial cash position and lack of debt allow us the financial flexibility to pursue inorganic growth opportunities and continue to fund our R&D pipeline, enabling us to continue our mission to become a premier and diversified specialty pharmaceutical company."

About Flamel Technologies – Flamel Technologies SA 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 has approvals for and markets two previously Unapproved Marketed Drugs ("UMDs") in the USA, Bloxiverz® (neostigmine methylsulfate injection) and Vazculep® (phenylephrine hydrochloride injection). The Company intends to add to this branded business by creating additional products, focusing on the development of products utilizing Flamel's proprietary drug delivery platforms, and recently announced FDA acceptance of its third NDA filing with an FDA-assigned PDUFA date of April 30, 2016. Flamel also has several products in development utilizing Micropump® (oral sustained release microparticles platform) along with

its tangent technologies, LiquiTime® and Trigger Lock™. The lead project for Micropump® is sodium oxybate. LiquiTime® allows for the extended-release of liquid medicines (such as ibuprofen and guaifenesin) and Trigger Lock™ is an abuse-resistant iteration of Micropump®, designed specifically for long-acting opioids (such as hydromorphone). Additionally, the Company has developed a long acting injectable platform, Medusa™, a depot technology currently being studied with exenatide. Flamel's products are targeting high-value molecules and will utilize either the 505(b)(2) approval process for NDAs or biosimilar pathways ultimately approved by FDA and other regulatory authorities. The Company is headquartered in Lyon, France and has operations in St. Louis, Missouri, USA, and Dublin, Ireland. 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 20-F for the year ended December 31, 2014, 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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