Flamel Technologies Announces Positive Interim Results of a First-in-Man Clinical Trial with Medusa™ Exenatide

Lyon, France – December 22, 2015 - Flamel Technologies (NASDAQ: FLML) today announced positive interim results from a Phase 1a clinical trial in healthy volunteers of a once weekly subcutaneous injection formulation of exenatide using its proprietary Medusa™ technology (FT228). The study achieved all safety and pharmacokinetic (PK) assessment objectives throughout ascending single dose administrations of FT228. Exenatide is a GLP1 analog used to treat patients suffering from Type 2 Diabetes Mellitus.

The trial was conducted in two periods. The first, a 2-arm study of 20 healthy volunteers in each arm, evaluated the safety and PK profiles of FT228 versus Byetta®, a twice daily injection of exenatide marketed by Astra Zeneca, at a total dose of 10 mcg. The second, a 2-arm study of 20 healthy volunteers in each arm, evaluated the safety and PK profiles of FT228 at total doses of 70 mcg and 140 mcg.

The safety profile of FT228 was favorable in healthy volunteers up to a dose of 140 mcg, with an extremely low incidence of the gastrointestinal side effects commonly related to twice daily subcutaneous administration of exenatide (nausea, vomiting, abdominal discomfort, loss of appetite), in addition to a low incidence of mild injection site reactions. Two subjects dropped out of the study prior to completion of the 140 mcg dosing for reasons unrelated to the clinical trial.

Michael Anderson, Chief Executive Officer of Flamel, commented, “In line with our expectations, the single administration of FT228, at a dose of 140 mcg, displayed continuous release of exenatide over a period of at least seven days.”

Flamel plans to initiate a Phase 1b study of FT228 in Type 2 Diabetes Mellitus patients in Q1 2016. One dose per week of FT228 will be administered over a one month period in order to assess safety in patients, the steady-state PK profile and the product’s potential effect on surrogate biomarkers for the disease.

Flamel’s Medusa™ technology is protected by intellectual property through at least 2031 in the United States and June 2027 in the EU. Medusa™ is a drug delivery platform for the parenteral delivery of proteins and peptides.

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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