



Flamel Technologies Announces Positive Results From First Clinical Trials With Trigger Lock™ Hydromorphone Abuse-Deterrent Product

Meeting With FDA Will Be Requested Before the End of 2015

Lyon, France – June 29, 2015 - Flamel Technologies (NASDAQ: FLML) today announced positive results from two pilot pharmacokinetic (PK) studies in healthy volunteers of FT227, an abuse-deterrent, extended-release, oral hydromorphone product using its proprietary Trigger Lock™ drug delivery platform. Flamel's Trigger Lock™ allows the development of abuse-deterrent extended release formulations of opioids and other drugs susceptible to abuse. Hydromorphone is used for relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.

The PK studies were intended to provide sufficient data for the Company to select a preferred prototype formulation to move forward into pivotal studies. The studies compared three FT227 prototypes to the comparator product Journista® (sold as Exalgo® in the United States) in both fasted and fed conditions at a dose of 32mg.

Under fasted conditions, comparing the area under the curve (AUC) and the peak plasma concentration (C_{max}) of FT227 to Journista® in 16 subjects, the results identified a FT227 formulation that met the bioequivalence criteria for both parameters. Under fed conditions (14 subjects), the same formulation was bioequivalent in terms of AUC to Journista® but outside of the C_{max} bioequivalence criterion at the lower confidence interval level. Comparing the effect of food on the PK parameters of the FT227 prototypes across the two studies, no notable difference is seen in either AUC or C_{max} in fed and fasted conditions. This suggests that administration of FT227 will not be subject to a clinically relevant food effect.

In both studies FT227 was well tolerated and no serious adverse events were reported.

In addition, Flamel has generated substantial in vitro data comparing the abuse deterrence properties of FT227 compared to other marketed abuse-deterrent opioid products. The Company is confident that Trigger Lock™ is a robust platform for opioids that will set a high standard in terms of abuse deterrence. Further abuse deterrence data are being generated by an independent contract research organization and will be subject to further announcements. Flamel is planning to meet with the U.S. Food and Drug Administration (FDA) before the end of 2015 to discuss the remainder of the development plan for FT227. The product is designed to be filed as a 505(b)(2) New Drug Application (NDA). Based on current



expectations, the selected formulation will be scaled-up over the coming months and the Company plans to begin pivotal registration studies by mid-2016.

"We are very pleased with these initial data on FT227 Trigger Lock™ and we are highly confident in our Trigger Lock™ abuse deterrent platform. We look forward to meeting with the FDA and to moving FT227 into pivotal studies in 2016," said Mike Anderson, Chief Executive Officer.

As of December 2014, Trigger Lock™ is protected by seven Flamel patent application families, which expire between November 2025 and December 2033

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 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. Flamel currently has several products in development utilizing Micropump® (oral sustained release microparticles platform) along with its related 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. Additionally, the Company has developed a long acting injectable platform, Medusa™, a hydrogel 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 includes statements concerning our operating results (including product sales), financial condition and product development milestones, which are "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 possibility that we may cease to qualify as a foreign private issuer, which would increase the costs and expenses we incur to comply with U.S. securities laws; 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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