



Flamel Technologies Announces FDA Acceptance of Third NDA Filing

Lyon, France – September 9, 2015 – Flamel Technologies (NASDAQ: FLML) today announced that it has received a Prescription Drug User Fee Act (PDUFA) date of April 30, 2016 from the U.S. Food and Drug Administration (FDA) for its third New Drug Application (NDA). This is Flamel’s third filing to seek FDA approval of an Unapproved Marketed Drug (UMD), consistent with Flamel’s successful strategy in this portion of its product portfolio. Based on IMS and other third-party data, the Company estimates that current U.S. market sales of the unapproved versions of this drug are in the range of \$70-\$80 million per year. Flamel currently has two FDA-approved products on the market, including Bloxiverz® (neostigmine methylsulfate) and Vazculep® (phenylephrine hydrochloride).

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 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 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.

Contact:

Michael S. Anderson
Chief Executive Officer
Phone: 33 (0)4 72 78 34 34
E-mail: anderson@flamel.com

Investor Relations
Bob Yedid
ICR Inc.
Phone: 646-277-1250
Email: bob.yedid@icrinc.com