Flamel Technologies Receives FDA Approval of Akovaz™

Lyon, France – May 2, 2016 - Flamel Technologies (NASDAQ: FLML) today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's New Drug Application (NDA) for Akovaz™ (ephedrine sulfate), a drug administered parenterally as a pressor agent to address clinically important hypotension in surgical settings. Flamel obtained NDA approval for Akovaz as scheduled on April 29 and is the first to receive approval from the FDA for ephedrine sulfate. Flamel expects to launch Akovaz during the third quarter 2016 in a strength of 50 mg/mL.

"We are very excited to receive FDA approval for Akovaz, the third product from our Éclat portfolio, and in line with the PDUFA date expectations. Revenue expectations associated with this product were included in our previously issued 2016 revenue guidance of $110 - $130 million. Our Éclat portfolio of products, which includes Bloxiverz® and Vaculep®, has produced significant cash flow for Flamel, allowing us to operate independently of partners, fund strategic acquisitions and continue development of our proprietary pipeline products," said Mike Anderson, Chief Executive Officer of Flamel.

Currently, there is one "unapproved marketed" formulation of ephedrine sulfate 50 mg/mL injection sold by Akorn Pharmaceuticals, and according to IMS Health, the market size is over five million vials per year.

About Akovaz

Akovaz is the brand name for the Company's ephedrine sulfate injection, USP, an alpha- and beta-adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. Akovaz injection, 50 mg/mL, (equivalent to 38 mg ephedrine base) must be diluted before administration and is injected intravenously as a bolus.

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). 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. 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.

****

Contacts: **Michael S. Anderson**
Chief Executive Officer
Phone: (636) 449-1830
E-mail: anderson@flamel.com

Michael F. Kanan
Chief Financial Officer
Phone: (636) 449-1844
E-mail: kanan@flamel.com

Lauren Stival
Sr. Director, Investor Relations and Corporate Communications
Phone: (636) 449-5866
Email: stival@flamel.com

Stephanie Carrington
ICR Inc.
Phone: (646) 277-1282
Email: stephanie.carrington@icrinc.com