

Flamel Technologies Announces Positive Results of First-in-Man Clinical Trial with LiquiTime[®] Ibuprofen

Lyon, France – September 29, 2014 - Flamel Technologies (NASDAQ: FLML) today announced the results of a First-in-Man (FIM) clinical study in healthy volunteers using its proprietary LiquiTime[®] drug delivery platform applied to ibuprofen, a broadly used medication for pain. LiquiTime is designed to provide a controlled, extended release of oral liquids principally for pediatric and geriatric patients.

The trial was designed as a 15-subject three-way crossover in healthy volunteers evaluating two different BID (twice daily) formulations of LiquiTime ibuprofen with an immediate release ibuprofen oral suspension as the control arm. One formulation of LiquiTime ibuprofen was shown to be bioequivalent to the immediate release ibuprofen oral suspension using the U.S. Food and Drug Administration's (FDA) requirements for bioequivalence. There were no safety or tolerability issues. LiquiTime is protected by the Company's intellectual property through late 2025 in the United States and through early 2023 in Europe.

"We are very pleased with this initial data on LiquiTime ibuprofen as it is the first of two planned programs in our pipeline of proprietary products using the Company's LiquiTime technology for the Over-The-Counter or OTC market. The next step will be to move this product into a pivotal bioequivalence study in 2015," said Mike Anderson, Chief Executive Officer of Flamel. "The ibuprofen market is large and presents a solid product opportunity for Flamel. We will seek a licensing partner for this product at the most opportune time for the Company."

About Flamel Technologies - Flamel Technologies SA's (NASDAQ: FLML) business model is to blend highvalue internally developed products with its leading drug delivery capabilities. The company markets Bloxiverz[™] (neostigmine methylsulfate) in the USA and manufactures Micropump-based microparticles under FDA-audited GMP guidelines for Coreg CR[®] (carvedilol phosphate), marketed in the USA by GlaxoSmithKline. The Company has a proprietary pipeline of niche specialty pharmaceutical products, while its drug delivery platforms are focused on the goal of developing safer, more efficacious formulations of drugs to address unmet medical needs. Its pipeline includes chemical and biological drugs formulated with its Micropump[®] (and its applications to the development of liquid formulations LiquiTime[®] and of abuse-deterrent formulations Trigger Lock[™]) and Medusa[™] proprietary drug delivery platforms. Several Medusa-based products have been successfully tested in clinical trials. The Company is headquartered in Lyon, France and has operations in St. Louis, Missouri, USA, and manufacturing facilities in Pessac, France. Additional information may be found at <u>www.flamel.com</u>.



Cautionary Statements Regarding Forward-Looking Information - This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the timeframe for additional studies with respect to the development of LiquiTime ibuprofen. All statements that are not clearly historical in nature are forward-looking, and the words "anticipate," "assume," "believe," "expect," "estimate," "plan," "will," "may," and similar expressions are generally intended to identify forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond Flamel's control that could cause actual results to differ materially from those contemplated in such forward-looking statements. These risks include risks that the timing for additional studies may be delayed or may not achieve the same level of results as the FIM clinical study. These and other risks are described more fully in the Company's Annual Report on Form 20-F for the year ended December 31, 2013 that has been filed with the Securities and Exchange Commission (SEC). All forward-looking statements included in this report are based on information available at the time of filing. Flamel undertakes no obligation to update or alter its forward-looking statements as a result of new information, future events or otherwise, except as required by law.

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