# Flamel Technologies Announces Positive Results of a First-in-Man Clinical Trial with Micropump® Sodium Oxybate

***Potential Elimination of the "middle-of-the-night dose" achieved***

***Current study continues to allow for more information on higher doses***

***Conference call with management to take place at 8:45 AM EST on April 7, 2014***

**Lyon, France – April 7, 2014** - Flamel Technologies (NASDAQ: FLML) today announced that its First-in-Man (FIM) clinical study in healthy volunteers using its proprietary Micropump® technology applied to sodium oxybate has identified formulations that demonstrate the potential to eliminate the second nighttime dose for patients suffering from narcolepsy. The current dosing regimen for the standard of care, Xyrem® (sodium oxybate), in the United States is two equal, divided doses: the first dose at bedtime and the second dose 2.5 to 4 hours later. The elimination of the second dose for narcolepsy patients would not only provide more convenience, but may improve the benefit sodium oxybate provides as there will be no disruption to nighttime sleep. The potential for additional benefits, including improved safety, will be studied.

The trial was designed as a 16 subject four-way crossover evaluating three different formulations of Micropump sodium oxybate and Xyrem at a nightly dose of 4.5g (two doses of 2.25g for Xyrem) with an extension phase at 6g for successful Micropump formulations. Each subject consumed a standard meal two hours prior to dosing. Subjects were instructed to maintain a consistent meal time and dosing schedule throughout the study. When a subject took Xyrem they were instructed to take the second dose 4 hours after the first dose. Two subjects dropped out of the study prior to the completion of the 4.5g dosing portion for reasons unrelated to drug. The key data for the 14 evaluable subjects at 4.5g are:

- Onset of action similar to Xyrem
- Cmax lower than Xyrem
- Mean blood concentration (ug/ml) at hours 7 and 8 similar to Xyrem

For the extension phase of the study, two formulations were moved forward for dosing at 6g. Thirteen subjects were evaluable as one subject dropped out for a reason unrelated to drug. The profiles for both formulations were consistent with expectations.

The current study will continue to treat subjects at higher doses.

Given these results, Flamel plans to begin a new clinical study before the end of 2014 in a larger number of subjects further evaluating its formulations as well as certain pharmacodynamic endpoints. This study is not expected to be a registration study. Flamel plans to meet with regulatory authorities prior to embarking upon registration studies which are expected to begin prior to the end of 2015.

Flamel's Micropump technology is protected by intellectual property through at least 2025 in the United States. Micropump is a proven drug delivery platform for the oral delivery of small molecules.

Narcolepsy is a sleep disorder involving irregular patterns in Rapid Eye Movement (REM) sleep and significant disruptions of the normal sleep/wake cycle. People with narcolepsy experience excessive daytime sleepiness, sleep attacks, cataplexy, sleep paralysis, hallucinations and disrupted nighttime sleep.

Xyrem® is sold in the United States by Jazz Pharmaceuticals plc, in Canada by Valeant Canada Limited (via license from Jazz) and in twenty-two EU countries and Mexico by UCB Pharma Limited (via license from Jazz).

A conference call to discuss these results and other updates is scheduled for **8:45 AM Eastern Standard Time on April 7, 2014**. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-857-6930 (U.S.) or 719-457-2615 (international). The conference ID number is 9695267. The conference call webcast may be accessed at www.flamel.com. A replay of the webcast will be archived on Flamel's website for 90 days following the call.

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**About Flamel Technologies.** Flamel Technologies SA's (NASDAQ: FLML) business model is to blend high-value internally developed products with its leading drug delivery capabilities. 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 partnered pipeline includes biological and chemical drugs formulated with its Medusa™ and Micropump® (and its applications to the development of liquid formulations, i.e. LiquiTime® and of abuse-deterrent formulations Trigger Lock™) proprietary drug delivery platforms. Several Medusa-based products have been successfully tested in clinical trials. The Company has developed products and manufactures Micropump-based microparticles under FDA-audited GMP guidelines. Flamel Technologies has collaborations with a number of leading pharmaceutical and biotechnology companies, including GlaxoSmithKline (Coreg CR®, carvedilol phosphate). 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 www.flamel.com.

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**Contact:** **Michael S. Anderson**
**Chief Executive Officer**
Phone: 33 (0) 4 72 78 34 34
Fax: 33 (0) 4 72 78 34 35
E-mail: anderson@flamel.com

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

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*This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including certain plans, expectations, goals and projections regarding financial results, product developments and technology platforms. 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 our control that could cause actual results to differ materially from those contemplated in such forward-looking statements. These risks include risks that the launch of Bloxiverz will not be as successful as anticipated; our ability to bring other R&D projects of the former Éclat Pharmaceuticals to market may be unsuccessful; FDA may not take action on the status of unapproved versions of neostigmine still on the market; clinical trial results may not be positive or our partners may decide not to move forward; products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements; products in development may not achieve market acceptance; competitive products and pricing may hinder our commercial opportunities; we may not be successful in identifying and pursuing opportunities to develop our own product portfolio using Flamel's technology; and the risks associated with our reliance on outside parties and key strategic alliances. These and other risks are described more fully in Flamel's Annual Report on Form 20-F for the year ended December 31, 2012 that has been filed with the Securities and Exchange Commission (SEC). All forward-looking statements included in this release are based on information available at the time of the release. We undertake no obligation to update or alter our forward-looking statements as a result of new information, future events or otherwise.*