Flamel Technologies Announces Positive Results of a Second Clinical Trial with Micropump® Sodium Oxybate

Results confirm elimination of the "middle-of-the-night dose" achieved in previous study

Meeting with FDA will be requested in the first quarter of 2015

Lyon, France – December 19, 2014 - Flamel Technologies (NASDAQ: FLML) today announced that its second clinical study in healthy volunteers using its proprietary Micropump® technology applied to sodium oxybate has achieved the objective of one single dose before bedtime for patients suffering from narcolepsy, confirming the results of a previous, first-in-man, study. 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 2-arm study with 12 patients in each arm evaluating two different formulations of Micropump® sodium oxybate at a nightly dose of 4.5g, 6g and 7.5g. 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. One subject dropped out of the study prior to the completion of the 7.5g dosing portion for reasons unrelated to drug. The data for both formulations at the 4.5g and 6g doses were consistent with the data seen in the previous study which showed:

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

The data at the 7.5g dose for both formulations were consistent with expectations given the data generated at the lower doses. While both formulations were successful, Flamel has chosen to move forward with the optimal formulation.

To date, Micropump® sodium oxybate has been tested in 40 healthy subjects across three doses among three different formulations with no safety or tolerability issues.

Flamel plans to meet with the U.S. Food and Drug Administration (FDA) before the middle of 2015. Based on current expectations, the Company plans to begin registration studies 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).

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 markets Bloxiverz® (neostigmine methylsulfate) and Vazculep™ (phenylephrine hydrochloride) in the US and licenses the Micropump-based microparticles technology to Recipharm AB for application to the manufacturing under FDA-audited GMP guidelines of 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 Dublin, Ireland. Additional information may be found at www.flamel.com.

Safe Harbor: *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®* and Vazculep™ *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; 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, 2013 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.

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