

Flamel Notified of FDA Communication to Unapproved Manufacturers of Neostigmine Methylsulfate

Lyon, France – August 4, 2014 – Flamel Technologies S.A. (NASDAQ: FLML), has received communication from the U.S. Food and Drug Administration (FDA) that all manufacturers of unapproved versions of neostigmine methylsulfate have been notified by the FDA to cease manufacturing of the unapproved product as of July 30, 2014. Current inventory in the channel of the unapproved product can continue to be sold. Flamel has not been provided with information on the inventory levels held by these manufacturers.

"We sincerely appreciate the communication from the FDA which clearly indicates their commitment to the integrity of the unapproved drugs initiative. Our inventories are sufficient to provide 100% of the market demand for neostigmine methylsulfate with Bloxiverz™, the only approved FDA-approved version of the product in the market," said Mike Anderson, Chief Executive Officer of Flamel.

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) 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 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 forwardlooking 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, 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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