

## **Theralpha Announces Collaboration and Business Agreement with Flamel Technologies to develop controlled-release formulation of analgesic peptide**

Sophia Antipolis, France – May 9, 2011. Theralpha SAS today announced that it has entered into a joint development program with Flamel Technologies (NASDAQ: FLML) for a Medusa®-enabled, long-acting formulation of Theralpha's THA-902. THA902 is a natural peptide that is a potent and highly specific Acid Sensing Ion Channel 3 (ASIC 3) inhibitor. It is effective in inflammatory pain animal models following subcutaneous injection and has a number of possible indications, including post-operative pain, osteoarthritis pain and fibromyalgia. The development agreement has been structured to leverage Theralpha's pioneering intellectual property regarding Acid Sensing Ion Channels (ASICs) and Flamel's expertise in creating fully bioactive long-acting formulations of peptides, proteins, and other biologics.

The compound to be developed, THA902 XL, is a Medusa-based controlled-release formulation of THA 902. Flamel Technologies will be responsible for formulation chemistry with the objective to potentially improve tolerability and dosing, by reducing administration frequency, and consequently, allowing better patient compliance. Theralpha will be responsible for pre-clinical testing of THA902 XL pharmacodynamics.

Stephen H. Willard, Flamel's CEO, commented, "We are very excited to enter into this development agreement with Theralpha. ASIC inhibitors are a highly promising class of drugs that could substantially contribute to improved quality of life for the large number of patients who suffer from chronic pain due to inflammation and other causes. THA-902 XL has the promise to be a first in class compound with strong efficacy and safety advantages versus the current standards of care."

"At Theralpha we believe that lack of adequate pain control, particularly in patients with moderate to severe inflammatory pain, represents a significant therapeutic gap in current pain management. There is continued need across inflammatory pain syndromes for novel agents like THA902. We are confident that the formulation developed by Flamel Technologies may improve tolerability and long-term efficacy" commented David Dellamonica, CEO of Theralpha.

Financial terms of the Collaboration and Business Agreement were not disclosed.

### **About Theralpha**

**Theralpha SAS** is a product development-oriented company, focusing on preclinical and clinical development of new pain therapeutics. Theralpha drug candidates originate from worldwide exclusive licenses from IPMC (Institut de Pharmacologie Moleculaire, CNRS, Sophia Antipolis, France) based on research made by Professor Michel Lazdunski and his team who have pioneered the discovery of peptides found in animal venoms that selectively inhibit Acid Sensing Ion Channels (ASICs) which are directly implicated in pain signal

transmission. Theralpha is also developing an analgesic venom derived peptide generated at Protherapeutics, a National University of Singapore (NUS) spin-off, and licensed worldwide to Theralpha. To learn more about Theralpha, please visit [www.theralpha.com](http://www.theralpha.com)

### **About Flamel Technologies**

**Flamel Technologies SA** (NASDAQ: FLML) is a leading drug delivery company focused on the goal of developing safer, more efficacious formulations of drugs that address unmet medical needs. Its product development pipeline includes biological and chemical drugs formulated with the **Medusa®** and **Micropump®** proprietary platforms. Several Medusa-based products are at various clinical stages of development; Medusa's lead internal product candidate IFN- $\alpha$  XL (long-acting interferon alpha-2b) is currently the subject of a Phase 2 trial in HCV patients. The Company's has developed FDA- and EMA-approved products and manufacture Micropump-based microparticles. Flamel Technologies has collaborations with a number of leading pharmaceutical and biotechnology companies, including Baxter, GlaxoSmithKline (Coreg CR®, carvedilol phosphate), Merck Serono and Pfizer. Additional information can be found at [www.flamel.com](http://www.flamel.com).

### **About Medusa®**

Medusa® is a proprietary nanogel for the formulation and/or the extended release of a broad range of biologics (including proteins, antibodies, peptides and vaccines) and of small molecules (injectable drugs). The nanogel has been proven to be safe and biodegradable: Flamel Technologies filed a DMF for Medusa with the FDA in February 2011. Medusa enables the controlled delivery from 1 day up to 14 days of non-denatured or non-modified drugs that remain fully active (as opposed to protein engineering or chemical modification approaches). It is used to develop Biobetters with potentially improved efficacy, reduced toxicity and enhanced patient compliance. Medusa drug delivery platform is being developed in partnerships with leading industry companies such as Baxter (blood clotting factors), Merck Serono (long-acting interferon beta in phase 1), Pfizer and numerous other undisclosed large pharmaceutical and biotechnology companies.

### **Theralpha SAS**

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