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U.S. FDA Grants Fast-Track Designation to Sanofi Pasteur and KaloBios' Novel Biologic Candidate for Pseudomonas aeruginosa

CHICAGO, April 23, 2013 /PRNewswire/ --

Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), and KaloBios Pharmaceuticals (Nasdaq: KBIO) announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Sanofi Pasteur for the investigation of KB001A, an antibody fragment, intended for protection against bacterial pneumonia caused by *Pseudomonas aeruginosa (Pa)* in mechanically-ventilated patients. The Fast Track Drug Development Program of the FDA is designed to facilitate the clinical development and expedite the review of new drugs and vaccines that are intended to treat or prevent serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The joint announcement was made on this second day of the BIO International Convention, the 20th annual meeting of the world's largest biotechnology organization.

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(Logo: http://photos.prnewswire.com/prnh/20130423/610748-b)

Most serious *Pa* infections occur in hospitalized and critically or chronically ill patients--primarily affecting the respiratory system in susceptible individuals--and are a serious clinical problem due to the bacteria's resistance to antibiotics. Sanofi Pasteur, which is responsible for the clinical development under the terms of the agreement with KaloBios, is currently conducting a phase I trial of the monoclonal antibody in the United States and has started the planning of a phase IIb study.

"Sanofi Pasteur is currently targeting the antibody for use in primary prevention of Pa-associated pneumonia in mechanically ventilated patients in hospitals and we are also interested in providing prevention of relapses and improvement of treatment outcomes in patients with an ongoing Pa infection," according to Michel DeWilde, Ph.D., Senior Vice President, Research and Development. *"Additional indications may be considered later in the lifecycle of the product."*

Under the terms of the current agreement, Sanofi Pasteur has worldwide rights to KaloBios' KB001A technology for all disease indications related to *Pa* infections, except cystic fibrosis and bronchiectasis, the rights in which were retained by KaloBios, and Sanofi Pasteur has the option to obtain at a later date.

"Hospital-based pneumonias, especially those associated with mechanically ventilated patients in the ICU, are a life-threatening complication that can significantly increase mortality and morbidity as well as add tens of thousands of dollars to the cost of a hospital stay," said David Pritchard, President and CEO, KaloBios. *"KB001's novel mechanism of action against Pa may provide a unique means of fighting these infections, which are often resistant to antibiotic therapies. The FDA fast-track designation recognizes that this novel biologic could address an important unmet medical need."*

About KB001A

KB001A, a Humaneered™ antibody fragment, is designed to fight *Pseudomonas aeruginosa* (*Pa*) by blocking a virulence mechanism (the Type Three Secretion System or TTSS) on the bacterium's external surface that enables *Pa* to evade human immune defenses by killing white blood cells and epithelial cells, and triggering tissue-damaging inflammation. By blocking *Pa*'s killing mechanism, KB001A is intended to reduce the damage done to the lungs by *Pa* and potentially enable the patient's own immune system to effectively fight and clear the bacteria from sites of infection. KB001A avoids known mechanisms of antibiotic resistance and does not contribute to broad-spectrum resistance, making it optimal for use as a single agent or in synergy with antibiotics in the preventive or therapeutic setting. KB001, a precursor, has completed two clinical studies in mechanically ventilated patients colonized with Pa and in chronically Pa infected patients with cystic fibrosis. KaloBios is currently conducting a 180-patient phase 2 study in cystic fibrosis in the United States with KB001A.

About KaloBios

KaloBios Pharmaceuticals, Inc. is developing a portfolio of patient-targeted, first-in-class monoclonal antibodies to treat serious medical conditions with a primary clinical focus on respiratory diseases and cancer. For more information on KaloBios Pharmaceuticals, please visit our web site at http://www.kalobios.com.

About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Pasteur, the vaccines division of Sanofi, provides more than 1 billion doses of vaccine each year, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, Sanofi Pasteur offers the broadest range of vaccines protecting against 20 infectious diseases. The company's heritage, to create vaccines that protect life, dates back more than a century. Sanofi Pasteur is the largest company entirely dedicated to vaccines. Every day, the company invests more than EUR 1 million in research and development. For more information, please visit: http://www.sanofipasteur.com or http://www.sanofipasteur.us

Forward Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's and KaloBios' management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi and KaloBios, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's or KaloBios' ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi or the SEC made by KaloBios, including those listed under"Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2012 and in corresponding sections of KaloBios' annual report on Form 10-K for the year ended December 31, 2012. Other than as required by applicable law, neither Sanofi nor KaloBios undertakes any obligation to update or revise any forward-looking information or statements.

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