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U.S. FDA Grants Orphan Drug Designation for KaloBios' KB001-A in Treatment of Cystic Fibrosis Patients

SOUTH SAN FRANCISCO, Calif., Oct. 30, 2013 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq: KBIO) today announced that the U.S. Food & Drug Administration (FDA) has granted the company orphan drug designation for KB001-A, an anti-PcrV monoclonal antibody (mAb) fragment, for the treatment of cystic fibrosis (CF) patients with *Pseudomonas aeruginosa (Pa)*.

(Logo: http://photos.prnewswire.com/prnh/20130225/MM66380LOGO)

KaloBios is currently enrolling patients in a Phase 2 multiple-dose, randomized, double-blind, placebo-controlled clinical trial with KB001-A in CF patients chronically infected with *Pa*. This 180-patient study is intended to evaluate the efficacy and safety of repeat doses of KB001-A. The primary endpoint is time-to-need for antibiotics. To learn more about this study, including eligibility criteria, please visit http://clinicaltrials.gov/ct2/show/NCT01695343?term=kb001a&rank=1

"The FDA's designation of KB001-A as an orphan drug is another milestone for KaloBios as we continue the clinical development work required for potential FDA approval," said David W. Pritchard, KaloBios' President and Chief Executive Officer. "We are working hard to complete enrollment of our Phase 2 trial and look forward to evaluating and reporting on the activity of KB001-A in late 2014."

Orphan drug designation is granted by the FDA Office of Orphan Products Development to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the United States. The designation provides the drug developer with a seven-year period of U.S. marketing exclusivity if the drug is the first of its type approved for the specified indication or if it demonstrates superior safety, efficacy, or a major contribution to patient care versus another drug of its type that was previously granted the designation for the same indication. Orphan designation also provides tax credits for clinical research costs, the ability to apply for annual grant funding, clinical research trial design assistance and waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

About KaloBios

KaloBios Pharmaceuticals, Inc. is developing a portfolio of proprietary, patient-targeted, first-in-class monoclonal antibodies designed to treat severe life-threatening or debilitating diseases for which there is an unmet medical need, with a clinical focus on severe respiratory diseases and cancer.

Currently, KaloBios has three drug development programs:

- KB003, an anti-GM-CSF mAb with potential to treat inflammatory diseases, being developed for the treatment of severe asthma. Enrollment of 160 patients has been completed in a Phase 2 study in the United States, Europe and Australia.
- KB001-A, an anti-PcrV mAb fragment that is partnered exclusively with Sanofi Pasteur and is being developed for the prevention and treatment of *Pa* infections. KaloBios has retained rights for the CF indication and has initiated a 180 patient Phase 2 study in CF subjects with chronic *Pa* lung infection in the United States. KaloBios has received Orphan Drug designation from both the FDA and the European Commission for KB001-A for the treatment of *Pa* lung infection in CF. Sanofi is pursuing a ventilator-associated pneumonia prevention indication in the intensive care setting, an indication which has received U.S. FDA Fast Track Designation.
- KB004, an anti-EphA3 mAb, has potential in treating hematologic malignancies and solid tumors. KaloBios is currently testing this drug in a Phase 1 study in subjects with hematologic malignancies.

All of the company's antibodies were generated using its proprietary Humaneered® technology, a method that converts nonhuman antibodies (typically mouse) into recombinant antibodies that have a high binding affinity to their target and are designed for chronic therapeutic use. The company believes that antibodies produced using its Humaneered® technology offer important clinical and economic advantages over antibodies generated by other methods in terms of high binding affinity, high manufacturing yields, and minimal to no immunogenicity (inappropriate immune response) upon repeat administration in humans.

For more information on KaloBios Pharmaceuticals, please visit our web site at http://www.kalobios.com.

Forward Looking Statements

This release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including: the statements under the heading "Anticipated Upcoming Milestones for 2013-2014"; and statements regarding the company's clinical development of KB001-A, KB003 and KB004. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the company's limited cash reserves and its ability to obtain additional capital on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that the company has initiated or plans to initiate; the company's dependence on Sanofi Pasteur for the development and commercialization of KB001-A; the company's ability to successfully complete further development of its programs; the uncertainties inherent in clinical testing, including time to enroll clinical studies; the timing, cost and uncertainty of obtaining regulatory approvals; the company's ability to protect the company's intellectual property; competition; changes in the regulatory landscape or the imposition of regulations that affect the company's products; and other factors listed under "Risk Factors" in the company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2013, the quarterly reports on Form 10-Q filed on May 14, 2013 and August 19, 2013, and the company's other filings with the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. The company has no obligation, and expressly disclaims any obligation to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

For more information, visit http://www.kalobios.com.

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