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KaloBios Initiates Phase 2 Expansion Portion of Study of KB004 in Hematologic Malignancies

-- Study Focused on Patients with Acute Myeloid Leukemia or Myelodysplastic Syndrome Who are EphA3 Positive --

SOUTH SAN FRANCISCO, Calif., Feb. 11, 2014 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq: KBIO) today announced that the company has begun treating patients in the Phase 2 expansion portion of study KB004-01 evaluating KB004, the company's anti-EphA3 Humaneered® monoclonal antibody (mAb). The company is targeting enrollment of 30 patients for this portion of the Phase 2 expansion focusing solely on patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) who are prescreened prior to treatment for EphA3 positivity. EphA3 is a tyrosine kinase receptor that is highly expressed on malignant stem cells in different hematological and solid tumors.

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

"We are pleased to have begun the Phase 2 portion of our Phase 1/2 study, which will focus on EphA3 positive patients only," said Nestor A. Molfino, MD, MSc, Chief Medical Officer of KaloBios. "The ongoing Phase 1 dose-escalation portion of this study has shown some signs of clinical activity, and has demonstrated KB004 to be well-tolerated, with transient infusion reactions being the most common side effects."

The Phase 2 expansion portion of the study will be comprised of both low dose and high-dose cohorts, and the company is currently targeting enrollment of 10 AML patients at the low dose of 20 mg, as well as 10 AML patients and 10 MDS patients at the high dose. All patients will be prescreened prior to treatment for EphA3 expression and must be refractory to or unsuitable for the current standard of care. The primary endpoint for this portion of the study is clinical activity, and secondary endpoints include pharmacokinetic measurements. The company will continue to evaluate safety and tolerability as well.

"We expect to complete enrollment of at least one of the two currently planned indications for this Phase 2 expansion portion by the end of this year, and would expect to announce top-line data for the AML or MDS cohorts mid-2015. Given the open label nature of the study, we will be monitoring patient responses closely throughout the trial," said Dr. Molfino.

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 programs in clinical development:

- KB001-A is an anti-PcrV mAb fragment, partnered exclusively with Sanofi Pasteur, and is being developed for the prevention and treatment of *Pa* infection. KaloBios has retained rights for the cystic fibrosis (CF) indication and is conducting a 180 patient Phase 2 study in CF subjects with chronic *Pseudomonas aeruginosa* (*Pa)* lung infection. KaloBios has received Orphan Drug designation from both the U.S. FDA and the European Medicines Agency for KB001-A for the treatment of *Pa* lung infection in CF patients. 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 is an anti-EphA3 mAb with potential in treating hematologic malignancies and solid tumors. KaloBios is running an ongoing Phase 1/2 study evaluating KB004 in hematologic malignancies. The Phase 1 dose escalation portion of that study in subjects with hematologic malignancies is ongoing. KaloBios initiated the Phase 2 expansion portion of the study focused on EphA3 positive patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) in early 2014.
- KB003 is an anti-GM-CSF mAb with potential to treat inflammatory diseases that was being developed for the treatment of severe asthma. A Phase 2 clinical study in 160 patients with severe asthma has been completed in the United States, Europe and Australia, which did not meet its primary endpoint of improvement in FEV_1 from baseline as compared to placebo.KaloBios has discontinued development of this compound in severe asthma, and is continuing to analyze the Phase 2 data to review with thought leaders in order to determine next steps, if any, in the development of KB003.

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, and statements regarding the company's clinical development of KB001-A, KB004 and KB003. 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 potential outcomes of clinical studies of KB004 undertaken now or in the future, the potential, if any, for future development of KB003, 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 progress or complete further development of its programs; the uncertainties inherent in clinical testing; 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, August 19, and November 12, 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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