KaloBios Announces Preliminary Phase 1 Results in Advanced Hematologic Malignancies with KB004, an Anti-EphA3 Monoclonal Antibody

- Data Presented as Poster at American Society of Hematology Annual Meeting and Exhibition

SOUTH SAN FRANCISCO, Calif., Dec. 10, 2013 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq: KBIO) today announced preliminary results of an ongoing multi-center Phase 1 study of KB004, an anti-EphA3 monoclonal antibody (mAb), which the company is developing as a treatment for hematologic malignancies. Forty-four patients with refractory disease or who were unfit for chemotherapy have been enrolled in the dose escalation portion of the study. The experimental patient-targeted therapeutic has been well tolerated, with initial evidence of clinical activity.

Preliminary results of the study were presented yesterday by lead investigator, Jeffrey E. Lancet, M.D. of the H. Lee Moffitt Cancer Center & Research Institute, Tampa, Florida at the 55th American Society of Hematology Annual Meeting and Exhibition (ASH), held this week in New Orleans, Louisiana.

"We are encouraged by the results seen with KB004 to date, which has been well-tolerated at doses up to 190 mg, with mild to moderate transient infusion reactions the most common toxicity," said Dr. Lancet. "There are some signs of activity as well, including a patient with relapsed acute myeloid leukemia (AML) who had sustained remission for over 1 year."

Escalating doses of KB004 were administered as a 1 or 2 hour infusion on days 1, 8, and 15 of a 21 day cycle at incremental doses of 20, 40, 70, 100, 140, 190 and 250 mg and will thereafter increase at 33% increments up to a planned maximum of 700 mg. The primary study objective is to determine a maximum tolerated dose, which has not yet been reached. Secondary objectives included evaluation of pharmacokinetics, immunogenicity and clinical activity. The investigators also evaluated EphA3 expression on tumor, stromal and endothelial cells.

Nestor Molfino, M.D., MSc, KaloBios' Chief Medical Officer, commented, "KB004 targets EphA3, which is expressed in adults on hematologic malignancies and solid tumors, including tumor stem cells, but not on normal blood or bone marrow stem cells. The
targeted nature of this antibody may represent a promising approach to selectively treat patients with hematologic malignancies. As we have not yet reached a maximum tolerated dose, we will continue to study higher doses of KB004 as part of this ongoing trial to determine an optimum high-end dose for the Phase 2 expansion portion of the study in patients with AML or myelodysplastic syndrome (MDS) which is expected to begin by the end of the year."

The poster presented at ASH can be viewed on the KaloBios website.

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, partnered exclusively with Sanofi Pasteur and is being developed for the prevention and treatment of *Pseudomonas aeruginosa* (*Pa*) infection. KaloBios has retained rights for the cystic fibrosis indication and is conducting 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 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**, 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"; 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; 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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