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Publication by KaloBios and Collaborators Shows EphA3 as Target for Highly Selective Anticancer Therapy

-- Anti-EphA3 Agents Inhibit Tumor Growth by Disrupting or Destroying the Tumor Microenvironment: Malignant Stem Cells, Stromal Cells, and New Tumor Vasculature --

SOUTH SAN FRANCISCO, Calif., Aug. 14, 2014 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq: KBIO) today announced the publication of preclinical findings describing EphA3 as a novel target expressed by a broad range of human tumors, and whose activation can lead to the selective disruption of the tumor microenvironment and newly formed tumor blood vessels. The expression and function of EphA3 in the tumor microenvironment but not in adult normal tissues together with the favorable safety profile as observed thus far in a Phase 1-2 clinical study, where infusion reactions have been the most common adverse event, supports the development of KB004 (KaloBios' Humaneered® anti-EphA3 monoclonal antibody [mAb]) as a potential treatment for both hematologic and solid tumors.

The new research findings, published online this week by the journal of the American Association for Cancer Research, are described by scientists from Monash University School of Biomedical Sciences and Ludwig Institute for Cancer Research in Melbourne, Australia, and KaloBios.

"Eph receptors constitute the largest family of receptor tyrosine kinases, and EphA3 is important in human fetal development. EphA3 is also found in the mesenchymal tissues of various developing organs but is virtually undetectable in normal adult tissues," said Professor Andrew Scott, from the Ludwig Institute for Cancer Research. "However, EphA3 is over-expressed in many solid and hematologic tumors where it is implicated in cell positioning and possible tumor stem cell survival."

He continued, "In this publication, we show that EphA3 is prominently expressed and functional in the tumor microenvironment, where it contributes to the formation of new blood vessels, and is also found on stromal tissue. We have also demonstrated that treatment of human tumor xenografts with a highly specific anti-EphA3 monoclonal antibody can effectively kill tumor-resident mesenchymal/stromal stem cells and inhibit tumor growth by disrupting the architecture and function of the tumor microenvironment."

"These data add to the rationale for our current clinical program using anti-EphA3 to treat leukemias and represent a clear rationale for the potential expansion of our investigation of KB004, KaloBios' Humaneered® anti-EphA3 mAb, into solid tumor indications," said Geoffrey Yarranton, Ph.D., KaloBios' chief scientific officer and executive vice president of research and development. KaloBios is currently conducting a Phase 1/2 clinical trial of KB004 in hematologic malignancies, with the Phase 2 expansion portion of that trial focused on acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and myelofibrosis (MF) patients with EphA3-positive malignancies.

"Research points to stromal cells playing a key role in chemoresistance, protecting tumors from the killing effects of many anticancer drugs. Thus, if KB004 is able to kill these cells protecting either solid tumors or tumors in the bone marrow, it might offer a particular powerful new way to fight such cancers," Dr. Yarranton noted.

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 advanced three programs to clinical development:

- KB001-A is an anti-PcrV mAb fragment being developed for the prevention and treatment of *Pseudomonas aeruginosa* (*Pa)* infection. KaloBios is conducting a 180 patient Phase 2 study in cystic fibrosis (CF) subjects with chronic *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. KB001-A has also received Fast Track Status from the U.S. FDA for the prevention of ventilator associated pneumonia. KaloBios is planning to seek a partner to help accelerate the development of this program.

- 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 fully enrolled with dosing ongoing. KaloBios initiated the Phase 2 expansion portion of the study focused on patients with certain EphA3 positive hematologic malignancies in 2014.
- KB003 is an anti-GM-CSF mAb with potential to treat inflammatory diseases that was being developed for the treatment of severe asthma. In early 2014, KaloBios completed a Phase 2 clinical study in 160 patients with severe asthma which did not meet its primary endpoint of improvement in FEV_1 from baseline as compared to placebo. As a result, KaloBios discontinued development of this compound in severe asthma, and is continuing to analyze the Phase 2 data to review with thought leaders. KaloBios is currently evaluating other possible indications 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 timing and outcomes of clinical studies of KB001-A and 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 manufacture, 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 most recent quarterly report on Form 10-Q filed with the Securities and Exchange Commission on May 8, 2014, the Annual Report on Form 10-K filed on March 13, 2014, 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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