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KaloBios Presents Clinical Results with Anti-GM-CSF Antibody in Persistent Asthma

Data from KB002 Phase 1/2 Study Presented at the American Academy of Allergy, Asthma and Immunology Meeting

South San Francisco, CA (February 26, 2013): [KaloBios Pharmaceuticals, Inc.](#) (NASDAQ:KBIO) presented data from its Phase 1/2 study in persistent asthma for KB002 (precursor chimeric anti-GM-CSF monoclonal antibody to KB003) at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in Austin, Texas. The findings demonstrated preliminary safety, tolerability, and signs of activity of anti- GM-CSF antibodies in asthma and support continued development of the company's Humaneered® KB003 anti-GM-CSF monoclonal antibody in severe asthma. KB003 is currently in a Phase 2 trial in severe asthma patients inadequately controlled by corticosteroids.

"These initial clinical results with KB002 in asthma are highly encouraging," said Néstor Molfino, Chief Medical Officer of KaloBios. "KB002 was well-tolerated, with no significant adverse events in the study population. When KB002 was added to patients' standard of care treatment, the study also showed a reduction in airway inflammation (eosinophils) and improvements in FEV₁ (a measure of lung function). Moreover, asthmatics with reversible FEV₁ at baseline showed greater FEV₁ responses than non-reversible patients. As a result, we are targeting this patient population in our ongoing Phase 2 KB003 study."

Methodology and Results

The KB002 Phase 1/2 asthma study, which screened over 50 patients to enroll both atopic (eosinophilic) and non-atopic (neutrophilic) asthma subjects, randomized 24 subjects (2:1, active treatment versus placebo). The objectives of the study primarily were to evaluate safety and tolerability, effects on sputum inflammatory markers, and lung function after a single dose of KB002. KB002 was found to be generally safe and well tolerated. Mean FEV₁ value for the active treatment group increased 120ml from baseline to day 42 and decreased 40ml for the placebo group. Of the 24 subjects enrolled (17 on KB002 and 7 on placebo), 59% on KB002 versus 29% on placebo had a >100ml FEV₁ increase at day 42. In addition, when patients were segmented retrospectively by the criteria of "reversibility," with reversible patients defined as having a >12% improvement in FEV₁ from baseline after a beta agonist, reversible patients on KB002 experienced a greater increase in FEV₁ from baseline at day 42 versus those on

placebo. A majority of responders showed an FEV₁ improvement of more than 10%, which is a level that is generally accepted as clinically meaningful. At day 42, 78% of KB002-treated reversible subjects had at least a 100-mL increase in FEV₁ compared with 38% of KB002-treated nonreversible subjects, 33% of placebo-treated reversible subjects, and 25% of placebo-treated nonreversible subjects. A majority of KB002-treated patients who had an improvement in FEV₁ also had measureable antibody in the sputum in addition to a decrease in eosinophils or neutrophils at day 28.

About KB002/ KB003

KB002 and KB003 are recombinant monoclonal antibodies designed to target and neutralize human granulocyte macrophage colony-stimulating factor (GM-CSF), with potential for use in inflammatory and autoimmune indications. GM-CSF is an important part of an inflammatory cascade that stimulates white blood cells (granulocytes, including eosinophils, neutrophils, and macrophages) and maintains them in an active state. However, as described in a number of scientific publications, excessive GM-CSF may be involved in tissue damage associated with inflammatory diseases including asthma.

KB003 is a Humaneered[®] version of the chimeric KB002 antibody, with the same epitope target and therefore the same mechanism of action. We plan to use KB003 for all future clinical studies in this program.

About KaloBios

KaloBios Pharmaceuticals, Inc. is developing a portfolio of proprietary, patient-targeted, first-in-class monoclonal antibodies (mAbs) designed to significantly improve the lives of seriously ill patients with difficult-to-treat diseases.

Currently, KaloBios has three drug development programs:

- KB003, an anti-GM-CSF mAb with potential to treat inflammatory diseases, is being developed for the treatment of severe asthma and is currently enrolling patients in a 150 patient Phase 2 study in the United States, Europe and Australia.
- KB001-A, an anti-PcrV mAb fragment, is 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 (CF) indication and has initiated a 180 patient Phase 2 study in CF subjects with chronic *Pa* infection in the United States. Sanofi is pursuing a ventilator associated pneumonia prevention indication in the intensive care setting.
- 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>.

This release contains “forward-looking statements” made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including those related to the company’s clinical development of 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 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 Form S-1 filed with the Securities and Exchange Commission on January 31, 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.

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