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KaloBios Announces FDA Clearance of Investigational New Drug Application for KB003 in Patients with Chronic Myelomonocytic Leukemia

SOUTH SAN FRANCISCO, July 29, 2015 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq: KBIO), a monoclonal antibody company focused on developing innovative therapies to benefit patients with diseases of unmet medical need, with a focus on oncology, announced today that the U.S. Food and Drug Administration (FDA) has cleared the company's investigational new drug (IND) application for KB003, an anti-GM-CSF monoclonal antibody (mAb), in patients with chronic myelomonocytic leukemia (CMML), and that the IND is now active.

The acceptance of this IND allows KaloBios to initiate an open-label Phase I study designed to evaluate the safety, pharmacokinetics and clinical activity of KB003 in previously treated CMML patients. The study will consist of an accelerated dose escalation component starting at 200 mg and escalating up to 600 mg, followed by a cohort expansion of up to 13 additional patients to explore clinical activity at the selected dose level. Site initiation activities are underway, and the company anticipates that enrollment will begin later this year.

"I am very excited to be able to explore KB003, an anti-GM-CSF agent, as a potential therapeutic for CMML patients given the significant unmet medical need these patients face," said Dr. Eric Padron of the Department of Hematologic Malignancies at H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida. "Given the hyper-sensitivity of CMML cells to GM-CSF, and the cell killing we have seen in our pre-clinical work as a result of depriving CMML cells of GM-CSF using KB003, we are hopeful that KB003 will prove to be an effective therapeutic for patients suffering from CMML."

CMML is a life-threatening hematologic malignancy characterized by elevated levels of monocytes, immature blood cells, or blast cells, and abnormal cells in the peripheral blood as well as in the bone marrow. According to the American Cancer Society, there are approximately 1,100 new diagnoses of CMML each year in the United States and median survival from diagnosis is 15 to 20 months. Current approved treatment options for CMML patients are limited and generally consist of hypomethylating agents or hydroxyurea.

About KaloBios

KaloBios Pharmaceuticals, Inc. is seeking to improve the lives of patients by developing innovative therapies to treat diseases of high unmet medical need, with a focus on oncology.

Currently, KaloBios is focused on advancing the following oncology programs in clinical development:

- KB004 is a non-fucosylated mAb targeting EphA3 with the potential to treat hematologic malignancies and solid tumors. KB004 is designed to kill tumor cells through multiple mechanisms, including antibody directed cellular cytotoxicity (ADCC) from the patient's own immune system, direct apoptosis or disruption of the tumor stem cell environment and the vasculature that feeds it. KaloBios is conducting an ongoing Phase 1/2 study evaluating KB004 in hematologic malignancies. The Phase 1 dose escalation portion of the study is fully enrolled, and KaloBios is currently enrolling in the Phase 2 expansion portion of the study. The Phase 2 portion of the study, which requires screening patient tumors for EphA3 expression, is currently focused on patients with myelofibrosis (MF) or myelodysplastic syndrome (MDS). KaloBios is evaluating other potential oncology indications for KB004, including additional hematologic malignancies as well as solid tumors.

- KB003 is an anti-GM-CSF mAb that KaloBios intends to evaluate in oncology indications where GM-CSF may play a key role, such as chronic myelomonocytic leukemia (CMML). The IND for KB003 in CMML, an orphan oncology indication, has been cleared by the FDA, and KaloBios is currently undertaking site initiation activities for a Phase 1 study of KB003 in previously treated CMML patients. KaloBios expects to commence dosing patients in this study during the second half of 2015.

All of the company's antibodies were generated using its proprietary Humaneered® technology, a method that converts non-human antibodies (typically mouse) into recombinant antibodies that have a high binding affinity to their target and are designed

for chronic therapeutic use.

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 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 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 potential timing and outcomes of clinical studies of KB004 and KB003 undertaken now or in the future; the ability of the company to timely source adequate supply of its development products from third party manufacturers on whom the company depends; the potential, if any, for future development of any of its present or future products; the company's ability to successfully progress, partner 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 11, 2015, the Annual Report on Form 10-K filed on March 16, 2015, 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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