

KaloBios Announces Positive Guidance from FDA for Benznidazole

- *Minutes received from recent FDA meeting on benznidazole*
- *505(b)(2) regulatory pathway using existing safety and efficacy data is acceptable*
- *Benznidazole eligible for neglected tropical disease priority review voucher*
- *KaloBios to present company update at Biotech Showcase™ 2017*

BRISBANE, Calif., Jan. 05, 2017 (GLOBE NEWSWIRE) -- [KaloBios Pharmaceuticals, Inc.](#) (OTC:KBIO), a biopharmaceutical company focused on advancing medicines for patients with neglected and rare diseases, today announced positive guidance in the minutes from a recent meeting with the U.S. Food and Drug Administration (FDA) to discuss the development plans for benznidazole for the treatment of Chagas disease, a neglected tropical disease.

Meeting minutes received from the FDA's Division of Anti-Infective Products confirmed key elements of the company's overall plan for benznidazole, including:

- The company's proposed 505(b)(2) approach to demonstrate safety and efficacy using some data drawn from previously conducted studies is acceptable to FDA.
- If approved as a treatment for Chagas, benznidazole is currently expected to be eligible for a priority review voucher (PRV), awarded to sponsors of certain treatments for neglected tropical diseases that meet criteria specified by the Federal Food, Drug, and Cosmetic (FD&C) Act.

"This guidance makes it clear that we are on the right track with our development of benznidazole for Chagas disease, and we expect we will progress expeditiously toward a submission," said Cameron Durrant, MD, KaloBios chairman and CEO. "Our team continues to execute and we look forward to further collaborative engagement with FDA."

Separately, KaloBios will present at Biotech Showcase™ 2017 on Tuesday, January 10, 2017, at 8 a.m. PST at the Hilton San Francisco Union Square in San Francisco, Calif. For more information or to schedule a meeting, visit <https://ebdgroup.knect365.com/biotech-showcase/partnering>.

About Benznidazole

Benznidazole is an oral anti-parasitic medication used in the treatment of Chagas disease, caused by a protozoan parasite *Trypanosoma cruzi* carried and transmitted by triatomine insects (often called "kissing bugs"). According to the Centers for Disease Control and

Prevention (CDC), an estimated 300,000 people in the United States are infected with Chagas disease, which, if left untreated, can lead to serious and potentially life-threatening cardiovascular, gastro-intestinal and neurological complications. Benznidazole is the current preferred treatment for Chagas disease in other parts of the world but is not currently approved by the FDA in the U.S. Legislation is in place to incentivize companies to bring treatments to the U.S. market for certain neglected tropical diseases, including Chagas. If approved, benznidazole could be eligible to receive a priority review voucher.

About KaloBios Pharmaceuticals, Inc.

KaloBios Pharmaceuticals, Inc. (OTC:KBIO) is an emerging biopharmaceutical company focused on advancing medicines for patients with neglected and rare diseases through innovative and responsible business models. Lead compounds in the KaloBios portfolio are benznidazole for the potential treatment of Chagas disease in the U.S., and the proprietary monoclonal antibodies, lenzilumab and ifabotuzumab (formerly KB004), for the potential treatment of various solid and hematologic cancers such as CMML and potentially JMML. For more information, visit www.kalobios.com.

Forward-Looking Statements

This release contains forward-looking statements that are intended to be subject to protection afforded by the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. 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 events or results may differ materially from those contained in the forward-looking statements. Words such as "will," "expect," "intend," "plan," "potential," "possible," "goals," "accelerate," "continue," and similar expressions identify forward-looking statements, including, without limitation, statements related to expectations regarding the regulatory pathway for benznidazole and the Company's other product candidates, including the possible eligibility of such products for receipt of a priority review voucher; the Company's opportunity to benefit from the application of our Responsible Pricing Model; and expectations for the Company's future financial position. Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, our lack of profitability and the need for additional capital to operate our business as a going concern; the uncertainties inherent in the development and launch of any new pharmaceutical product; our ability to successfully and timely complete clinical trials for our drug candidates in clinical development; our ability to obtain the necessary U.S. and international regulatory approvals for our drug candidates and to qualify for or benefit from various regulatory incentives; the scope and validity of intellectual property and other competitive protection for our drug candidates; our ability to identify, in-license and acquire additional product candidates or to form partnerships for the sale, licensing, collaborative development or marketing of our existing product candidates; our ability to maintain or engage third-party manufacturers to manufacture, supply, store and distribute supplies of our drug candidates for our clinical trials; and the success of any product; and the various risks and uncertainties described in the "Risk Factors" and elsewhere in the Company's periodic and other filings with

the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You should not place undue reliance on any forward-looking statements, which speak only as of the date of this release. We undertake no obligation to revise or update any forward-looking statements made in this press release to reflect events or circumstances after the date hereof or to reflect new information or the occurrence of unanticipated events, except as required by law.

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