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# KaloBios Submits IND Application for Benznidazole to FDA

BRISBANE, Calif., May 30, 2017 (GLOBE NEWSWIRE) -- [KaloBios Pharmaceuticals, Inc.](#) (OTC:KBIO), a biopharmaceutical company focused on advancing medicines for patients with neglected and rare diseases, today announced it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for benznidazole for the treatment of Chagas disease, a neglected tropical disease.

The IND application is a critical part of the Company's previously outlined plan to advance benznidazole for potential U.S. approval for Chagas disease.

"Our team continues to deliver on key milestones, progressing benznidazole on an accelerated timeline to an expected filing of a New Drug Application in the first quarter of 2018," said Cameron Durrant, MD, chairman and CEO of KaloBios. "This work addresses enduring unmet need. People infected with Chagas disease carry a dramatic and significant increased risk of death. According to a recent [PLOS Neglected Tropical Diseases](#) paper, those infected have an almost 18 times higher risk of death from Chagas-related cardiac issues than those not infected."

## 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.

## 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. Lenzilumab has potential for treatment of various rare diseases, including hematologic cancers such as chronic myelomonocytic leukemia (CMML) and potentially juvenile myelomonocytic leukemia (JMML). For more information, visit [www.kalobios.com](http://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 regarding our expectations as to the timing for submission of our NDA for benznidazole. 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; the acceptability to FDA of a 505(b)(2) development pathway for approval of benznidazole using data drawn from previously conducted studies 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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