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# Benznidazole on Track in Progress to IND and NDA Submissions

- *Investigational new drug (IND) application on track to be submitted in May 2017*
- *Manufacturing preparations in line to produce tablets, clinical batches produced*
- *Company anticipates filing new drug application (NDA) in first quarter of 2018*

BRISBANE, Calif., April 06, 2017 (GLOBE NEWSWIRE) -- [KaloBios Pharmaceuticals, Inc.](#) (OTC:KBIO), a biopharmaceutical company focused on advancing medicines for patients with neglected and rare diseases, today provided an update on the company's progress advancing its lead program benznidazole for the treatment of Chagas disease, a neglected tropical disease.

"We continue to execute on our internal deadlines and remain on track for the advancement of benznidazole for the significant unmet need of Chagas disease here in the U.S.," said Cameron Durrant, MD, chairman and CEO, who today is also taking part in the International Society for Neglected Tropical Diseases (ISNTD) Chagas conference in Washington, D.C. Visit [ISNTD Chagas](#) for more information.

The company has made significant progress advancing its development plan for benznidazole as a potential U.S. treatment for Chagas disease, including:

- **Regulatory:** The company is on track to submit its IND with the Food and Drug Administration (FDA) in May 2017. Future meetings with the FDA are expected to provide further refinement of the development plan.
- **Manufacturing:** Batches of the drug are complete and prototype tablets have been made. The company is on schedule for the delivery of final tablets. Work is also underway to develop efficiencies and begin scale-up for manufacturing processes.
- **Clinical Data:** The company has secured safety and efficacy databases necessary for its regulatory dossier. In January 2017, the FDA confirmed the acceptability of a 505(b)(2) development pathway using data drawn from previously conducted studies.

Overall, these activities are expected to support the filing of an NDA with the FDA for benznidazole in the first quarter of 2018.

For more information, please visit [www.kalobios.com](http://www.kalobios.com).

## 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, for the potential treatment of various solid and hematologic cancers such as CMML and potentially 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 related to expectations regarding the timing of our submission of an IND for benznidazole; our statements regarding the manufacturing process for benznidazole tablets; and 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; our ability to obtain the necessary U.S. and international regulatory approvals for benznidazole and to qualify for, or benefit from, various regulatory incentives; the scope and validity of intellectual property and other competitive protection for benznidazole; our ability to maintain or engage third-party manufacturers to manufacture, supply, store and distribute supplies of benznidazole; 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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