

AntriaBio Announces Promising Preclinical Results for Once-Weekly Basal Insulin AB101

LOUISVILLE, CO -- (Marketwired) -- 06/08/15 --

- AB101 drug substance retained similar receptor binding affinity and receptor-mediated biological activity compared to native insulin
- Single dose subcutaneous administration of AB101 in rats and dogs led to slow onset, peakless and sustained insulin increases with corresponding glucose reductions over the course of a week
- *PK/PD* profiles support the target product profile of AB101 as a once-weekly basal insulin therapy for type 1 and type 2 diabetes

<u>AntriaBio, Inc.</u> ("AntriaBio" or the "Company") (OTCQB: ANTB), a biopharmaceutical corporation developing novel extended release therapies, released preclinical results for its lead product candidate, <u>AB101</u>, at the American Diabetes Association 75th Scientific Sessions[®] in Boston. The results demonstrated that AB101 has comparable in vitro pharmacology to native insulin, and in two animal species exhibited a prolonged subcutaneous insulin absorption profile, resulting in slow onset, peakless and sustained insulin levels with corresponding glucose reductions, without acute hypoglycemia caused by an insulin burst. These observations occurred at clinically relevant dose projections, demonstrating proof of concept of the potential for AB101 as a weekly subcutaneous basal insulin therapy in patients with diabetes mellitus.

"We are delighted by the results of our preclinical proof of concept pharmacology studies of AB101," said Brian Roberts, M.D., Vice President of Clinical Development at AntriaBio. "In addition to enabling significant progress toward filing our IND, these results affirmed our predicted dose-response and can be readily translated to clinically relevant doses and dose volumes in humans. We now have even greater confidence that similar safety and long-acting clinical pharmacology will be observed in clinical trials, which we are hopeful will one day translate into an important new treatment option for clinicians and patients."

"The availability of a longer-acting basal insulin therapy would provide physicians with a new treatment tool for their patients," said Philip Home, M.A., D. Phil., D.M., F.R.C.P., Professor of Diabetes Medicine at Newcastle University and previous clinical lead to the International Diabetes Federation (IDF) guidelines. "These results are encouraging, as they show that AB101 could be a promising new insulin therapy option for people with diabetes."

In receptor binding studies, AB101 drug substance was found to have an affinity for the

insulin receptor that is similar to native insulin once bound, which predicts insulin activity in humans. The drug substance also displayed a low affinity for the IGF-1 receptor, which would indicate a low risk of mitogenicity. In liver cells, AB101 drug substance inhibited glucose production to the same magnitude and with the same potency as native insulin. The inhibitory effect on glucose production occurred at an IC50 of 0.24 nM, which was nearly identical to that of native insulin at an IC50 of 0.23 nM.

In vivo studies were conducted in rats and dogs. Fasting insulin and glucose were measured at baseline and multiple times over a 14-day period after a single subcutaneous dose (37.5 mg/kg or vehicle control in rats [n=6/group]; 10 mg/kg or 37.5 mg/kg in dogs [n=3/group]). In both species, slow and sustained increases in insulin were observed, with a Cmax of > 30 ng/mL at 7 - 9 days post dose, and corresponding dose and species-dependent maximum reductions in glucose of 30 - 50%. The ratio of AUC(0-24h) to AUC(0-total) for insulin and glucose was < 1%. A similar sustained PK/PD profile was demonstrated in a diabetes animal model.

The data presentation that was presented by Dr. Roberts during the "Basal Insulin Analogs - New Evidence" oral session at the American Diabetes Association 75th Scientific Sessions[®] in Boston can be found <u>here</u>.

AntriaBio is currently engaged in additional studies for AB101 that support the filing of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration.

About AntriaBio, Inc.

AntriaBio is a biopharmaceutical company that develops novel extended release therapies by combining proprietary formulation and manufacturing capabilities with well-known molecules to significantly improve standards of care. AntriaBio's lead product candidate is AB101, an injectable once-weekly basal insulin for type 1 and type 2 diabetes that addresses a \$11 billion market where the current standard of care is a once-daily basal insulin injection. For more information visit: <u>www.antriabio.com</u>.

Forward-Looking Statements

This release, like many written and oral communications presented by AntriaBio, Inc., and our authorized officers, may contain certain forward-looking statements regarding our prospective performance and strategies within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, and are including this statement for purposes of said safe harbor provisions. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of the Company, are generally identified by use of words "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "seek," "strive," "try," or future or conditional verbs such as "could," "may," "should," "will," "would," or similar expressions. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Readers are cautioned not to place undue reliance on these forwardlooking statements, which speak only as of the date of this release. Except as required by applicable law or regulation, AntriaBio undertakes no obligation to update these forwardlooking statements to reflect events or circumstances that occur after the date on which

such statements were made.

AntriaBio, Inc. Contact: Noopur Liffick VP of Corporate Development (650) 549-4175 investor-relations@antriabio.com

Source: AntriaBio, Inc.