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Amarantus
BioScience

Amarantus Announces First Alzheimer's Biomarker Services Collaboration for LymPro Test(R) With Anavex Life Sciences Corp.

- *Investigational Alzheimer's drug candidate ANAVEX 2-73 and drug combination ANAVEX PLUS pharmacodynamic activity to be evaluated using Amarantus' LymPro Test[®] in blood samples from Alzheimer's disease patients*
- *Companies to establish scope of biomarker services (initial patient screening for enrollment and ongoing monitoring of drug activity) for clinical trial following ongoing Phase 2a study for ANAVEX 2-73 and ANAVEX PLUS in Alzheimer's disease*

SAN FRANCISCO, GENEVA and NEW YORK, Feb. 18, 2015 (GLOBE NEWSWIRE) -- [Amarantus BioScience Holdings, Inc.](#) (OTCQB:AMBS), a biotechnology company focused on developing diagnostics in neurology, and therapeutic products with the potential for orphan drug designation in the areas of neurology, psychiatry, ophthalmology and regenerative medicine, and [Anavex Life Sciences Corp.](#) (Anavex) (OTCQX:AVXL), a biopharmaceutical company dedicated to the development of novel drug candidates to treat Alzheimer's disease (AD), other central nervous system (CNS) diseases, pain and various types of cancer, today announced the execution of a biomarker services agreement in which Amarantus will evaluate the pharmacodynamic effect of [ANAVEX 2-73](#) and [ANAVEX PLUS](#) on the expression of the biomarker CD69 in specific sub-populations of peripheral blood lymphocytes using Amarantus' proprietary Alzheimer's blood diagnostic LymPro Test[®]. In parallel, the companies have entered into a Letter of Intent ("LOI") for Amarantus to assist Anavex in planning the scope of the blood-based biomarker components of Anavex' next larger, potentially Phase 3, Alzheimer's disease clinical trial that is expected to follow the [ongoing Phase 2a study](#) currently enrolling subjects to collect additional safety and exploratory efficacy data in mild to moderate AD patients. Initial data from Anavex' Phase 2a AD trial is expected in the third quarter of 2015. ANAVEX 2-73 and ANAVEX PLUS, which combines ANAVEX 2-73 with donepezil (Aricept[®]), are Anavex' lead drug candidate and drug candidate combination, respectively, for Alzheimer's disease.

"We are pleased to assist Anavex, our first customer, in evaluating the potential of ANAVEX 2-73 and ANAVEX PLUS to increase CD69 expression using LymPro in blood derived from AD patients," said Gerald E. Commissiong,

President & CEO of Amarantus. "Based on data generated in [two previous peer-reviewed publications](#), our recently completed LP-002 clinical study, as well as studies presented by Amarantus in 2014 at the Alzheimer Association International Conference, [CD69 expression](#)

[as measured by LymPro is decreased in patients](#) with AD, as compared to healthy controls and patients with confounding dementias. The ability of a new drug candidate to increase CD69 expression, as measured by LymPro, may be indicative of a modification in the fundamental Alzheimer's disease process known as cell cycle dysregulation (a/k/a 'ectopic cell cycle re-entry'). Cell cycle dysregulation has been directly implicated as a key driver of the neuronal death in the areas of the brain affected by AD that is triggered by [amyloid beta signaling through Tau](#). Our premier diagnostics division, [Amarantus Diagnostics](#), is well positioned to add value to pharmaceutical companies' Alzheimer's therapeutics programs by helping them better execute AD therapeutic clinical studies. We will assist companies by enriching the population of subjects enrolling in Alzheimer's clinical studies, the key unmet need for therapeutic Alzheimer's programs, as well as evaluating drug activity of cell cycle dysregulation, and potentially lipidomics and exosomes via an [exclusive option agreement](#) the Company currently holds with Georgetown University. We are currently in active discussions with both emerging and large pharma companies as we work to build a significant customer base for blood-based biomarker services in Alzheimer's disease, with the ultimate shared goal of improving the current standard of care used to treat AD. We are positioning Amarantus Diagnostics to be the market leader in Alzheimer's blood-based biomarkers for the Investigational Use Only (IUO) market, and we believe this agreement is the first important revenue generating step in this direction for Amarantus."

"While the Phase 2a clinical trial for ANAVEX 2-73 and ANAVEX PLUS in Alzheimer's disease is currently underway, Anavex is already planning and exploring options for the next stage of clinical trials, potentially Phase 3, for ANAVEX 2-73 and ANAVEX PLUS given the high unmet need in Alzheimer's," said Christopher U. Missling, Ph.D., President and Chief Executive Officer for Anavex. "ANAVEX 2-73 has demonstrated in preclinical studies to block Tau and amyloid-beta proteins and memory deficits by targeting mixed muscarinic and Sigma-1 receptors, targets which are further 'upstream' in the Alzheimer's disease cascade and thus its potential to halt and/or reverse the course of AD. Being an orally available drug candidate combined with a favorable safety profile as established in a recently completed [Phase 1 clinical study](#) of ANAVEX 2-73, we are looking forward to collecting continued safety data and exploratory efficacy data in patients. Assuming a successful Phase 2a outcome, we will evaluate the scope of blood-based biomarker services that could be included in the design for our next AD clinical studies for ANAVEX 2-73 and ANAVEX PLUS."

Amarantus recently [completed 'Fit-for-Purpose' assay validation for LymPro at Icon Central Laboratories](#) in Farmingdale, NY, enabling the assay to be offered to the pharmaceutical industry for IUO for evaluation of pharmacodynamic changes in CD69 expression, as well as patient screening and pharmacodynamics drug monitoring in therapeutic AD clinical trials. The company is in the process of building a portfolio of pharmaceutical customers preparing to execute clinical studies in AD.

"This is the type of collaboration that becomes possible with new diagnostic tools to help therapeutic interventions in AD. The mechanisms involved may begin to validate emerging targets in the field of AD, and I am excited to help bring this collaboration forward," commented [Robert A. Stern, Ph.D.](#), Professor of neurology, neurosurgery, anatomy and neurobiology at Boston University School of Medicine, Director of the Clinical Core of the Boston University Alzheimer's Disease Center, Director of Clinical Research for the CTE Center at Boston University and member of Amarantus Diagnostics Scientific Advisory Board.

About Alzheimer's disease

According to the Alzheimer's Association, it is estimated that over 5.4 million people in the United States suffer from Alzheimer's disease. Over 500,000 patients are diagnosed annually, with nearly one-in-eight older Americans affected by the disease. Alzheimer's disease is the third leading cause of death in the United States. The cost of unpaid care in the United States is estimated at over \$210 billion annually. Total payments for care are estimated at over \$200 billion annually, including \$140 billion in cost to Medicare and Medicaid. Alzheimer's expenditures in the United States are expected to exceed \$1.2 trillion by 2050. There is no cure or effective treatment for Alzheimer's disease. Worldwide, about 35.6 million individuals have the disease and, according to the World Health Organization, the number will double every 20 years to 115.4 million people with Alzheimer's by 2050.

About ANAVEX 2-73 and ANAVEX PLUS

ANAVEX 2-73 is an orally available small molecule being investigated for the treatment of Alzheimer's disease. In addition to preclinical data indicating that ANAVEX 2-73 has the potential to prevent, halt and/or reverse the course of Alzheimer's disease, there was a highly encouraging synergistic effect observed between ANAVEX 2-73 and donepezil (Aricept®). The combined therapeutic, called ANAVEX PLUS, produced up to 80% greater reversal of memory loss in Alzheimer's disease models versus when the drugs were used individually.

About Anavex Life Sciences Corp.

Anavex Life Sciences Corp. (OTCQX:AVXL) is a publicly traded biopharmaceutical company dedicated to the development of novel drug candidates to treat Alzheimer's disease, other Central Nervous System (CNS) diseases, pain and various types of cancer. Anavex's lead drug candidates, ANAVEX 2-73 and ANAVEX PLUS, the combination of ANAVEX 2-73 and donepezil (Aricept®), are currently in a Phase 2a clinical trial for Alzheimer's disease. ANAVEX 2-73 is an orally available drug candidate that targets sigma-1 and muscarinic receptors and successfully completed Phase 1 with a clean data profile. Preclinical studies demonstrated its potential to halt and/or reverse the course of Alzheimer's disease. The drug combination ANAVEX PLUS produced up to 80% greater reversal of memory loss in Alzheimer's disease models versus when the drugs were used individually. Further information is available at www.anavex.com.

About LymPro Test®

The Lymphocyte Proliferation Test (LymPro Test®) is a diagnostic blood test that determines the ability of peripheral blood lymphocytes to withstand an external mitogenic stimulation that induces them to enter the cell cycle. It is believed that certain diseases, most notably Alzheimer's disease, are the result of compromised cellular machinery that leads to aberrant cell cycle re-entry by neurons. LymPro is unique in the use of peripheral blood lymphocytes (PBLs) as a surrogate for neuronal cell function, suggesting a common immune-based relationship between PBLs and neurons in the brain.

About Amaranthus BioScience Holdings, Inc.

Amarantus BioScience Holdings (AMBS) is a biotechnology company developing treatments

and diagnostics for diseases in the areas of neurology, psychiatry, ophthalmology and regenerative medicine. AMBS has licensed Eltoprazine, a Phase 2b ready small molecule indicated for Parkinson's disease Levodopa-induced dyskinesia and adult ADHD. AMBS has an exclusive worldwide license to the Lymphocyte Proliferation test, (LymPro Test[®]), which was developed by Prof. Thomas Arendt, Ph.D., from the University of Leipzig, for Alzheimer's disease and owns the intellectual property rights to a therapeutic protein known as mesencephalic-astrocyte-derived neurotrophic factor ("MANF") and is developing MANF-based products as treatments for brain and ophthalmic disorders. AMBS also owns intellectual property for the diagnosis of Parkinson's disease (NuroPro) and the discovery of neurotrophic factors (PhenoGuard[™]).

In November 2014, AMBS entered into an exclusive option agreement with Lonza Walkersville, Inc., a subsidiary of Lonza Group Ltd., to acquire Cutanogen Corporation, a subsidiary of Lonza Walkersville, to develop Engineered Skin Substitute (ESS-W), an autologous skin replacement product for the treatment of Stage 3 and Stage 4 intractable severe burns.

On January 12, 2015, AMBS announced the acquisition of DioGenix, Inc., a specialized neuro-diagnostics company, and owns the rights to MSPrecise[®], a proprietary next-generation DNA sequencing (NGS) assay for the identification of patients with relapsing-remitting multiple sclerosis (RRMS) at first clinical presentation. On January 15, 2015, AMBS executed a one-year exclusive option agreement with Georgetown University to enter into a license for the patent rights related to certain blood based biomarkers for memory loss and Alzheimer's disease jointly owned by Georgetown University and University of Rochester. For further information please visit www.Amarantus.com, or connect with the Company on [Facebook](#), [LinkedIn](#), [Twitter](#) and [Google+](#).

Forward-Looking Statements

Certain statements, other than purely historical information, including estimates, projections, statements relating to our business plans, objectives, expected operating results, and the assumptions upon which those statements are based, are forward-looking statements. These forward-looking statements generally are identified by the words "believes," "project," "expects," "anticipates," "estimates," "intends," "strategy," "plan," "may," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties which may cause actual results to differ materially from the forward-looking statements. Our ability to predict results or the actual effect of future plans or strategies is inherently uncertain. Factors which could have a material adverse effect on our operations and future prospects on a consolidated basis include, but are not limited to: changes in economic conditions, legislative/regulatory changes, availability of capital, interest rates, competition, and generally accepted accounting principles. These risks and uncertainties should also be considered in evaluating forward-looking statements and undue reliance should not be placed on such statements.

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