

# Amarantus Announces Positive LP-002 Data for Alzheimer's Blood Diagnostic LymPro Test(R)

SAN FRANCISCO and GENEVA, Oct. 9, 2014 (GLOBE NEWSWIRE) -- Amarantus Bioscience Holdings, Inc. (OTCQB:AMBS), a biotechnology company focused on developing diagnostics and therapeutics for Alzheimer's disease, Parkinson's disease and ophthalmological disorders, reported positive data from its LP-002 study of the Lymphocyte Proliferation Test (LymPro Test®) blood diagnostic for Alzheimer's disease (AD). LymPro achieved highly statistically significant results in correctly distinguishing patients with moderate-to-severe AD from healthy controls. As a result of these positive findings, Amarantus is expanding the study to assess LymPro's predictive value in diagnosing early-stage AD patients. Amarantus anticipates launching LymPro in the fourth quarter of 2014.

In a 72 subject study, including 36 patients with moderate-to-severe AD versus a control group of 36 healthy subjects, the expression of the marker CD69 on specific sub-populations of lymphocytic cells was statistically significantly lower in the AD groups versus the control group, as measured under two different stimulation conditions (LymPro Version 1 and LymPro Version 2).

CD69 is a protein expressed when lymphocytic blood cells are in the process of proliferating, and is considered an early marker that cell division is imminent. Low levels of CD69 under cell division conditions in AD patients is suggestive of lymphocytic cell cycle dysregulation and a surrogate marker for the neuronal cell cycle dysregulation that has been observed in the brains of AD patients at autopsy. Cell cycle dysregulation has been identified as a potential link between amyloid beta plaques and tau tangles in AD.

In Version 1, LymPro correctly classified AD patients and healthy controls with an overall accuracy of 87% (p=0.0015), with a high degree of sensitivity (80%) and specificity (86%). In Version 2, LymPro correctly classified AD patients and healthy controls with an overall accuracy of 83% (p=.0059) while maintaining a high degree of sensitivity (90%) and specificity (71%). The range of variations observed in sensitivity and specificity between LymPro Version 1 and LymPro Version 2 are common findings in diagnostic testing in heterogeneous indications such as Alzheimer's. Of particular importance is the consistency of the overall accuracy between Version 1 and Version 2. Further, the expression of CD69 did not change with disease severity, which is consistent with previous work suggesting that LymPro is measuring a fundamental stage-independent biology in AD patients. Amarantus believes the results from both Version 1 and Version 2 of LymPro are suitable for commercialization, and is validating both Version 1 and Version 2 for use in the Research Use Only (RUO) market. Amarantus plans to launch LymPro for RUO in the fourth quarter of 2014, primarily targeting pharmaceutical clinical trials. The company does not require Clinical Laboratory Improvement Amendments (CLIA) certification to launch LymPro in the

### RUO market.

"LymPro will have great utility to the pharmaceutical companies developing drugs for Alzheimer's disease, as it will permit a more reliable way of selecting subjects for inclusion in trials, thereby assuring an enriched population and mitigating the risk of including non-Alzheimer's disease subjects," said Colin Bier, PhD, member of the Amarantus Board of Advisors who is tasked with the development of LymPro.

Based on the strength of these results, the company has expanded the inclusion criteria to also enroll patients diagnosed with mild Alzheimer's disease. 68 additional subjects will be recruited, including 34 mild-to-severe Alzheimer's patients, and 34 healthy controls. Amarantus anticipates completing enrollment of the 68 patient LP-002 extension in the fourth quarter and will announce data from an in-depth analysis from the full cohort of 140 subjects (72 patients + 68 patient extension) shortly thereafter.

"Amarantus is aiming to be first to market with an accurate, reliable and commercially- viable diagnostic blood test for Alzheimer's disease," said Gerald E. Commissiong. "Today's data gives us all the information we need to move full steam ahead with this strategy. We can now tailor our initial marketing efforts towards the \$150M RUO market, primarily targeting pharmaceutical companies engaged in Alzheimer's disease therapeutic trials. We have nearly completed assembling the resources needed to launch LymPro to the RUO community in the fourth quarter. Thereafter, we intend to market LymPro to the broader medical community, initially under CLIA. We estimate the worldwide market for an Alzheimer's diagnostic is \$3B"

The company will make a final decision on which version of LymPro (Version 1 or Version 2) to launch under the CLIA designation, which will be marketed to the general population, following an in-depth analysis from the full cohort of 140 subjects. The company anticipates launching LymPro under CLIA shortly after product launch in the RUO marketplace.

#### **About Alzheimer's disease**

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 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 \$1.4 trillion by 2050.

## About LymPro Test®

The Lymphocyte Proliferation Test (LymPro Test®) is a diagnostic blood test that measures the ability of peripheral blood lymphocytes to withstand an external mitogenic stimulation that induces them to enter the cell cycle. It is hypothesized 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 Amarantus Bioscience Holdings, Inc.**

Amarantus Bioscience Holdings (AMBS) is a biotechnology company developing treatments and diagnostics for diseases associated with neurodegeneration and protein misfolding-related apoptosis. AMBS has licensed Eltoprazine, a Phase 2b-ready small molecule drug indicated for Parkinson's Levodopa induced dyskinesia and adult ADHD. AMBS has an exclusive worldwide license to the Lymphocyte Proliferation test (LymPro Test®) for Alzheimer's disease and owns the intellectual property rights to a therapeutic protein known as Mesencephalic-Astrocyte-derived Neurotrophic Factor (MANF). Amarantus is developing MANF-based products as treatments for orphan ophthalmological disorders and other indications. AMBS also owns intellectual property for the diagnosis of Parkinson's disease (NuroPro) and the discovery of neurotrophic factors (PhenoGuard). Amarantus operations are located in offices and labs at Janssen Labs @QB3. For further information please visit www.Amarantus.com, or connect with the Company on Facebook, LinkedIn, Twitter and Google+.

Certain statements, other than purely historical information, including estimates, projections, statements relating to our business plans, objectives, and 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.

CONTACT: Amarantus Bioscience Holdings, Inc.
Aimee Boutcher, Investor Relations
408.737.2734 x 101
ir@amarantus.com

Planet Communications
Deanne Eagle, Media Contact
(917) 837-5866

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