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# **Amarantus BioScience Announces Positive Efficacy Data for MANF in a Nigral Delivery Neurorestoration Animal Model of Parkinson's Disease**

SUNNYVALE, Calif., Jan. 9, 2013 /PRNewswire/ -- Amaranthus BioScience, Inc. (OTCQB: AMBS), a biotechnology company discovering and developing treatments and diagnostics for diseases associated with protein misfolding and apoptosis centered around its patented therapeutic protein Mesencephalic Astrocyte-derived Neurotrophic Factor (MANF), today presented positive preclinical efficacy data for MANF in a neurorestoration 6-hydroxydopamine (6-OHDA) rat model of Parkinson's disease. The data demonstrate that unlike Glial cell-Derived Neurotrophic Factor (GDNF), MANF significantly reduces behavioral deficits, increases dopaminergic (DA) nerve terminal reinnervation of the striatum, and increases dopamine concentrations in the striatum when MANF is administered directly to the substantia nigra (SNc). GDNF is an agent currently in clinical trials for Parkinson's disease. Dr. John W. Commissiong, Chief Scientific Officer of Amaranthus, presented the data at the OneMedForum 2013 conference on January 8, 2013. The webcast is available online at <http://www.onemedplace.com/database/list/cid/13336/>.

"Today's data support previously reported behavioral data where MANF demonstrated superiority over GDNF," said Dr. John W. Commissiong. "Going forward, the Company is in a strong position to advance MANF as a potential disease-modifying treatment for Parkinson's based on unique behavioral, morphological and neurochemical data in standard animal models of the disease."

In humans and animals, dopamine is a chemical released by DA neurons to send signals to other neurons, and is known as a neurotransmitter. DA neurons are the cells responsible for releasing dopamine, and degenerate in the SNc of Parkinson's disease patients. This degeneration causes DA nerve terminals from the striatum to retract towards their cell bodies in the SNc. The loss of DA nerve terminals in the striatum leads to reduced dopamine levels in the striatum. Therefore, drug treatment to the SNc that increases innervation of the striatum is critical as a basis for functional recovery in Parkinson's disease.

The data produced comparing optimal doses to the SNc of MANF = 10 ug and GDNF = 10 ug in this model indicate the following at four weeks post-treatment:

1. MANF reduced behavioral deficits by 53%, whereas behavioral deficits with GDNF increased by 20%;
2. MANF produced a 14.4% reinnervation of the striatum, whereas striatum innervation with GDNF was reduced by 9.9%;
3. MANF increased dopamine concentrations in the striatum, whereas striatum dopamine concentrations with GDNF did not increase.

"We are excited about our results with MANF as we have demonstrated superiority to GDNF in a number of key areas related to recovery of function in Parkinson's disease," added Dr. Joseph Rubinfeld, Amaranthus advisor and Amgen Co-Founder. "We intend to continue to move our Parkinson's program forward, while also evaluating other disease indications for MANF with potentially accelerated regulatory pathways, including certain orphan diseases. This strategy may significantly reduce MANF's overall time to market versus a Parkinson's-only strategy."

In the study, rodents were lesioned with 6-OHDA on one side of their brain (t = 0). Behavior was tested for baseline (t = 1 week) and vehicle, MANF (3 ug, 10 ug or 36 ug) and GDNF (10ug) were injected in different groups of animals at t = 2 weeks. Behavior was tested for drug effect at t = 4 weeks (2 weeks post-treatment) and at t = 6 weeks (4 weeks post-treatment).

The behavioral data achieved statistical significance with a p value of less than 0.03 with animal groups of N=12. The striatum reinnervation data and dopamine concentration data did not achieve statistical significance because the animals sacrificed from the behavioral study were divided into 2 separate groups of N=6 for the analysis of densitometry (striatum reinnervation) and neurochemistry (dopamine concentration in the striatum). The method of analysis of the rat brains did not allow for the densitometry and neurochemistry to be analyzed simultaneously in the same animals, leading to groups of N = 6 or less, which was insufficient to achieve statistical significant.

The Company believes the data are positive, even without statistical significance due to small groups of animals in the densitometry and chemistry data, because there are consistent internal results correlating behavior, stereology, densitometry and neurochemistry, most notably at MANF = 10 ug and GDNF = 10 ug. The Company is preparing to initiate IND enabling studies for MANF as a disease-modifying drug candidate for Parkinson's disease.

### **About Mesencephalic-Astrocyte-derived Neurotrophic Factor (MANF)**

MANF (Mesencephalic-Astrocyte-derived Neurotrophic Factor) is a protein that corrects protein misfolding, one of the major causes of apoptosis (Programmed Cell Death). Mesencephalic-Astrocyte-derived Neurotrophic Factor (MANF) is believed to have broad potential because it is a naturally-occurring protein produced by the body for the purpose of reducing and preventing apoptosis (in response to injury or disease), via the unfolded protein response. By manufacturing MANF and administering it to the body, Amaranthus is

seeking to use a regenerative medicine approach to assist the body with higher quantities of MANF when needed. Amaranthus is the front-runner and primary holder of intellectual property (IP) around MANF, and is initially focusing on the development of MANF-based protein therapeutics. MANF's current lead indication is Parkinson's disease with additional focus on Traumatic Brain Injury (TBI). Future indications may include myocardial infarction and certain rare and ultra-rare orphan diseases where MANF is currently being evaluated.

The Company also owns an inventory of 88 cell lines referred to as "PhenoGuard Cell Lines." MANF was the first therapeutic protein discovered from a PhenoGuard Cell Line, and it is anticipated that additional therapeutic proteins useful for various therapeutic approaches to the Central Nervous System will be identified from the Company's inventory of PhenoGuard Cell Lines.

### **About Amaranthus BioScience, Inc.**

Amaranthus BioScience, Inc. is a development-stage biotechnology company founded in January 2008. The Company has a focus on developing certain biologics surrounding the intellectual property and proprietary technologies it owns to treat and/or diagnose Parkinson's disease, Traumatic Brain Injury and other human diseases. The Company 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 disorders. The Company also is a Founding Member of the Coalition for Concussion Treatment (#C4CT), a movement initiated in collaboration with Brewer Sports International seeking to raise awareness of new treatments in development for concussions and nervous-system disorders. For further information please visit [www.Amaranthus.com](http://www.Amaranthus.com).

### **Forward Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the possible benefits of MANF therapeutic applications and/or advantages presented by Amaranthus' PhenoGuard technology, as well as statements about expectations, plans and prospects of the development of Amaranthus' new product candidates. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including the risks that the anticipated benefits of the therapeutic drug candidates or discovery platforms, as well as the risks, uncertainties and assumptions relating to the development of Amaranthus' new product candidates, including those identified under "Risk Factors" in Amaranthus' most recently filed Annual Report on Form 10-K and Quarterly Report on Form 10-Q and in other filings Amaranthus periodically makes with the SEC. Actual results may differ materially from those contemplated by these forward-looking statements. Amaranthus does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this presentation.

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