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Adeona Announces Positive Results of Part 1 of CopperProof-2 Study in Alzheimer's Disease and Mild Cognitive Impairment

Results Show Zinthionein ZC (Zinc Cysteine) Has Greater Tolerability and Oral Bioavailability Compared to Currently Marketed Zinc Therapy

Conference Call Scheduled for 2:00 p.m. EDT Today

ANN ARBOR, MI--(Marketwire - April 14, 2010) - Adeona Pharmaceuticals, Inc., (AMEX: AEN) announced positive results of Part 1 of its CopperProof-2 clinical study of Zinthionein ZC (zinc cysteine) in Alzheimer's disease and mild cognitive impairment.

Adeona will hold a conference call today at 2:00 p.m. EDT to discuss these results and answer questions. Adeona's Chief Executive Officer, James S. Kuo, M.D., M.B.A., will host the call and will be joined by David A. Newsome, M.D., Senior Vice President of Research and Development.

In order to participate in the conference call, please call toll free: 888-811-5456 (US); international dial-in: 913-312-0644, conference identification: 8274725. The audio recording will be available for replay at <http://www.adeonapharma.com> for a period of at least 15 days after the call.

CopperProof-2 Clinical Study

Adeona's clinical study, named CopperProof-2, seeks to compare Zinthionein ZC to placebo, as well as a currently marketed prescription zinc product, Galzin® (zinc acetate). The clinical study, "A Prospective, Randomized, Double Blind Trial of a Novel Oral Zinc Cysteine Preparation in Alzheimer's Disease (CopperProof-2)" previously received institutional review board approval to proceed. The principal investigator of the study is Diana Pollock, M.D., Associate Director, Memory Disorder Center, Clearwater, Florida.

CopperProof-2 is designed as a controlled, 60-patient, randomized, double-blind, placebo-controlled clinical study and is divided into two parts. Part 1, recently completed, is a 13-subject, three-arm, single-dose, comparator study in Alzheimer's disease and mild cognitive impairment subjects that compared the tolerability and bioavailability of Zinthionein ZC to Galzin®, the only Food and Drug Administration-approved zinc preparation and placebo. The Galzin® arm tested two separate individual dose levels, 50 mg and 100 mg zinc acetate (two 50 mg doses taken together). Part 2 of the study has 60 Alzheimer's disease and mild cognitive impairment subjects randomized to receive either once-daily Zinthionein ZC or matching placebo for six months.

Results

Tolerability

Results from Part 1 of the study, announced today, demonstrate a substantially lower incidence of adverse effects in Alzheimer's disease and Mild Cognitive Impairment subjects (33% versus 100%) in favor of Zinthionein ZC (containing 150 mg of elemental zinc acetate and 100 mg of cysteine) compared to Galzin® (containing either 50 mg or 100 mg of elemental zinc as zinc acetate). 100% of the Galzin® subjects experienced gastrointestinal distress, ranging from 100% nausea to 40% vomiting, 40% diarrhea, and 20% heartburn. The high rate of gastrointestinal adverse effects of Galzin® are consistent with prior published results of oral zinc therapy.(1) In comparison, only 33% of Zinthionein ZC subjects experienced nausea, with only one of such subjects (17% of group) having experienced vomiting. No adverse effects were noted in the placebo group.

Adverse effects for the three groups are as follows:

	Placebo	%	Galzin 100 mg	%	Galzin 50 mg	%	Galzin All	%	Zinthionein ZC 150 mg	%
Any Adverse Effect	(0/2)	0%	(3/3)	100%	(2/2)	100%	(5/5)	100%	(2/6)	33%
Nausea	(0/2)	0%	(3/3)	100%	(2/2)	100%	(5/5)	100%	(2/6)	33%
Vomiting	(0/2)	0%	(1/3)	33%	(1/2)	50%	(2/5)	40%	(1/6)	17%
Diarrhea	(0/2)	0%	(1/3)	33%	(1/2)	50%	(2/5)	40%	(0/6)	0%
Dizziness	(0/2)	0%	(0/3)	0%	(0/2)	0%	(0/5)	0%	(2/6)	33%
Abdominal Pain	(0/2)	0%	(0/3)	0%	(0/2)	0%	(0/5)	0%	(1/6)	17%
Heartburn	(0/2)	0%	(0/3)	0%	(1/2)	0%	(1/5)	20%	(0/6)	0%

Bioavailability

Zinthionein ZC also demonstrated superior serum zinc bioavailability in Alzheimer's disease and Mild Cognitive Impairment subjects compared to both the 50 mg and 100 mg dose levels of Galzin®. Average baseline serum zinc levels of the subjects was 76.8 microg/dL (range: 63-92 microg/dL), consistent with Adeona's earlier findings of a subclinical zinc deficiency in Alzheimer's disease patients. The area under the curve (a serum measurement of bioavailability) of Zinthionein ZC was approximately 166% that of the 50 mg Galzin® dose and 116% that of 100 mg Galzin® dose (two 50 mg doses taken together).

The bioavailability results are also supplemented from results of a separate uncontrolled repeat dose pilot study conducted by Adeona in a small number of normal subjects who took Zinthionein ZC once-daily for 14 weeks, also being announced today. Following 14 weeks, subjects demonstrated an average 80% increase in serum zinc levels from baseline measured at least 12 hours after last dose, demonstrating Zinthionein ZC's ability to maintain consistently elevated serum zinc levels. In addition, a 17% reduction in serum copper levels was observed after 14 weeks, demonstrating Zinthionein ZC's ability to favorably improve serum copper/zinc ratios with once-daily dosing.

Part 2 of the Clinical Study

Part 2 of the clinical study is intended to enroll 60 Alzheimer's disease and mild cognitive impairment subjects and is currently ongoing with 11 of 13 enrolled subjects from Part 1 electing to continue to Part 2 of the study. In Part 2, subjects are randomized on a 50:50 basis to either Zinthionein ZC or matching placebo. Subjects will be assessed at 3 and 6 months for serum parameters of zinc and copper as well as changes in cognitive function using standard clinical tests used in Alzheimer's disease and Mild Cognitive Impairment. Some subjects have now completed three months of therapy. Adeona recently added two additional clinical sites in Florida to further expedite enrollment and complete Part 2 of the study.

Background of Zinc Therapy for Alzheimer's Disease and Mild Cognitive Impairment

The CopperProof-2 study grew out of observations by Adeona and now others documenting a subclinical zinc deficiency in Alzheimer's disease patients(2,3) as well as a significant body of published evidence implicating chronic copper exposure and elevated free serum copper levels in the progression of Alzheimer's disease and mild cognitive impairment. In 1992, results from an uncontrolled study of zinc therapy in Alzheimer's disease was reported to demonstrate cognitive improvement in 80% of subjects in as little as 3 to 6 months of treatment.(4) Due to the significant gastrointestinal side effects and intolerance of oral zinc therapy in such study, oral zinc therapy was discontinued and subjects were switched to zinc injections administered every other day, further underscoring the need for a better tolerated, convenient oral zinc therapy such as Zinthionein ZC.

The hippocampus, an area of the brain that plays a critical role in short-term memory and is generally most affected in Alzheimer's disease, is believed to contain the highest levels of zinc in the brain. Hippocampal zinc is believed to play an important dual role as a synaptic neurotransmitter that modulates NMDA (N-methyl-D-aspartic acid) receptor activity limiting excitotoxicity(5) and is a key component of hundreds of neuroprotective enzymes, a number of which are responsible for the degradation of amyloid beta. (6) Alzheimer's disease subjects have been reported to have lower levels of zinc in their cerebral spinal fluid,(7) and cerebral spinal fluid levels of copper and zinc highly correlate with levels of amyloid beta 42 in cerebral spinal fluid, a biomarker of Alzheimer's disease. (6) Zinc's role as an important NMDA receptor antagonist implies that by ameliorating the cerebral spinal fluid zinc deficiency in Alzheimer's disease patients, Zinthionein ZC may demonstrate near term acute cognitive benefits, such as those demonstrated in the 1992 study described above, as well as reducing neurodegeneration in the longer term. Current NMDA-receptor antagonists for Alzheimer's disease, such as Namenda® and Axura® (memantine), currently have estimated annualized sales of \$2.6 billion.

About Zinthionein™ ZC

Zinthionein™ ZC is a once-daily, gastroretentive, sustained-release, proprietary, oral tablet formulation of zinc and cysteine. Cysteine is an amino acid that has potent anti-oxidant properties and is a necessary component of the copper/zinc-binding protein, metallothionein. All of Zinthionein ZC's constituents have GRAS (Generally Regarded as Safe) status. Zinthionein ZC was specially invented and developed by Adeona to achieve the convenience of once-daily dosing, high bioavailability and to minimize gastrointestinal side effects of oral zinc therapy. Adeona is developing Zinthionein ZC as a prescription medical food for the dietary management of Alzheimer's disease and mild cognitive impairment. Zinthionein ZC is protected by multiple U.S. and international pending patent applications held by Adeona.

About Galzin®

Galzin® (zinc acetate) is a Food and Drug Administration-approved therapy for the treatment of Wilson's disease, an illness characterized by impaired copper excretion, elevated serum free copper levels and chronic copper toxicity. The highest Galzin® dose available contains 50 mg elemental zinc and requires administration three times per day to Wilson's disease patients, all three of which must be taken away from food. A major drawback to Galzin® is its high incidence of gastrointestinal side effects and difficult dosing regimen, which causes compliance issues and in some cases, discontinued use altogether.

Diana Pollock, M.D., principal investigator of the CopperProof-2 clinical study, commented, "I am pleased with the superior tolerability of Zinthionein ZC. I am also pleased to report that 100% of the subjects continuing in Part 2 of the study appear to be tolerating their clinical study materials with no side effects. The superior tolerability, bioavailability and convenience of once-daily dosing of Zinthionein ZC could fulfill a large unmet clinical need for neurodegenerative diseases in the mature population."

David A. Newsome, M.D., Senior Vice President of Research and Development at Adeona, remarked, "Having pioneered the use of zinc therapy in 1988, now the standard of care for millions of patients with dry age-related macular degeneration, I believe that Adeona's once-daily, superior bioavailability and improved tolerability oral zinc delivery technology has the potential to capture a significant percentage of, and substantially grow, the current \$300 million in-market sales of oral zinc-based therapies currently used for neurodegenerative disease (dry age-related macular degeneration being the dominant indication, but requiring twice-a-day dosing)."

James S. Kuo, M.D., M.B.A, Adeona's Chief Executive Officer, stated, "As several subjects have now continued beyond Part 1 with some having achieved 3 months of treatment, I am excited with the progress being made and that Zinthionein ZC may positively impact Alzheimer's disease and mild cognitive impairment in a disease-modifying fashion utilizing a proprietary oral zinc preparation consisting solely of GRAS constituents."

About Adeona Pharmaceuticals, Inc.

Adeona (AMEX: AEN) is a pharmaceutical company developing new medicines for serious central nervous systems diseases. Adeona's primary strategy is to in-license clinical-stage drug candidates that have already demonstrated a certain level of clinical efficacy and develop them further to either commercialization or a development collaboration. Trimesta (estriol) is an investigational oral drug for the treatment of relapsing remitting multiple sclerosis. A 150-patient, 16-center, randomized, double-blind, placebo-controlled clinical trial is currently underway. Zinthionein ZC (zinc cysteine) is an oral, gastro-retentive, sustained-release medical food candidate being developed for the dietary management of Alzheimer's disease and mild cognitive impairment. In December of 2009, Adeona initiated CopperProof-2, a 60-subject clinical study. Effirma (flupirtine) is a novel centrally-acting investigational oral drug for the treatment of fibromyalgia syndrome. It is ready for a 90-patient phase II clinical trial. dnaJp1 (hsp peptide) is an investigational oral drug for the treatment of rheumatoid arthritis. It has completed a 160-patient, multi-center, randomized, double-blind, placebo-controlled clinical trial. CD4 Inhibitor 802-2 (cyclic heptapeptide) is an investigational drug for the prevention of severe graft-versus-host disease.

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(3) Baum L, Chan IH, Cheung SK, Goggins WB, Mok V, Lam L, Leung V, Hui E, Ng C, Woo J, Chiu HF, Zee BC, Cheng W, Chan MH, Szeto S, Lui V, Tsoh J, Bush AI, Lam CW, Kwok T, Serum zinc is decreased in Alzheimer's disease and serum arsenic correlates positively with cognitive ability, *Biometals.* 2010 Feb; 23(1): 173-9.

(4) Constantinides J, Treatment of Alzheimer's Disease by Zinc Compounds, *Drug Dev. Res.*, 27: 1-14 (1992)

(5) Izumi Y, Auberson YP, Zorumski CF, Zinc modulates bidirectional hippocampal plasticity by effects on NMDA receptors, *J Neurosci.* 2006 Jul 5; 26(27): 7181-8.

(6) Strozkyk D, Launer LJ, Adlard PA, Cherny RA, Tsatsanis A, Voltakis I, Blennow K, Petrovitch H, White LR, Bush AI., Zinc and copper modulate Alzheimer Abeta levels in human cerebrospinal fluid, *Neurobiol Aging.* 2009 Jul; 30(7): 1069-77.

(7) Molina JA, Jiménez-Jiménez FJ, Aguilar MV, Meseguer I, Mateos-Vega CJ, González- Muñoz MJ, de Bustos F, Porta J, Orti-Pareja M, Zurdo M, Barrios E, Martínez-Para MC, Cerebrospinal fluid levels of transition metals in patients with Alzheimer's disease, *J Neural Transm.* 1998; 105(4-5): 479-88.

This release includes forward-looking statements on Adeona's current expectations and projections about future events. In some cases forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based upon current beliefs, expectations and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and include statements regarding the success of our clinical trials and our ability to capture a significant percent of the market. The forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from those reflected in Adeona's forward-looking statements include, among others, a failure of Adeona's product candidates to be demonstrably safe and effective, a failure of Part 2 of the clinical study to produce desired results, a failure to obtain regulatory approval for the company's products or to comply with ongoing regulatory requirements, regulatory limitations relating to the company's ability to promote or commercialize its products for awareness, prevention, diagnosis or treatment of zinc deficiency and chronic copper toxicity, a lack of acceptance of Adeona's product candidates in the marketplace, a failure of the company to become or remain profitable, our inability to obtain the capital necessary to fund the company's research and development activities, a loss of any of the company's key scientists or management personnel, and other factors described in Adeona's report on Form 10-K for the year ended December 31, 2009 and any other filings with the SEC. The information in this release is provided only as of the date of this release, and Adeona undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law. Galzin®, Namenda and Axura are registered trademarks of Gate Pharmaceuticals Inc., Forest Laboratories Inc. and Merz Pharma Group, respectively.

For Further Information Contact:

James S. Kuo, M.D., M.B.A.
Chairman and Chief Executive Officer
(734) 332-7800

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