



AVANIR Granted Special Protocol Assessment (SPA) From FDA for Confirmatory Phase III Trial of Zenvia in Patients With PBA

AVANIR Pharmaceuticals (NASDAQ:AVNR) today announced that it has reached a definitive agreement with the U.S. Food and Drug Administration (FDA), under the Special Protocol Assessment (SPA) process, on the design of a single confirmatory Phase III clinical trial of Zenvia™ (dextromethorphan/quinidine [DM/Q]) for the treatment of patients with pseudobulbar affect (PBA). AVANIR trial 07-AVR-123 "A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Safety and Efficacy and to Determine the Pharmacokinetics of Two Doses of AVP-923 (Dextromethorphan/Quinidine) in the Treatment of Pseudobulbar Affect (PBA) in Patients with Amyotrophic Lateral Sclerosis and Multiple Sclerosis" (otherwise known as the "STAR trial") is expected to begin enrolling patients by the end of 2007.

"We now have a clear path toward gaining regulatory approval for Zenvia in this important indication and continue on track to begin patient enrollment in this trial before 2007 calendar year end," said Randall Kaye, MD, Chief Medical Officer of AVANIR. "We have developed an alternative formulation of Zenvia with a lower dose of the quinidine component than the formulation used in earlier PBA studies. Based on our extensive PK/PD modeling, we expect that the new formulation of Zenvia will demonstrate acceptable safety and tolerability, while continuing to provide significant efficacy."

"The STAR trial represents an important milestone for greater than one million Americans thought to suffer from the debilitating episodes of PBA," said Jeffrey Cummings, MD, Executive Vice Chair of the Department of Neurology at the David Geffen School of Medicine at UCLA and lead investigator of the STAR trial. "With no currently approved treatment options available, the STAR trial is an essential step toward making Zenvia available to patients with PBA."

About the STAR Trial

The STAR trial (**S**afety, **T**olerability **A**nd **E**fficacy **R**esults of AVP-923 in PBA) will be a randomized, double-blind, placebo-controlled, multi-center international study that will enroll approximately 270 patients suffering from PBA secondary to either multiple sclerosis (MS) or amyotrophic lateral sclerosis (ALS). The trial will compare active treatment with Zenvia 30/10 mg (DM/Q) and Zenvia 20/10 mg (DM/Q) to placebo during a three month double-blinded phase followed by a three-month open-label extension study.

The primary efficacy analysis will be based on the changes in crying/laughing episode rates recorded in the patient diary. PBA episode counts will be reported and analyzed as a rate expressed as episodes per day. The secondary endpoints include: 1) Center for Neurologic Study-Lability Scale (CNS-LS) score, 2) Neuropsychiatric Inventory Questionnaire (NPI-Q), 3) SF-36 Health Survey, 4) Beck Depression Inventory (BDI-II), and 5) Pain Rating Scale score (MS patients only).

Safety and tolerability of Zenvia will be determined by reporting adverse events; physical exam, vital signs, electrocardiogram, respiratory function tests, and clinical assessment of clinical laboratory variables.

About a Special Protocol Assessment

A Special Protocol Assessment (SPA) from the FDA is a binding agreement that the Phase III

trial protocol design, clinical endpoints, planned conduct and statistical analyses are acceptable to support regulatory approval. For more information about the Agency's Special Protocol Assessment process see <http://www.fda.gov/cder/guidance/3764fnl.htm>.

About PBA

Pseudobulbar affect (PBA), also known as involuntary emotional expression disorder (IEED) and emotional lability, is a neurologic disorder that occurs secondary to neurologic disease or brain injury causing sudden and unpredictable episodes of crying, laughing, or other emotional displays. PBA is estimated to impact more than 1 million people in the United States with underlying neurologic conditions such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), Parkinson's disease, dementias including Alzheimer's disease, stroke, and traumatic brain injury. PBA episodes may occur when disease or injury damages the area of the brain that controls normal expression of emotion. This damage can disrupt brain signaling causing a "short circuit" and triggering involuntary PBA episodes. PBA has been shown to impair the lives of patients in both social and occupational settings. There are currently no FDA approved treatments for PBA.

About Zenvia

Zenvia is a combination of two well-characterized compounds: the therapeutically active ingredient dextromethorphan and the enzyme inhibitor quinidine, which serves to increase the bioavailability of dextromethorphan. This first-in-class drug candidate is believed to help regulate excitatory neurotransmission in two ways: through pre-synaptic inhibition of glutamate release via sigma-1 receptor agonist activity and through postsynaptic glutamate response modulation via uncompetitive, low-affinity NMDA antagonist activity. Zenvia is currently in development for the treatment of pseudobulbar affect (PBA) and diabetic peripheral neuropathic (DPN) pain. In October 2006, the Company received an approvable letter for the treatment of Zenvia in PBA. The Company is initiating a confirmatory Phase III study under a Special Protocol Assessment agreement with the FDA utilizing a new lower quinidine dose formulation of Zenvia to address safety concerns raised in the Agency's approvable letter for Zenvia in the treatment of PBA. For more information about the Agency's Special Protocol Assessment process see <http://www.fda.gov/cder/guidance/3764fnl.htm>. In April 2007 AVANIR announced successfully meeting all primary endpoints in the Phase III study of Zenvia in DPN pain. The Company is considering the future development plan for Zenvia in this indication and expects to provide an update on this program later this year.

About AVANIR

AVANIR Pharmaceuticals is focused on developing, acquiring and commercializing novel therapeutic products for the treatment of chronic diseases. AVANIR's products and product candidates address therapeutic markets that include the central nervous system (CNS), inflammation and infectious diseases. AVANIR's lead product candidate Zenvia is being developed for the treatment of pseudobulbar affect (PBA) and is the subject of an approvable letter from the FDA for that indication. Additionally, in April 2007 AVANIR announced meeting all primary endpoints in a Phase III clinical trial with Zenvia in patients with diabetic peripheral neuropathic (DPN) pain. AVANIR has licensed a compound to Novartis International Pharmaceutical Ltd. for the treatment of inflammatory disease. AVANIR's infectious disease drug candidate, AVP-21D9, is a human monoclonal antibody in pre-clinical development for the treatment of anthrax with funding provided to date from an NIH/NIAID grant. The Company's first commercialized product, Abreva®, is marketed in North America by GlaxoSmithKline Consumer Healthcare and is the leading over-the-counter product for the treatment of cold sores. Further information about AVANIR can be found at www.avanir.com.

Forward Looking Statements

Statements in this press release that are not historical facts, including statements that are preceded by, followed by, or that include such words as "estimate," "intend," "anticipate," "believe," "plan," "goal," "expect," or similar statements, are forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to differ materially from the future results expressed or implied by such statements. There can be no assurance that the proceeds received by the Company from the recent sale of the Company's FazaClo® operations, together with the Company's other available funds, will be sufficient to fund the Company's operations as currently anticipated, or that the Company will be able to commence and complete planned clinical trials within the projected time periods. There can also be no assurance that the planned Phase III trial for Zenvia will be successful, that the new dose of Zenvia will be safe and effective, or that the FDA will approve Zenvia for this or any other indication. Risks and uncertainties affecting the Company's financial condition and operations also include the risks set forth in AVANIR's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and from time-to-time in other publicly available information regarding the Company. Copies of this information are available from AVANIR upon request. AVANIR disclaims any intent to update these forward-looking statements.

To be included on AVANIR's e-mail alert list, click on the link below or visit AVANIR's website: <http://www.b2i.us/irpass.asp?BzID=958&to=ea&s=0>.