Media Contact:
Duke Merriman
Duke.Merriman@Autism-Therapeutics.com

Results of Type C Guidance Meeting with Food & Drug Administration (FDA) of ZYDIS® ODT Fluoxetine in the Treatment of Repetitive Behaviors in Autism

New York, NY, October 9, 2012 – Autism Therapeutics LLC ("Autism Therapeutics") announced today that the Type C Guidance Meeting with FDA to discuss the ZYDIS® ODT Fluoxetine / Autism program has taken place. The FDA and Autism Therapeutics discussed the completion of the Phase III development of the program including the use of differentiated doses and strategies to control placebo response. Autism Therapeutics will now be discussing final details of the upcoming pivotal Phase III trial design with FDA under Special Protocol Assessment (SPA).

"We are very pleased with the outcome of our recent Type C Guidance Meeting with FDA. We believe we reached a common understanding of the outstanding requirements to complete the ZYDIS® ODT Fluoxetine / Autism Phase III program and file a New Drug Application in the treatment of repetitive behaviors in Autistic Disorder. There are currently no FDA approved medications for the treatment of a core aspect of Autistic Disorder such as repetitive behaviors and there remains a clear unmet medical need. We are now discussing final details of our clinical design with FDA under Special Protocol Assessment and look forward to beginning a pivotal Phase III clinical trial shortly," said Dr. Paul Herscu, Chief Executive Officer of Autism Therapeutics.

About ZYDIS® ODT Fluoxetine

ZYDIS® ODT Fluoxetine is a taste masked, rapidly orally dissolving tablet, in three unique dose strengths, of the selective serotonin reuptake inhibitor (SSRI), fluoxetine. The pharmacologic actions of fluoxetine (Lilly 110140) as an antidepressant based on inhibiting serotonin reuptake in the central nervous system are well-established from numerous preclinical studies (Wong et al., 1995) and from clinical investigations in children and adults (NDA 18-936; Vasa et al., 2006). In vitro and in vivo preclinical investigations have shown fluoxetine (and norfluoxetine, its major metabolite) to be potent and selective inhibitors of neuronal pre-synaptic reuptake of serotonin (NDA 18-936). In vivo studies have demonstrated that fluoxetine can restore acquisition of

passive avoidance tasks in olfactory bulbectomized rats, enhance 5-HT-induced head twitch in mice, enhance 5-HT-induced depression of operant behaviors in pigeons, and enhance the behaviorsal effects of 5-HT in rats working on a milk reinforcement schedule (NDA 18-936). Fluoxetine has also been shown to reverse social interaction problems in a mouse model of autism (Chadman, 2011).

Eleven clinical trials on the effect of fluoxetine in autism spectrum disorders (seven open label studies and four placebo controlled studies), in children and adolescents, adults, or mixed populations, have been conducted.

The ZYDIS® formulation consists of a cherry flavored, rapidly orally disintegrating tablet (ODT) containing fluoxetine bound to an ion exchange resin, preventing the release of fluoxetine, which has a bitter taste when unbound, until it reaches the stomach where the higher acidity releases the drug.

About Autism

Autism is a Pervasive Developmental Disorder (PDD). Related developmental disorders defined in the DSM-IV are Asperger's Disorder, Autistic Disorder, and Pervasive Developmental Disorder – Not Otherwise Specified (PPD-NOS). Together these three are sometimes called Autistic Spectrum Disorders (ASD), or simply autism. Autism Spectrum Disorders have an estimated prevalence of 1 in 88 children in the United States.

There remains an unmet medical need for an effective pharmacotherapy to treat the core symptoms of this serious disorder given that there are no approved marketed drugs for this indication. Only two medications have received FDA approval to treat irritability (an associated, not "core", symptom of autism) in children with autism.

About Autism Therapeutics

Autism Therapeutics is a biopharmaceutical company seeking to develop pharmaceutical therapies to treat the unmet medical needs of patients with Autism Spectrum Disorders, Rett Syndrome and Fragile-X Syndrome. Autism Therapeutics, in part through it partnership with Personalized Pharmaceutical Systems LLC, is particularly focused on identifying and targeting specific subgroups within each diagnosis to achieve a safer and more effective drug development process. For more information, please visit **www.AutismTherapeutics.com**