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Confirmation of Orphan Drug Designation for the Use of Fluoxetine for the Treatment of Autism

New York, NY, March 27, 2012 – Autism Therapeutics announced today that it has received confirmation from the Office of Orphan Drug Products that the Company's Orphan Drug Designation for the treatment of repetitive behaviors in autism (autistic disorder) remains in good standing.

"We are extremely pleased to have this confirmation from the Office of Orphan Drug Products. Our Orphan Drug Designation for the use of fluoxetine to treat repetitive behaviors in autism is a key component of the SERELSA™ program," 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 behavior in pigeons, and enhance the behavioral 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 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 (stomach pH = 2 vs. pH=7 in the mouth) releases the drug**.** The tablet rapidly dissolves on contact with the saliva. Two successful bioequivalence studies have been conducted to demonstrate the formulation's bioequivalence to liquid fluoxetine.

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.

Although there is no cure, medical treatments for symptoms of ASDs comprise a variety of pharmacologic agents that are generally intended to treat common co-morbidities of ASD. 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 ("AT") 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. AT, 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**