Merz, Inc. Announces the Acquisition of CUVPOSA® (glycopyrrolate) Oral Solution, First and Only FDA-Approved Treatment for Pediatric Chronic Severe Drooling Associated With Neurologic Conditions

The addition of CUVPOSA® reflects Merz's commitment to neurology

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GREENSBORO, N.C., Aug. 27, 2012 /PRNewswire/ -- Merz, Inc. (U.S. affiliate of Merz Pharma Group) today announced the acquisition of CUVPOSA® (glycopyrrolate) oral solution for pediatric chronic severe drooling associated with neurologic conditions such as cerebral palsy.

Cerebral palsy (CP) is a lifelong condition that encompasses a group of non-progressive, neurological disorders affecting body movement and muscle coordination. According to previous estimates from a study reported by the CDC, the national prevalence of CP is approximately 0.2% in children (aged 3-16). About 10-30% of children with CP suffer from chronic severe drooling (sialorrhea), which can lead to various health issues such as skin irritation as well as a decreased quality of life.

"The FDA has classified CUVPOSA® as an orphan drug since sialorrhea is a rare disorder in pediatric patients with neurologic conditions," said Kapil D. Sethi, MD, FRCP, Professor of Neurology and Director of the Movement Disorders Program at Georgia Health Sciences University and Senior Medical Expert of Neurology at Merz Pharmaceuticals, LLC. "Due to the limited treatment options available, sialorrhea is an all-too-often poorly managed condition in pediatric patients suffering from neurologic disorders such as cerebral palsy. CUVPOSA®, the only FDA-approved treatment on the market, is an important advancement in the treatment of chronic severe drooling in children with neurologic disorders."

CUVPOSA® was approved by the FDA in July 2010 and has been commercially available in the U.S. since April 2011. It is the only FDA-approved treatment to reduce chronic severe drooling in pediatric patients (aged 3-16) with neurologic conditions associated with problem drooling. Sialorrhea is a common problem for individuals with neurologic conditions, especially children with cerebral palsy.

"The acquisition of CUVPOSA® is a promising addition to our neurology business and reflects our commitment to becoming a recognized leader in the treatment of movement disorders and related conditions in the U.S.," said Bill Humphries, president and chief executive officer of Merz, Inc. "Globally, the Merz Pharma Group is deeply committed to offering novel therapeutic options that address the large unmet medical needs that exists within the areas of Central Nervous System (CNS) and neurology."

Merz plans to continue the relationship with Diplomat Specialty Pharmacy and with Anda to help ensure caregivers have convenient access to CUVPOSA®.

About CUVPOSA®

CUVPOSA® is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues, including salivary glands. CUVPOSA® indirectly reduces the rate of salivation by preventing stimulation of these receptors. CUVPOSA® is available as a 1mg/5ml clear, cherry flavored oral solution.

Results of a randomized, double-blind, placebo-controlled Phase 3 study of 38 patients showed that 75% of children and adolescents, aged 3-16, treated with CUVPOSA®experienced an improvement in symptoms of chronic severe drooling at week 8, versus 11% who received placebo. Dry mouth, vomiting, constipation, flushing and nasal congestion were the most commonly reported adverse reactions.

Important Safety Information

CUVPOSA® is contraindicated in conditions that preclude anticholinergic therapy (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis). CUVPOSA® is contraindicated in patients taking solid oral dosage forms of potassium chloride. The passage of potassium chloride tablets through the GI tract may be arrested or delayed with coadministration of CUVPOSA®.

Constipation or intestinal pseudo-obstruction may occur when taking CUVPOSA®. Constipation is a common dose-limiting adverse reaction and may lead to discontinuation of CUVPOSA®. Intestinal pseudo-obstruction may present as abdominal distention, pain, nausea, or vomiting. It is important for physicians to assess patients for constipation, particularly within four to five days of initial dosing or after a dose increase. Diarrhea may be an early symptom of incomplete mechanical intestinal obstruction especially in patients with ileostomy or colostomy. If obstruction is suspected, discontinue CUVPOSA® and evaluate.

Avoid patient exposure to high ambient temperatures. Heat prostration (fever and heat stroke due to decreased sweating) can occur with use of anticholinergic drugs such as CUVPOSA®.

Patients should not engage in age-appropriate activities requiring mental alertness such as operating a motor vehicle or other machinery or perform hazardous work, as CUVPOSA®may cause drowsiness or blurred vision.

Use CUVPOSA® with caution in patients with conditions that are exacerbated by anticholinergic drug effects including:

- Autonomic neuropathy, renal disease and ulcerative colitis-large doses may suppress intestinal motility to the point of producing a paralytic ileus and for this reason may precipitate or aggravate "toxic megacolon," a serious complication of the disease.
- Hyperthyroidism, coronary heart disease, congestive heart failure, cardiac tachyarrhythmias,

Glycopyrrolate reduces GI transit time which may result in altered release of certain drugs when formulated in delayed or controlled-release forms. CUVPOSA® can increase serum levels of atenolol, metformin and digoxin (slow dissolution tablets; consider other oral dosage forms of digoxin). Dose reductions of atenolol or metformin may be needed.

CUVPOSA® may decrease serum levels of haloperidol or levodopa. Consider dose increase of levodopa and closely monitor haloperidol patients for worsening of schizophrenic symptoms and development of tardive dyskinesia.

The anticholinergic effects of CUVPOSA® may be increased with concomitant administration of amantadine. CUVPOSA® dose reduction should be considered.

CUVPOSA® should be used with caution in patients with renal impairment, as it is largely renally eliminated.

The most common adverse reactions (incidence >/=30%) are dry mouth (40%), vomiting (40%) constipation (35%), flushing (30%), and nasal congestion (30%).

To report SUSPECTED ADVERSE REACTIONS, contact Merz, Inc. at 1-877-743-8454or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Merz, Inc.
Merz, Inc. is responsible for developing and commercializing products in the United Statesfor Merz Pharma Group. Areas of therapeutic focus include Neurology, Aesthetics, and Dermatology.

About Merz Pharma Group
Globally, the companies of Merz Pharma Group are focused on medications for treating neurological and psychiatric illnesses and thereby assume a leading role in the field of Alzheimer research. Another important area of competency of Merz Pharma Group is Clinical Dermatology and Aesthetic Medicine. Merz Pharma Group is also active in the Health sector outside of the pharmacy. In the field of consumer products, with its established brands of tetesept® and Merz Spezial®, Merz Consumer Care is a leading provider of products for self-medication, nutritional supplements, and skin care. Merz Pharma Group is a privately owned company, founded in 1908 in Frankfurt, Germany.

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