

FOR IMMEDIATE RELEASE



**SHIONOGI INC. ANNOUNCES FDA APPROVAL OF CUVPOSA™
FOR THE TREATMENT OF CHRONIC SEVERE DROOLING IN PEDIATRIC
PATIENTS WITH NEUROLOGIC CONDITIONS**

Florham Park, NJ (July 29, 2010) – Shionogi Inc., a U.S.-based group company of Shionogi & Co., Ltd., today announced the U.S. Food and Drug Administration approval of CUVPOSA™ (glycopyrrolate), the first liquid treatment for patients ages 3-16 who suffer from chronic severe drooling associated with neurologic conditions such as cerebral palsy. CUVPOSA™ was designated an Orphan Drug by the FDA.

“The FDA approval of CUVPOSA provides parents and caregivers the first liquid medication indicated to reduce chronic severe drooling,” said Donald C. Manning, MD, PhD, Chief Medical Officer of Shionogi Inc. “Shionogi is proud to bring to market a product that treats an all-too-often unresolved yet damaging condition.”

Cerebral palsy 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 including 17 year olds. About 10-30 percent of children with CP suffer from excessive drooling, which can lead to various health issues such as skin irritation as well as a decreased quality of life.

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.

This approval is based on the results of a randomized, double-blind, placebo-controlled Phase III study which showed that 75% of children and adolescents treated with CUVPOSA™ experienced an improvement in symptoms, versus 11% who received placebo. Dry mouth, vomiting, constipation, flushing and nasal congestion were the most commonly reported adverse reactions.

Important Safety Information

- **Contraindications**
 - Medical conditions that preclude anticholinergic therapy.
 - Concomitant use of solid oral dosage forms of potassium chloride.
- **Warnings and Precautions**
 - Constipation or intestinal pseudo-obstruction: May present as abdominal distention, pain, nausea, or vomiting. Assess patients for constipation, particularly within 4-5 days of initial dosing or after a dose increase.
 - Incomplete mechanical intestinal obstruction: May present as diarrhea. If obstruction is suspected, discontinue CUVPOSA™ and evaluate.
 - High ambient temperature: To reduce risk of heat prostration, avoid high temperatures.

- Adverse Reactions
 - The most common adverse reactions are dry mouth, vomiting, constipation, flushing, and nasal congestion.
 - To report SUSPECTED ADVERSE REACTIONS, contact Shionogi Drug Safety Department at 1-800-849-9707 ext. 1454 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
- Drug Interactions
 - Digoxin tablets: Use with glycopyrrolate can increase digoxin serum levels. Monitor patients and consider use of alternative dosage forms of digoxin.
 - Amantadine: Effects of glycopyrrolate may be increased with concomitant administration of amantadine. Healthcare providers should consider decreasing the dose of glycopyrrolate during concomitant use.
 - Atenolol or metformin: Glycopyrrolate may increase serum levels of atenolol or metformin. Healthcare providers should consider dose reduction when used with glycopyrrolate.
 - Haloperidol or levodopa: Glycopyrrolate may decrease serum levels of haloperidol or levodopa. Healthcare providers should consider a dose increase when used with glycopyrrolate.
- Use in Specific Populations
 - Pediatric use: The safety and effectiveness of glycopyrrolate has not been established in patients under 3 years of age.
 - Renal impairment: Use CUVPOSA™ with caution in patients with renal impairment.

About Shionogi Inc.

Shionogi Inc. is a US-based company of Shionogi & Co., Ltd. Headquartered in Osaka, Japan, Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to placing the highest value on patients. Shionogi's Research and Development currently targets three therapeutic areas: Infectious Diseases, Pain, and Metabolic Syndrome. The Company has provided such innovative medicines as Crestor and Doripenem, which have been successfully delivered to millions of patients. In addition, Shionogi is engaged in new research areas such as allergy and cancer. Contributing to the health of patients around the world through development in these therapeutic areas is Shionogi's primary goal. For more details, please visit www.shionogi.co.jp. For more information on Shionogi Inc., headquartered in Florham Park, NJ, please visit www.shionogi-inc.com.

Forward Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive

products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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