DRAFT Press Release – Non-Approval
May 8, 2012

Covidien Reinforces Continued Availability of EXALGO for Patients with Moderate-to-Severe Chronic Pain

Supplemental NDA for EXALGO 32 mg does not gain FDA approval, but Company Continues to Manufacture Approved Doses

St. Louis, DATE – Mallinckrodt, the Pharmaceuticals business of Covidien (NYSE: COV), has received a complete response letter from the U.S. Food and Drug Administration (FDA) that the application for EXALGO® (hydromorphone HCl) Extended-Release Tablets (CII) 32 mg is not yet ready for approval. The Supplemental New Drug Application (sNDA) was submitted in January with post-marketing data to support the original application's compendium of pivotal trials demonstrating efficacy and tolerability in doses up to 64 mg once daily.

The FDA approved the three existing doses of EXALGO (8, 12 and 16 mg) in March 2010. EXALGO utilizes the OROS® Push-Pull™ osmotic delivery system designed to release the opioid at a controlled rate. By providing a steady release of hydromorphone throughout the day, the drug is formulated to help minimize the peaks and troughs that are sometimes experienced by chronic pain patients who rely on products that are dosed at more frequent intervals. Tamper-resistant properties like OROS® technology have been used in products for various therapeutic areas for more than 30 years.

"While we are disappointed by the decision about the 32 mg dose of EXALGO, Mallinckrodt is working closely with the agency to determine next steps," said Jeffrey Patrick, Vice President, Medical Affairs, Covidien. "We are committed to addressing any outstanding issues for the 32 mg dose of EXALGO to receive approval."

Chronic pain affects at least 116 million Americans each year,[1] impacting more people than heart disease, diabetes and cancer combined. Fifty-one percent of patients with chronic pain report that they feel they have little or no control over their pain.[2] It is critically important for these patients to work with their physicians to find the right medication at the right dosing regimen.

"As dedicated and responsible partners in pain management, we continue to manufacture and distribute EXALGO in doses ranging from 8 mg to 16 mg so that physicians can tailor their treatment to individual opioid-tolerant patients with moderate-to-severe chronic pain," said Mr. Patrick.

Mallinckrodt is committed to its comprehensive Risk Evaluation and Mitigation Strategy (REMS) program that is designed to assure the safe use of EXALGO. The REMS program for EXALGO includes a medication guide and a robust set of educational programs and materials help ensure appropriate prescribing, dispensing and use of EXALGO tablets. Under the program, healthcare provider education is required as an important element to assure safe use, with a focus on appropriate patient selection and dosing. There is no restricted distribution network for EXALGO, and no requirement for physicians, pharmacists or patients to enroll in a registry in order to access the product.

Additionally, Mallinckrodt is a founding member of the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance℠, a growing coalition of patient, provider, and community organizations focused on providing resources and tools to support the responsible prescribing and safe use of prescription pain treatments.

Mallinckrodt continues to be committed to ensuring that patients have access to medications that adequately control their pain. If a patient cannot afford their EXALGO prescription, Mallinckrodt may be able to help. More information about the Patient Assistance Program is available by calling 1-800-259-7765. Some rules and restrictions may apply.

Beyond the Patient Assistance Program, Mallinckrodt also offers EXALGO Co-Pay Cards, which can cover up to $60 of a co-pay after the patient pays $15 toward the prescription. Patients can show their Co-Pay Card to their pharmacist and save every time they fill or refill their prescription for EXALGO. A

patient can access a Co-pay Card from their physician or by visiting http://www.exalgo.com/patient/exalgo-co-pay-card.aspx.

PLEASE SEE IMPORTANT RISK INFORMATION, INCLUDING BOXED WARNING BELOW

EXALGO is contraindicated in opioid non-tolerant patients, in management of mild pain or pain not expected to persist, in patients with compromised respiratory function or in patients with narrowed or obstructed gastrointestinal tract or with known hypersensitivity to any components including hydromorphone hydrochloride and sulfites. Concurrent use of EXALGO with CNS depressants, including alcohol, increases risk of respiratory depression, hypotension, and profound sedation, potentially resulting in coma or death. Not recommended in patients who have received MAO inhibitors within 14 days of starting EXALGO.

See full package insert for full prescribing information.

BOXED WARNING

WARNING: POTENTIAL FOR ABUSE, IMPORTANCE OF PROPER PATIENT SELECTION AND LIMITATIONS OF USE

Potential for Abuse

EXALGO contains hydromorphone, an opioid agonist and a Schedule II controlled substance with an abuse liability similar to other opioid analgesics. EXALGO can be abused in a manner similar to other opioid agonists, legal or illicit. These risks should be considered when administering, prescribing, or dispensing EXALGO in situations where the healthcare professional is concerned about increased risk of misuse, abuse, or diversion. Schedule II opioid substances which include hydromorphone, morphine, oxycodone, fentanyl, oxymorphone and methadone have the highest potential for abuse and risk of fatal overdose due to respiratory depression *[see Drug Abuse and Dependence (9)]*.

Proper Patient Selection

EXALGO is an extended-release formulation of hydromorphone hydrochloride indicated for the management of moderate to severe pain in opioid tolerant patients when a continuous around-the-clock opioid analgesic is needed for an extended period of time. Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg of oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg of oral oxymorphone/day or an equianalgesic dose of another opioid, for a week or longer *[see*

***Indications and Usage (1) and Dosage and Administration (2)]*.**

EXALGO is for use in opioid tolerant patients only *[see Indications and Usage (1) and Dosage and Administration (2)]*.

Fatal respiratory depression could occur in patients who are not opioid tolerant.

Accidental consumption of EXALGO, especially in children, can result in a fatal overdose of hydromorphone *[see Warnings and Precautions (5.1)]*.

Limitations of Use

EXALGO is not indicated for the management of acute or postoperative pain *[see Indications and Usage (1)]*.

EXALGO is not intended for use as an as needed analgesic *[see Indications and Usage (1)]*.

EXALGO tablets are to be swallowed whole and are not to be broken, chewed, dissolved, crushed or injected. Taking broken, chewed, dissolved or crushed EXALGO or its contents leads to rapid release and absorption of a potentially fatal dose of hydromorphone *[see Warnings and Precautions (5)]*.

About Covidien

Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2009 revenue of $10.7 billion, Covidien has 42,000 employees worldwide in more than 60 countries, and its products are sold in over 140 countries. Please visit http://www.covidien.com to learn more about our business.

Forward-Looking Statements

Any statements contained in this communication that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or Company actions to differ materially from what is expressed or implied by these statements. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, our ability to effectively introduce and market new products or keep pace with advances in technology, the reimbursement practices of a small number of large public and private insurers, cost-containment efforts of customers, purchasing groups, third-party payers and governmental organizations, intellectual property rights disputes, complex and costly regulation, including healthcare fraud and abuse regulations, manufacturing or supply chain problems or disruptions, rising commodity costs, recalls or safety alerts and negative publicity relating to Covidien or its products, product liability losses and other litigation liability, including legacy Tyco-related litigation, divestitures of some of our businesses or product lines, our ability to execute strategic acquisitions of, investments in or alliances with other companies and businesses, competition, risks associated with doing business outside of the United States, foreign currency exchange rates or potential environmental liabilities. These and other factors are identified and described in more detail in our filings with the SEC. We disclaim any obligation to update these forward-looking statements other than as required by law.

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