Covidien Receives FDA Approval for Fentanyl Transdermal System Patch

Covidien

ST. LOUIS, Feb 10, 2011 (BUSINESS WIRE) --

Covidien (NYSE: COV), a leading global provider of healthcare products, today announced that Mallinckrodt Inc., a Covidien company, has received U.S. Food and Drug Administration (FDA) approval of its Abbreviated New Drug Application (ANDA) for its Fentanyl Transdermal System (FTS) patch. Covidien is the largest supplier of controlled pain medications in the United States based on number of prescriptions.

Covidien's FTS is a generic alternative to the branded DURAGESIC(R) patch. FTS, a Class II controlled substance, is an opioid analgesicindicated in opioid-tolerant patients for management of persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids.

"Pain is one of the most common reasons patients consult a physician, yet it is often inadequately treated," said Herbert Neuman, M.D., Chief Medical Officer, Pharmaceuticals, Covidien. "We are pleased our FTS product has been granted FDA approval, allowing us to introduce this treatment option for healthcare providers to better meet patients' needs."

Covidien expects to launch FTS in the U.S. in 25mcg/hr, 50mcg/hr, 75mcg/hr and 100mcg/hr strengths in the current quarter. The launch will be accompanied by an extensive risk management plan to help ensure the appropriate and safe use of this medication in accordance with both FDA guidance and Covidien's strong focus on patient safety. This plan is designed to minimize abuse and overdose, and includes patient and physician education material, a medication guide, and other tools to ensure patients who receive FTS understand the risks, appropriate use, storage, application and disposal of FTS.

"Covidien continues to build on its extensive pain treatment experience by focusing on providing patients with a variety of medications to make pain more manageable," said Matthew Harbaugh, Chief Financial Officer and Interim President, Pharmaceuticals, Covidien.

IMPORTANT RISK INFORMATION

FOR USE IN OPIOID-TOLERANT PATIENTS ONLY

Fentanyl transdermal system contains a high concentration of a potent Schedule II opioid agonist, fentanyl. Schedule II opioid substances which

include fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone have the highest potential for abuse and associated risk of fatal overdose due to respiratory depression. Fentanyl can be abused and is subject to criminal diversion. The high content of fentanyl in the patches (fentanyl transdermal system) may be a particular target for abuse and diversion.

Fentanyl transdermal system is indicated for management of persistent, moderate to severe chronic pain that:

- **requires continuous, around-the-clock opioid administration for an extended period of time, and**
- **cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids**

Fentanyl transdermal system should ONLY be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a total daily dose at least equivalent to fentanyl transdermal system 25 mcg/hr. Patients who are considered opioid-tolerant are those who have been taking, for a week or longer, at least 60 mg of morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid.

Because serious or life-threatening hypoventilation could occur, fentanyl transdermal system is contraindicated:

- **in patients who are not opioid-tolerant**
- **in the management of acute pain or in patients who require opioid analgesia for a short period of time**
- **in the management of post-operative pain, including use after out-patient or day surgeries (e.g., tonsillectomies)**
- **in the management of mild pain**
- **in the management of intermittent pain (e.g., use on an as needed basis)**

Since the peak fentanyl concentrations generally occur between 24 and 72 hours of treatment, prescribers should be aware that serious or life-threatening hypoventilation may occur, even in opioid-tolerant patients, during the initial application period.

The concomitant use of fentanyl transdermal system with all cytochrome

P450 3A4 inhibitors (such as ritonavir, ketoconazole, itraconazole, troleandomycin, clarithromycin, nelfinavir, nefazodone, amiodarone, amprenavir, aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, grapefruit juice, and verapamil) may result in an increase in fentanyl plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. Patients receiving fentanyl transdermal system and any CYP3A4 inhibitor should be carefully monitored for an extended period of time and dosage adjustments should be made if warranted.

The safety of fentanyl transdermal system has not been established in children under 2 years of age. Fentanyl transdermal system should be administered to children only if they are opioid-tolerant and 2 years of age or older.

Fentanyl transdermal system is ONLY for use in patients who are already tolerant to opioid therapy of comparable potency. Use in non-opioid tolerant patients may lead to fatal respiratory depression. Overestimating the fentanyl transdermal system dose when converting patients from another opioid medication can result in fatal overdose with the first dose. Due to the mean half-life of approximately 17 hours, patients who are thought to have had a serious adverse event, including overdose, will require monitoring and treatment for at least 24 hours.

Fentanyl transdermal system can be abused in a manner similar to other opioid agonists, legal or illicit. This risk should be considered when administering, prescribing, or dispensing fentanyl transdermal system in situations where the healthcare professional is concerned about increased risk of misuse, abuse or diversion.

Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. All patients receiving opioids should be routinely monitored for signs of misuse, abuse and addiction. Patients at increased risk of opioid abuse may still be appropriately treated with modified-release opioid formulations; however, these patients will require intensive monitoring for signs of misuse, abuse, or addiction.

Fentanyl transdermal systems are intended for transdermal use (on intact skin) only. Do not use a fentanyl transdermal system if the pouch seal is broken or the patch is cut, damaged, or changed in any way.

Avoid exposing the fentanyl transdermal system application site and surrounding area to direct external heat sources, such as heating pads or electric blankets, heat or tanning lamps, saunas, hot tubs, and heated water beds, while wearing the system. Avoid taking hot baths or sunbathing. There is a potential for temperature-dependent increases in

fentanyl released from the system resulting in possible overdose and death. Patients wearing fentanyl transdermal systems who develop fever or increased core body temperature due to strenuous exertion should be monitored for opioid side effects and the fentanyl transdermal system dose should be adjusted if necessary.

The Fentanyl Transdermal System is contraindicated in patients:

- **Who have or are suspected of having paralytic ileus.**
- **With known hypersensitivity to Fentanyl or any components of this product.**

In clinical trials, the 5 most common side effects >10% associated with DURAGESIC(R) were nausea, vomiting, sleepiness, constipation, and excessive sweating.There is a potential for severe constipation.

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 2010 revenue of $10.4 billion, Covidien has approximately 42,000 employees worldwide in more than 60 countries, and its products are sold in over 140 countries. Please visit www.covidien.com [1] to learn more about our business.

DURAGESIC is a registered trademark of Johnson and Johnson.

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 payors and governmental organizations, intellectual property rights disputes, complex and costly regulation, including healthcare fraud and abuse regulations and the Foreign Corrupt Practices Act, 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, 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 and environmental remediation costs. These and other factors are identified and described in more detail in our Annual Report on Form 10-K for the fiscal year ended September 24, 2010, and in subsequent filings with the SEC. We disclaim any obligation to update these forward-looking statements other than as required by law.

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