Cadence Pharmaceuticals Reaffirms FDA-Approved Dosing Recommendations for OFIRMEV® (acetaminophen) Injection

SAN DIEGO, July 28, 2011 /PRNewswire/ -- Cadence Pharmaceuticals, Inc. (NASDAQ:CADX) today confirmed that the U.S. Food and Drug Administration (FDA) approved dosing recommendations for OFIRMEV® (acetaminophen) injection remains 4,000 mg per day for adults and adolescents weighing at least 50 kg.

Cadence's announcement follows the issuance of a news release by a major manufacturer of over-the-counter (OTC) acetaminophen products announcing its plans to lower the recommended maximum daily dose of some oral acetaminophen products in an effort to reduce the risk of accidental acetaminophen overdose among consumers in the OTC setting.

"We believe it is important that healthcare providers know that the new recommended dosing guidelines for the OTC products do not affect the recommended dosing guidelines for OFIRMEV," said James Breitmeyer, M.D., Ph.D., Chief Medical Officer of Cadence Pharmaceuticals. "The safety and effectiveness of OFIRMEV at 4,000 mg per day has been well established in numerous clinical trials and is supported by extensive experience with the drug in Europe, where it has been the foundation of IV pain management since its introduction in 2002. Healthcare professionals should continue to administer OFIRMEV as recommended in the FDA-approved package insert."

About OFIRMEV® (acetaminophen) Injection (1000 mg / 100 mL, 10 mg / mL)
OFIRMEV (acetaminophen) injection, Cadence Pharmaceuticals' proprietary intravenous formulation of acetaminophen, is indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics, and the reduction of fever. The FDA approval of OFIRMEV was based on data from clinical trials in approximately 1,020 adult and 355 pediatric patients. These trials included two studies evaluating the safety and effectiveness of OFIRMEV in the treatment of pain, and one study evaluating OFIRMEV in the treatment of fever. The effectiveness of OFIRMEV for the treatment of acute pain and fever has not been studied in pediatric patients less than 2 years of age.

Important Safety Information
Do not exceed the maximum recommended daily dose of acetaminophen. Administration of acetaminophen by any route in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death. OFIRMEV is contraindicated in patients with severe hepatic impairment, severe active liver disease or with known hypersensitivity to acetaminophen or to any of the excipients in the formulation. Acetaminophen should be used with caution in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment. OFIRMEV should be administered only as a 15 minute intravenous infusion. Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur. Do not use in patients with acetaminophen allergy. The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients and nausea,

vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients. The antipyretic effects of OFIRMEV may mask fever in patients treated for post-surgical pain.

For more information, please see the complete OFIRMEV Prescribing Information, available at www.OFIRMEV.com or www.cadencepharm.com.

About Cadence Pharmaceuticals, Inc.

Cadence Pharmaceuticals is a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary products principally for use in the hospital setting. For more information about Cadence, please visit www.cadencepharm.com.

Forward-Looking Statements

Statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "plans," "believes," "expects," "anticipates," and "will," and similar expressions, are intended to identify forward-looking statements, and are based on Cadence's current beliefs and expectations. Actual results could differ materially from those stated or implied by these forward-looking statements due to risks associated with Cadence's business. Such risks are detailed under "Risk Factors" and elsewhere in Cadence's periodic reports and other filings made with the Securities and Exchange Commission from time to time. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995, and Cadence undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

Contact:

INVESTORS	MEDIA
Cadence Pharmaceuticals, Inc.	WCG
William R. LaRue	Kelli France
SVP & Chief Financial Officer	Media Relations
Phone: (858) 436-1400	Phone: (415) 946-1076
blarue@cadencepharam.com	kfrance@wcgworld.com

SOURCE Cadence Pharmaceuticals, Inc.

RELATED LINKS

http://www.cadencepharm.com
