



Cadence Pharmaceuticals Announces FDA Approval of OFIRMEV™ (acetaminophen) injection for the Management of Pain and Fever

First and Only Intravenous Formulation of Acetaminophen Approved for Use in the United States

-- Company to Host Conference Call and Webcast on November 2, 2010 at 5:00 ET --

SAN DIEGO, Nov. 2, 2010 /PRNewswire-FirstCall/ -- Cadence Pharmaceuticals, Inc. (Nasdaq: [CADX](#)) announced today that the U.S. Food and Drug Administration (FDA) has granted marketing approval for OFIRMEV™ (acetaminophen) injection, the first and only intravenous (IV) formulation of acetaminophen to be approved in the United States. OFIRMEV 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 approval of OFIRMEV is a significant milestone for Cadence as we advance our mission to improve the lives of hospitalized adults and children," said Ted Schroeder, President and CEO of Cadence. "IV acetaminophen is the unit market share leader among all injectable pain medications in Europe. With our planned launch early in the first quarter of 2011, we believe that OFIRMEV will fill a significant gap in the United States for the treatment of pain and fever in the hospital setting."

Acute pain, particularly postoperative pain, often requires a multi-modal approach in which two or more analgesics are used with the goal of providing better analgesic efficacy. U.S. physicians already prescribe acetaminophen frequently in combination with opioids for oral management of pain, where it is the most widely used non-opioid in fixed combination therapies. In clinical studies, OFIRMEV improved pain relief, reduced opioid consumption, and improved patient satisfaction when used as part of a multi-modal regimen.

"OFIRMEV is a long-awaited and much needed addition to postoperative pain management,"

said Eugene R. Viscusi, M.D., Director of Acute Pain Management at Thomas Jefferson University in Philadelphia. "With the approval of OFIRMEV, clinicians will now be better able to use a multi-modal approach to pain management in the hospital setting, when oral medication can't be used."

Clinical Trial Results Supporting FDA Approval

The FDA approval of OFIRMEV was based on data from clinical trials in which a total of 1020 adult and 355 pediatric patients received IV acetaminophen. 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. In a study of 101 orthopedic patients undergoing hip or knee replacement surgery, OFIRMEV 1000 mg every six hours was statistically superior to placebo for the reduction of pain intensity over 24 hours ($p < 0.01$) with significantly reduced morphine consumption (33% over 24 hours, $p < 0.01$). In a second study of 244 patients undergoing abdominal laparoscopic surgery, OFIRMEV 1000 mg every six hours, or 650 mg every four hours, demonstrated a significant reduction in pain intensity over 24 hours compared to placebo ($p < 0.02$).

In a study of adult volunteers with induced fever, a single dose of OFIRMEV 1000 mg demonstrated a statistically significant reduction in temperature through six hours in comparison to placebo ($p < 0.01$), with an onset of action within 15 minutes after treatment.

OFIRMEV was well tolerated in clinical trials assessing safety in a range of patient and surgery types.

The safety and effectiveness of OFIRMEV for the treatment of pain and fever in pediatric patients older than two years is supported by evidence from adequate and well controlled studies in adults and additional safety and pharmacokinetic data for this age group. The effectiveness of OFIRMEV for the treatment of acute pain and fever has not been studied in pediatric patients less than two years of age.

Future Commitments

As required under its existing license agreement for OFIRMEV, Cadence will make a milestone payment of \$15 million as a result of the U.S. approval of the product.

In accordance with a Pediatric Research Equity Act (PREA) requirement included in the new drug application (NDA) approval for OFIRMEV, Cadence will conduct a post-marketing efficacy study of OFIRMEV in infants and neonates. The company expects to commence this study in 2011.

Conference Call and Webcast Details

Cadence management will host a conference call on Tuesday, November 2, 2010 at 2:00 p.m. Pacific Time/ 5:00 p.m. Eastern Time and interested investors may participate in the conference call by dialing (877) 303 – 9145 (domestic) or (760) 536-5203 (international). To access the

webcast, please visit the company's website at www.cadencepharm.com and go to the Investor Relations page. A replay of the webcast will be available approximately two hours after the call and remain available on the company's website for thirty days through December 2, 2010.

About OFIRMEV™ (Acetaminophen) Injection

OFIRMEV (acetaminophen) injection is Cadence Pharmaceuticals' proprietary intravenous formulation of acetaminophen. OFIRMEV 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.

For more information, please see the complete OFIRMEV Prescribing Information, available at <http://www.Ofirmev.com> or www.cadencepharm.com.

Important Safety Information:

OFIRMEV should be administered only as a 15 minute intravenous infusion. 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. 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.

About Cadence Pharmaceuticals

Cadence Pharmaceuticals is a biopharmaceutical company committed to in-licensing, developing and commercializing proprietary product candidates to improve the lives of hospitalized patients. 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. Forward-looking statements include, but are not limited to, statements regarding: the timing of the planned commercial launch of OFIRMEV, the market potential for OFIRMEV, OFIRMEV's ability to fulfill unmet medical needs in the treatment of pain and fever in the hospital setting, and the timing of a post-marketing efficacy study of OFIRMEV in infants and neonates. Actual results may differ materially from those set

forth in this press release and the conference call due to the risks and uncertainties inherent in the company's business, including, without limitation: our dependence on the successful commercialization of OFIRMEV; the potential that we will require substantial additional funding in order to effectively commercialize OFIRMEV, and the risk that we may not be able to raise sufficient capital when needed, or at all; the risk that delays in commercially launching OFIRMEV would enable competitors to further entrench their existing products or develop and bring new products to market before OFIRMEV; our ability to ensure an adequate and continued supply of OFIRMEV to successfully launch commercial sales or meet anticipated market demand; our ability to comply with the terms of our loan agreement, and draw down additional amounts under our loan agreement; the potential for an event of default under our loan agreement, and the corresponding risk of acceleration of repayment and potential foreclosure on the assets pledged to secure the line of credit; the impact of healthcare reform legislation; and other risks detailed in Cadence's prior press releases as well as in Cadence's periodic public filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Cadence undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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