# Cadence Pharmaceuticals Estimates Fourth Quarter and Full Year 2013 Product Revenue and Provides Full Year 2014 Revenue Guidance

January 13, 2014

SAN DIEGO, Jan. 13, 2014 /PRNewswire/ -- Cadence Pharmaceuticals, Inc. (NASDAQ: CADX), a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting, today announced preliminary (unaudited) estimates for net product revenues from sales of OFIRMEV® (acetaminophen) injection for the three months ended December 31, 2013, of approximately $33.3 million, and net product revenue for the twelve months ended December 31, 2013, of approximately $110.5 million.

"The fourth quarter and full year 2013 were exciting for Cadence as OFIRMEV sales continued to grow driven by robust demand and fueled by an increasing desire for non-narcotic analgesic options in the hospital setting," said Ted Schroeder, President and CEO of Cadence. "We anticipate that sales of OFIRMEV will continue to increase in 2014, and expect full year 2014 net revenue for OFIRMEV to range between $173.0 million and $177.0 million."

**Revenue Guidance**
As of January 13, 2014, Cadence expects that net product revenue from sales of OFIRMEV for the twelve months ending December 31, 2014, will range between $173.0 million and $177.0 million.

Cadence will provide a more complete discussion of its financial results for the year ended December 31, 2013, during the Company's regularly scheduled quarterly conference call.

**About OFIRMEV® (Acetaminophen) Injection**
OFIRMEV (acetaminophen) injection (1000 mg / 100 mL, 10 mg / mL; for intravenous use only), 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**

**RISK OF MEDICATION ERRORS AND HEPATOTOXICITY**

Take care when prescribing, preparing, and administering OFIRMEV injection to avoid dosing errors which could result in accidental overdose and death.OFIRMEV contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death.

Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits, and often involve more than one acetaminophen-containing product.

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. Rarely, acetaminophen may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur, or at the first appearance of skin rash. 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 with postsurgical pain. OFIRMEV is approved for use in patients ≥ 2 years of age. Do not exceed the recommended maximum daily dose of OFIRMEV. OFIRMEV should be administered only as a 15-minute infusion.

For more information, please see the full OFIRMEV Prescribing Information, including the complete boxed warning, which is available at www.OFIRMEV.com or www.cadencepharm.com.

**About Cadence Pharmaceuticals, Inc.**
Cadence Pharmaceuticals is a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting. The current version of Cadence Pharmaceuticals' corporate overview may be viewed on the Investors page of www.cadencepharm.com under "Events & Presentations" by selecting "Corporate Overview."

**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. Such statements include, without limitation, statements regarding: Cadence's net product revenue estimates from sales of OFIRMEV for the three and twelve month periods ended December 31, 2013; the company's guidance regarding anticipated net product revenue for the twelve months ending December 31, 2014; and the increasing desire for non-narcotic analgesic options in the hospital setting. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Cadence's actual future results may differ materially from Cadence's current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: Cadence's dependence on the successful commercialization of OFIRMEV, which is the company's only product; Cadence's ability to achieve broad market acceptance and generate revenues from sales of OFIRMEV; Cadence's dependence on its contract manufacturers and its ability to ensure an adequate and continued supply of OFIRMEV to meet market demand; Cadence's ability to successfully enforce its marketing exclusivities and intellectual property rights, and to defend the patents covering OFIRMEV, including in current intellectual property litigation with the parties that have submitted new drug applications ("NDAs") or abbreviated new drug applications ("ANDAs") for generic versions of OFIRMEV; the potential that Cadence may be required to continue intellectual property litigation for substantial lengths of time or file additional lawsuits to defend its patent rights from challenges by companies that have submitted NDAs or ANDAs for generic versions of OFIRMEV, and the substantial costs associated with such lawsuits; the potential for the U.S. patent and trademark office to grant the reexamination of U.S. patent no. 6,992,218 (the "'218 patent"), which is related to OFIRMEV, and the potential that any claims in the '218 patent or in U.S. patent no. 6,028,222, which also relates to OFIRMEV and is currently undergoing reexamination, are invalidated or narrowed in scope; the potential introduction of generic competition to OFIRMEV in the event Cadence is unsuccessful in defending the patents covering OFIRMEV or in current or future intellectual property litigation, and the impact it may have on the sales and pricing of the product; Cadence's dependence on its licensors for the maintenance and enforcement of its intellectual property rights; the potential product liability exposure associated with pharmaceutical products such as OFIRMEV and other products Cadence may in-license or acquire; Cadence's ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to its commercial activities; public concern regarding the safety of drug products such as OFIRMEV, and the potential implementation by regulatory agencies of new requirements to include unfavorable information in the labeling for OFIRMEV; the risk that Cadence may not be able to raise sufficient capital when needed, or at all ; and other risks 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: | William R. LaRue |
| | SVP & Chief Financial Officer |
| | Cadence Pharmaceuticals, Inc. |
| | Phone: 858-436-1400 |


SOURCE Cadence Pharmaceuticals, Inc.