Cadence Pharmaceuticals Comments on USPTO's Non-Final, Initial Office Action on Reexamination of Patent

August 15, 2013

SAN DIEGO, Aug. 15, 2013 /PRNewswire/ -- Cadence Pharmaceuticals, Inc. (Nasdaq: CADX) today announced that the United States Patent and Trademark Office (USPTO), has issued a non-final, initial office action in the Ex Parte Reexamination of US Patent No. 6,028,222, or the '222 patent, one of the two licensed patents covering OFIRMEV® (acetaminophen) injection. Although the USPTO made an initial determination to reject certain claims, all of the claims of the '222 patent remain valid and in force until the USPTO issues a final action in this reexamination.

"This initial office action by the USPTO is not a final decision, rather, it's just one step in the reexamination process, which can take many years to complete. It's very common for the USPTO to reject some or all of the claims of a patent in an initial office action, however, claims that are initially rejected may be subsequently allowed. Importantly, we don't expect this action to have an adverse impact on the pending litigation against Exela," said Ted Schroeder, President and CEO of Cadence. "We strongly believe that the scope and validity of the patent claims in the '222 patent are appropriate and that the USPTO's prior issuance of the patent was correct."

The '222 patent covers the formulation of OFIRMEV, and expires in August 2017, and US Patent No. 6,992,218, covers the process used to manufacture OFIRMEV, and expires in June 2021. Upon completion of the company's ongoing pediatric clinical trial of OFIRMEV, both patents will be eligible for an additional six months of marketing exclusivity. In September 2012, a third party filed with the USPTO a Request for Ex Parte Reexamination of the '222 patent, and in December 2012, Cadence received notice that the USPTO had granted the Request for Reexamination. The reexamination process requires the USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO.

Cadence intends to continue with the reexamination of all of the rejected claims of the '222 patent and the company is confident in its ability to make a strong case for the patentability of the rejected claims as the process continues. Additionally, as permitted under USPTO rules, Cadence plans to file additional claims under the '222 patent. From this point forward, third parties are barred from providing additional information in this reexamination.

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

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 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 the company's expectation that the initial office action will not have an adverse impact on the company's pending litigation against Exela, Cadence's belief that the scope and validity of

the '222 patent are appropriate and that the USPTO's prior issuance of the patent was correct, the company's plans to continue the reexamination and file additional claims, and Cadence's ability to make a strong case in favor of the patentability of the rejected claims. 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 the company'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 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 introduction of generic competition to OFIRMEV in the event Cadence is unsuccessful 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; the Company's ability to raise capital when needed; and other risks detailed under "Risk Factors" and elsewhere in Cadence's periodic reports and other filings made with the SEC 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 the company undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

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