Cadence Pharmaceuticals Announces Strategic Plan to Secure Long-Term Manufacture and Supply of OFIRMEV® (acetaminophen) Injection

March 6, 2013

SAN DIEGO, March 6, 2013 /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 a new supply agreement with Laboratorios Grifols, S.A. for the development, manufacture and supply of commercial quantities of OFIRMEV (acetaminophen) injection in flexible plastic bags. Previously, Cadence announced the extension of its supply arrangement for OFIRMEV in glass vials with Lawrence Laboratories, a member of the Bristol Myers Squibb group of companies, through December 31, 2018. Additionally, the company has terminated its development and supply agreement for OFIRMEV in glass vials with Baxter Healthcare Corporation.

"We are very pleased to extend our existing relationship with Lawrence Laboratories, which we believe will allow us to meet our customers' growing demand for OFIRMEV packaged in glass vials. As a result of our new collaboration with Grifols, we anticipate that by the second half of 2014, we will be able to offer our customers the option of purchasing OFIRMEV in flexible IV bags. We believe that the combination of these two sources will ensure an adequate long-term supply of the product, while also supporting our risk management objectives through geographic diversification," said Ted Schroeder, President and CEO of Cadence. "Additionally, the termination of our supply agreement with Baxter marks the amicable end to our collaboration for the development and initial commercial supply of OFIRMEV."

According to Jose Antonio Garcia, President of Laboratorios Grifols, "The agreement with Cadence will further enhance Grifols' third-party drug manufacturing activities, contributing to the geographical diversification of the division, and helping to maximize the use of the manufacturing facilities at Parets del Valles (Barcelona, Spain)."

Extension of Existing Supply Arrangement with Lawrence Laboratories

On February 28, 2013, Cadence announced that it had entered into an agreement with Lawrence Laboratories, an operating division of Swords Laboratories, and a member of the BMS group of companies, to extend the company's supply agreement with Lawrence Laboratories through December 31, 2018. Bristol-Myers Squibb Srl, or BMS Anagni, an indirect subsidiary of BMS located in Anagni, Italy, manufactures OFIRMEV on behalf of Lawrence Laboratories. BMS Anagni has manufactured intravenous acetaminophen for more than ten years for sale and distribution by BMS and its affiliates in a number of countries outside of the U.S. and Canada. BMS Anagni is currently Cadence's sole supplier of OFIRMEV.

Manufacturing and Supply Agreement with Laboratorios Grifols, S.A.

On March 4, 2013, Cadence entered into an agreement with Laboratorios Grifols, S.A., or Grifols, a division of Grifols, S.A., a global healthcare company headquartered in Barcelona, Spain, for the development, manufacture and supply of commercial quantities of OFIRMEV in flexible IV bags. Grifols has supplied IV acetaminophen in flexible plastic bags to BMS for distribution in certain markets outside of the U.S. and Canada since 2010. Cadence plans to submit a supplemental NDA to the FDA in the second half of 2013, seeking approval of the product to be manufactured by Grifols.

Pursuant to the terms of the agreement, Cadence will pay Grifols a set price for the OFIRMEV it purchases, which price may be adjusted annually by Grifols, subject to specified limitations. In addition, the company will be obligated to pay Grifols a reservation fee, in lieu of any minimum purchase commitment, calculated by multiplying the shortfall between the annual production capacity it has reserved with Grifols and the amount of product actually ordered during that year by a fixed amount. The agreement will terminate on the sixth anniversary of the approval by the FDA of the product manufactured by Grifols, unless it is terminated sooner by Cadence upon the termination of its license agreement for the product with BMS, or after 60 days written notice following the discontinuation of the distribution of the product by Cadence. In addition, either party may terminate the agreement after 60 days written notice in the event of a material uncured breach of the agreement by the other party (or 30 days in the case of a payment default), or immediately upon an insolvency event.

Termination Supply Agreement with Baxter Healthcare Corporation

On March 5, 2013, Cadence and Baxter Healthcare Corporation mutually agreed to terminate their Amended and Restated Development and Supply Agreement for OFIRMEV, which was effective as of January 2011. Under the termination agreement, Cadence is required to remove its manufacturing equipment from Baxter's facility within 180 days, and pay for anticipated costs or expenses related to such removal, but is not required to restore Baxter's manufacturing facility to its condition prior to the installation of OFIRMEV-related improvements. Cadence is not required to reimburse Baxter for any remaining materials purchased by Baxter in connection with the manufacture of OFIRMEV. The termination agreement also contains customary mutual releases.

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."

About Grifols

Grifols (MCE:GRF, MCE:GRF.P and NASDAQ:GRFS) is a global healthcare company focused on producing life-saving plasma medicines, hospital pharmacy products and diagnostic technology for clinical use. As the third largest global producer of plasma medicines and is the world leader in plasma collection, with 150 plasma donation centers across the U.S. Grifols is committed to increasing patient access to its life-saving plasma medicines through significant manufacturing expansions and the development of new therapeutic applications of plasma proteins. The company is headquartered in Barcelona, Spain and employs more than 11,000 people worldwide. For more information visit www.grifols.com.

Forward-Looking Statements

Statements included in this press release and Cadence's conference call 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 expectation regarding the time when it will be able to offer OFIRMEV in flexible IV bags; and Cadence's belief that it will have an adequate long-term supply of OFIRMEV. 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 patent litigation with the parties that have submitted abbreviated new drug applications ("ANDAs") for generic versions of OFIRMEV; the potential that Cadence may be required to continue patent litigation for substantial lengths of time or file additional lawsuits to defend its patent rights from challenges by companies that have submitted 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 patent litigation; 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, which could result in the 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	Kelli France
	SVP & Chief Financial Officer	Media Relations
	Cadence Pharmaceuticals, Inc.	WCG
	Phone: 858-436-1400	Phone: 415-946-1076

SOURCE Cadence Pharmaceuticals, Inc.

News Provided by Acquire Media