



Cadence Pharmaceuticals Submits Acetavance New Drug Application for the Treatment of Acute Pain and Fever

SAN DIEGO, May 14, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Cadence Pharmaceuticals, Inc. (Nasdaq: CADX) announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its investigational product candidate, Acetavance(TM) (intravenous acetaminophen), for the treatment of acute pain and fever in adults and children. If approved, Acetavance would become the first new intravenous analgesic approved in the United States in more than 20 years and the only approved intravenous agent for the treatment of fever in the United States.

"Submission of the Acetavance NDA is a major milestone for Cadence and demonstrates our commitment to develop products that address unmet needs in the hospital market," said Ted Schroeder, President and Chief Executive Officer of Cadence. "We believe that the data supporting the NDA for Acetavance are strong and look forward to working with the FDA throughout the regulatory review process."

The company's 505(b)(2) NDA submission for Acetavance includes data from one pivotal clinical trial for the treatment of acute pain in patients following orthopedic surgery and one pivotal clinical trial for the treatment of endotoxin-induced fever. The NDA is also supported by data from a total of nine placebo-controlled clinical trials, four active-controlled clinical trials, and seven other safety or pharmacokinetic clinical trials. The submission includes safety data from over 1,400 patients who received Acetavance in clinical trials, including 350 children, and data from safety reports that collectively represent more than 53 million patient exposures to intravenous acetaminophen in countries outside the United States.

Acetavance is Cadence Pharmaceuticals' proprietary intravenous formulation of acetaminophen. Acetaminophen is the most widely used medication for the treatment of pain and fever in the United States and is available in more than 600 combination and single-ingredient prescription and over-the-counter products. Cadence acquired the exclusive rights to Acetavance in the United States and Canada in 2006 from Bristol-Myers Squibb Company, which markets the product as Perfalgan(R) in Europe and other parts of the world. Intravenous acetaminophen is approved in approximately 80 countries, including major markets in Europe, where the product is the market leader among all injectable analgesics. Approximately 90 million vials of intravenous acetaminophen were sold in Europe in 2008.

There is an unmet medical need for new agents to treat pain or fever in hospitalized patients who cannot take medications by mouth. Only two classes of intravenous analgesics, opioids and non-steroidal anti-inflammatory drugs, or NSAIDs, are currently available in the United States for the treatment of acute pain. Opioids may be associated with a variety of unwanted side effects, including respiratory depression, excessive sedation, nausea, vomiting, constipation, cognitive impairment, and others. The only non-opioid intravenous analgesic currently available in the United States is the NSAID, ketorolac. Post-operative use of intravenous ketorolac is limited due to its potential to cause increased bleeding. Renal toxicity and the potential for increased cardiovascular events further limit the post-operative use of NSAIDs. Dipyrrone (metamizole) was the last injectable drug for the reduction of fever in the United States, but since it was taken off the market in 1976, there has been no approved parenteral antipyretic drug available.

About Cadence Pharmaceuticals, Inc.

Cadence Pharmaceuticals is a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. The company is currently developing Acetavance(TM) (intravenous acetaminophen), its product candidate for the treatment of acute pain and fever. For more information about Cadence, 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 that are based on Cadence's current beliefs and expectations. Forward-looking statements include statements regarding the potential that FDA will accept for filing and, ultimately, approve Cadence's NDA for Acetavance; the company's belief in the strength of the data supporting the NDA; and statements regarding unmet medical needs in the United States and the commercial and therapeutic potential for Acetavance. The inclusion of forward-looking statements should not be regarded as a representation by Cadence that any of its plans will be achieved. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in the company's business, including, without limitation: Cadence's dependence on the success of Acetavance, and uncertainty as to whether this product candidate will receive regulatory approval or be successfully commercialized; the potential that the FDA may not accept the Acetavance NDA for review, or that the clinical trial

data and other information included in the company's NDA for Acetavance may not adequately support this product candidate's safety and efficacy; the potential that the prevalence or severity of adverse side effects associated with Acetavance may be greater than anticipated, which could prevent or significantly delay its regulatory approval; the potential that changes made in transferring the manufacturing process for Acetavance may result in a lack of comparability between the commercial product and the material used in clinical trials, and that the FDA may require the company to perform additional non-clinical or clinical studies; the potential that the FDA may impose other requirements to be completed before or after regulatory approval; the company's reliance on third parties to assist with its clinical trials, regulatory submissions, manufacturing and other important aspects of the Acetavance development program, and the risk that regulatory approval may be delayed if their performance is found to have been substandard; risks associated with FDA heightened scrutiny over the new drug approval process and the potential for accidental and intentional overdoses of acetaminophen, primarily in the outpatient setting; intense competition from existing and new products, which could diminish the commercial potential for Acetavance; the possibility that the patent rights covering Acetavance, which are limited to a specific intravenous formulation of acetaminophen and do not cover the active ingredient, may not be sufficient to preclude other formulations of intravenous acetaminophen from being developed by competitors; the potential that Cadence may require substantial additional funding in order to obtain regulatory approval of Acetavance and, if approved, to successfully launch this product candidate, and that the company may not be able to raise sufficient capital when needed, or at all; 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.

Cadence(TM) and Acetavance(TM) are trademarks of Cadence Pharmaceuticals, Inc. Perfalgan is a registered trademark of Bristol-Myers Squibb Company.

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