



Cadence Pharmaceuticals Announces Priority Review and Acceptance of NDA Submission for Acetavance(TM) for Treatment of Acute Pain and Fever

SAN DIEGO, July 15, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Cadence Pharmaceuticals, Inc. (Nasdaq: CADX) announced today that its New Drug Application (NDA) for Acetavance(TM) (intravenous acetaminophen), its investigational product candidate for the treatment of acute pain and fever in adults and children, has been accepted for filing by the U.S. Food and Drug Administration (FDA) and designated for Priority Review. Priority Review is granted to those products that address significant unmet medical needs or have the potential to provide a significant improvement compared to marketed products and provides for a review period of six months from the date of NDA submission. The FDA has issued an action date for the NDA of November 13, 2009 under the Prescription Drug User Fee Act (PDUFA).

"We are very pleased with the FDA's decision to grant the Acetavance NDA a Priority Review, which we believe reflects the potential of Acetavance to fulfill a significant unmet need for a new class of intravenous medication to treat acute pain and fever in adults and children, for which there remains a large gap in the U.S. treatment paradigm," said Ted Schroeder, President and CEO of Cadence.

The Priority Review designation reduces the target review period for the NDA from ten months to six months. Acceptance of the NDA submission indicates that the FDA has made a threshold determination that the NDA is sufficiently complete to permit a substantive review.

The company's 505(b)(2) NDA 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 pediatric patients, from premature neonates to adolescents, and data from safety reports that collectively represent more than 53 million patient exposures to intravenous acetaminophen in countries outside the United States.

About Acetavance

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 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 representing an increase of approximately 13% over 2007.

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 (intravenous acetaminophen), an investigational 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 anticipated action date for the FDA to complete its review of the Acetavance NDA and the company's belief that this product candidate may fulfill an unmet medical need for a new class of intravenous medication to treat acute pain and fever in adults and children. The inclusion of forward-looking statements such as these 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: the possibility that the clinical trial and other data and information included in the NDA for Acetavance may be insufficient to support FDA approval or that adverse side effects associated with this product candidate may be more prevalent or severe than anticipated, which could prevent or significantly delay its regulatory approval; the potential that the FDA may require Cadence to perform additional

studies, tests or other activities, or request additional information or clarification regarding information already provided, which could substantially delay the approval of the NDA; the possibility that the FDA's evaluations of the NDA or the company's clinical and manufacturing procedures and facilities may raise issues that must be resolved prior to obtaining final approval of the NDA; the risk that heightened scrutiny by the FDA over the new drug approval process and concerns regarding accidental and intentional overdoses of acetaminophen, primarily in the outpatient setting, may delay or prevent the approval of Acetavance, limit the indications for use or otherwise adversely impact the approved labeling for this product candidate; intense competition from existing and new products, which could diminish the commercial potential for Acetavance; the possibility that the patent rights covering Acetavance may not be sufficient to preclude other intravenous formulations of acetaminophen from being developed by competitors; the potential for Cadence to require substantial additional funding in order to obtain regulatory approval for and commercialize Acetavance, and the risk 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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