



Cumberland Pharmaceuticals Announces Extension of FDA Review of Acetadote(R) Supplemental New Drug Application

NASHVILLE, Tenn., Aug 20, 2010 /PRNewswire via COMTEX News Network/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced the U.S. Food and Drug Administration (FDA) has extended its review of the supplemental new drug application (sNDA) for the use of Acetadote(R) (*acetylcysteine*) Injection in patients with non-acetaminophen acute liver failure. The review has been extended by three months resulting in a new Prescription Drug User Fee Act (PDUFA) goal date in December 2010.

"We look forward to continued discussion with the FDA regarding this potentially life-saving treatment for patients who have few alternatives," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals.

Acute liver failure is a rare syndrome associated with a high mortality rate and frequent need for liver transplantation. Approximately 50 percent of acute liver failure cases are caused by acetaminophen poisoning. Other causes of acute liver failure not induced by acetaminophen overdose include hepatitis B disease, autoimmune hepatitis, Wilson disease, fatty liver of pregnancy, and HELLP (hemolysis, elevated liver enzymes, low platelets) syndrome. Currently, transplantation of the liver is the only treatment for patients with liver failure not caused by acetaminophen overdose. In March 2010, Cumberland submitted the sNDA to the FDA for the use of Acetadote in patients with non-acetaminophen acute liver failure. The FDA formally accepted the application for review and designated the review classification as Priority in May 2010.

Acetadote was launched by Cumberland in 2004 as the first U.S.-approved injectable drug to treat acetaminophen overdose. In 2006, the FDA approved Acetadote for use in pediatric patients. The Company also received FDA approval for updated labeling regarding the safety of Acetadote in 2008 based on new information from a post-marketing safety study reporting a lower-incidence of side effects compared to previously reported data.

About Acetadote

Acetadote(R) (*acetylcysteine*) Injection is used in the emergency department to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many over-the-counter painkillers. It is the only approved injectable product in the United States for the treatment of acetaminophen overdose. Acetadote is contraindicated in patients with hypersensitivity or previous anaphylactoid reactions to acetylcysteine or any components of the preparation. Serious anaphylactoid reactions, including death in a patient with asthma, have been reported in patients administered acetylcysteine intravenously. Acetadote should be used with caution in patients with asthma, or where there is a history of bronchospasm. The total volume administered should be adjusted for patients less than 40 kg and for those requiring fluid restriction. To avoid fluid overload, the volume of diluent should be reduced as needed. If volume is not adjusted, fluid overload can occur, potentially resulting in hyponatremia, seizure, and death. For full prescribing information, visit www.acetadote.net.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a Tennessee-based specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's product portfolio includes Acetadote(R) (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning and Kristalose(R) (*lactulose*) for Oral Solution, a prescription laxative. The Company also recently launched Caldolor(R) (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States. Cumberland is dedicated to providing innovative products which improve quality of care for patients. The Company completed the initial public offering of its common stock in August 2009. For more information on Cumberland Pharmaceuticals, please visit www.cumberlandpharma.com.

Important Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that reflect Cumberland's current views with respect to future events, based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. As with any business, all phases of operations are subject to influences outside of the Company's control. Risk factors that could materially affect results of operations include, among others, those factors discussed in Cumberland's Registration Statement declared effective by the SEC on August 10, 2009. There can be no assurance that results or developments anticipated by Cumberland will be realized or, even if realized, that they will have the expected effects. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Cumberland undertakes no obligation to release publicly any revisions to these statements to reflect events or circumstances after the date hereof or to reflect the occurrence

of unanticipated events.

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