



Acetadote(R) Supplemental New Drug Application for Acute Liver Failure Submitted to FDA

Study shows patients given Acetadote versus placebo have a higher transplant-free survival rate and are less likely to require liver transplant

NASHVILLE, Tenn., March 30, 2010 /PRNewswire via COMTEX News Network/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) has submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for the use of Acetadote(R) (*acetylcysteine*) Injection in patients with non-acetaminophen acute liver failure. Acetadote was launched by Cumberland in 2004 as the first U.S.-approved injectable drug to treat acetaminophen overdose.

The sNDA includes data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that acute liver failure patients treated with Acetadote have a significantly improved chance of survival without a transplant. These patients can also survive a significant number of days longer without transplant, providing patients requiring transplant increased time for a donor organ to become available.

"This study establishes that Acetadote is an excellent treatment for people suffering from non-acetaminophen acute liver failure," said William M. Lee, M.D., professor of internal medicine at UT Southwestern Medical Center in Dallas and lead author of the study. "Acetadote is safe and easy to administer, and provides the first glimmer of hope that something can help these direly ill patients."

The results from the study, which is the largest clinical trial studying acute liver failure to date, were presented at the most recent national gastroenterology meeting and have been published in the medical journal *Gastroenterology*(1). This was a multi-center, randomized, double-blind trial involving 173 patients with acute liver failure not due to acetaminophen toxicity. Patients enrolled in the study were stratified according to coma grade, with coma grade one representing the earliest stages of hepatic encephalopathy and coma grade four representing late-stage conditions. The study results indicate that the transplant-free survival rate was significantly higher at three weeks, one year and two years for patients in coma grades one and two receiving Acetadote than for those receiving placebo.

"We are pleased to take the next step in expanding the use of this important product," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Since its approval in 2004, Acetadote has become a standard of care for treating liver damage associated with acetaminophen overdose. If approved for this new indication, we believe Acetadote will bring potentially life-saving treatment to a broader group of patients who have few alternatives."

Cumberland requested expanded labeling for Acetadote to include the new indication following discussion of the important new data with the FDA. The Company has requested a priority review of the application as well as additional exclusivity for the product if the new indication is approved.

The sNDA application is part of a larger effort to support ongoing development of Acetadote for other indications where the product can provide benefit. 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 Acute Liver Failure

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.

References

(1) Lee WM, Hynan LS, Rossaro L, Fontana RJ, Stravitz RT, Larson AM, Davern TJ 2nd, Murray NG, McCashland T, Reisch JS, Robuck PR; Acute Liver Failure Study Group. Intravenous N-acetylcysteine improves transplant-free survival in early stage non-acetaminophen acute liver failure. *Gastroenterology*. 2009 Sep;137(3):856-64.

SOURCE: Cumberland Pharmaceuticals Inc.

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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