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Cumberland Pharmaceuticals Announces Favorable Acetadote® Patent Ruling

NASHVILLE, Tenn., Nov. 20, 2015 /PRNewswire/ -- On November 17, 2015, an Illinois judge issued a final ruling in favor of Cumberland Pharmaceuticals Inc. in a patent case associated with its Acetadote® product. Cumberland (**NASDAQ:CPIX**) is a specialty pharmaceutical company focused on hospital acute care and gastroenterology.



Cumberland developed, registered, and launched Acetadote building it into a standard of care for the leading cause of poisoning in the U.S. The challenged patent has claims associated with Cumberland's next-generation formulation of Acetadote that is free of EDTA or any other preservative, chelating, or stabilizing agent. Through this new formulation of Acetadote, Cumberland has been able to retain significant market share in spite of generic competition that utilizes the old formulation of the product. By ruling in Cumberland's favor, the court upheld the validity of the patent which encompasses Cumberland's EDTA-Free formulation and has a term until August 2025. The court also granted a permanent injunction preventing the challenger from marketing a generic version of Acetadote before the expiration of Cumberland's patent in August 2025.

"We are very pleased with this outcome," said A.J. Kazimi, Cumberland CEO. "We look forward to continuing the supply of this potentially life-saving product in support of the healthcare professionals who administer it, and especially the patients who need it. Meanwhile, we will also continue to protect and defend Cumberland's intellectual property."

The Company continues to seek additional patent claims to protect its intellectual property associated with Acetadote and has additional patent applications related to Acetadote pending with the US Patent and Trademark Office (USPTO).

About Cumberland Pharmaceuticals Inc.

Cumberland Pharmaceuticals Inc. is a 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 marketed products include Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, Vaprisol® (*conivaptan*) Injection, for the treatment of hyponatremia and Omeclamox-Pak® for the treatment of *H. pylori* and duodenal ulcer disease. Cumberland is dedicated to providing innovative products that improve quality of care for patients. For more information on Cumberland, please visit the Company's website www.cumberlandpharma.com.

About Acetadote® (acetylcysteine) Injection

Acetadote, administered intravenously within 8 to 10 hours after ingestion of a potentially hepatotoxic quantity of acetaminophen, is indicated to prevent or lessen hepatic injury. Used in the emergency department, Acetadote is approved in the United States to treat overdose of acetaminophen, a common ingredient in many over-the-counter medications. 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 weighing 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.com.

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