January 30, 2017

U.S. Court Of Appeals Affirms Cumberland Pharmaceuticals' Victory In Patent Litigation Case

NASHVILLE, Tenn., Jan. 30, 2017 /PRNewswire/ -- Cumberland Pharmaceuticals Inc. **(NASDAQ: CPIX)**, a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced that on January 26, 2017, the U.S. Court of Appeals for the Federal Circuit ruled in favor of Cumberland in a patent case associated with its Acetadote® product.

The Appeals Court ruling affirmed the September 30, 2015 decision reached by the United States District Court for the Northern District of Illinois upholding Cumberland's patent and expressly rejecting Mylan Inc. and Mylan Institutional LLC's challenge of patent validity.

Cumberland developed, registered, and launched Acetadote, which is now a standard of care for the leading cause of poisoning in the U.S. The patent that was challenged 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 a significant market share in spite of generic competition that utilizes the old formulation of the product. By ruling in Cumberland's favor, the Appeals Court upheld the validity of the patent which encompasses Cumberland's EDTA-Free formulation and has a term until 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 Trademark Office (USPTO).

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on acquisition, development, and commercialization of high-quality products that improve the quality of care for patients. The Company has a diverse product portfolio with a focus in the areas of 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, Omeclamox-Pak® for the treatment of *H. pylori* and duodenal ulcer disease, and Ethyol® (*amifostine*) for Injection, for the prevention of treatment-related adverse reactions in oncology patients. Cumberland is also dedicated to developing innovative products that address unmet medical needs.

The Company's product candidates in clinical development include: Hepatoren® (*ifetroban*) Injection for the treatment of hepatorenal syndrome, Boxaban® (*ifetroban*) Oral Capsule for patients suffering from aspirin exacerbated respiratory disease, Vasculan™ *(ifetroban*) Oral Capsule for the treatment of systemic sclerosis and Portaban™ *(ifetroban*) Oral Capsule for the treatment of portal hypertension.

For more information on Cumberland Pharmaceuticals Inc., please visit 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.