Cumberland Pharmaceuticals Signs Exclusive Licensing Agreement For Distribution In China

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Agreement gives Winhealth Pharma Group exclusive rights for Acetadote® and Caldolor® in China

NASHVILLE, Tenn., May 15, 2019 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a specialty pharmaceutical company, today announced it has entered into an exclusive agreement with China's**Winhealth Pharma Group** for the licensing rights of Acetadote® (*acetylcysteine*) Injection, used to prevent or reduce liver damage resulting from acetaminophen overdose, and Caldolor® (*ibuprofen)* Injection, which is used to treat pain and fever in the hospital setting. The agreement will provide Winhealth licensing rights to commercialize both FDA approved drugs in China, the second largest market for pharmaceuticals in the world after the U.S. There have been patents issued for both brands in China.

Winhealth currently markets 12 pharmaceutical brands throughout China via partnerships with Boehringer Ingelheim, Novartis, Pfizer, and Roche, among others. Under the terms of the agreement with Cumberland, Winhealth is responsible for seeking regulatory approval for the two injectable brands in China and will handle ongoing regulatory reporting, product marketing, distribution and sales in China (including Hong Kong and Macau) following approval. Cumberland maintains responsibility for intellectual property, product formulation, development, and other supporting activities. In exchange for the license to the product, Cumberland will receive upfront and milestone licensing payments, as well as royalties on future sales of both drugs.

"Winhealth has grown tremendously in recent years, making them an ideal partner as we look to bring our medicines to patients in China," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We are delighted that, through this agreement, Chinese hospitals will have the opportunity to improve the quality of care offered to their patients."

Cumberland has significantly expanded its international network of partners in recent years. In addition to its arrangement with Winhealth, Cumberland has licensed rights for Caldolor to partners in South Korea, Spain, and India. The Company has also licensed rights for both Caldolor and Acetadote in Australia and New Zealand.

"We are very selective in the brands we add to our portfolio," said Mr. Wang Wei, Chairman of Winhealth Pharma Group. "We believe Acetadote and Caldolor are innovative products with a strong track record and an excellent fit for the Chinese market. In addition, it ties nicely to our company's *Contract Development and Commercialization Organization* (CDCO) positioning and will allow us to continue our advancement in the Chinese pharmaceutical and healthcare industry."

Following regulatory approval, Winhealth will use its existing sales force to promote these injectable products throughout China. Both offer unique benefits for hospitalized patients in China.

In the U.S., Acetadote is used in emergency departments to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many over-the-counter pain relief and fever-reducing products. Acetadote has become a standard of care for treating acetaminophen poisoning in the U.S. since its introduction. Cumberland has developed a next generation formulation of the product that does not contain any stabilizing or preservative agents.

Caldolor features analgesic, antipyretic and anti-inflammatory properties and is designed for the treatment of pain and fever, primarily in hospitalized patients who are unable to receive oral therapies. In clinical trials, Caldolor has demonstrated significant reductions in post-operative pain when compared with opioids alone while significantly reducing opioid requirements.

Both brands are approved by the FDA for use in adults as well as children.

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 U.S. 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.

About Caldolor® (ibuprofen) Injection

Caldolor is indicated in adults and pediatric patients for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. It was the first FDA-approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with a history of asthma or other allergic type reactions after taking aspirin or other NSAIDs. Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Caldolor should be used with caution in patients with prior history of ulcer disease or GI bleeding, in patients with fluid retention or heart failure, in the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors. Blood pressure should be monitored during treatment with Caldolor. For full prescribing information, including boxed warning, visit www.caldolor.com.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high quality prescription brands to improve patient care. The Company develops, acquires and commercializes brands for the hospital acute care, gastroenterology and oncology market segments. These medical specialties are categorized by moderately concentrated prescriber bases that we believe can be penetrated effectively by targeted sales forces. The Company's portfolio of FDA approved brands includes:

- **Acetadote®** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- **Caldolor®** (*ibuprofen*) Injection, for the treatment of pain and fever;
- **Kristalose®** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- **Omeclamox®-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease;
- **Vaprisol®** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- **Ethyol®** *(amifostine)* Injection, for the reduction of xerostomia (dry mouth) in patients undergoing post-operative radiation treatment for head and neck cancer and the renal toxicity associated with the administration of cisplatin in patients with advanced ovarian cancer;
- **Totect®***(dexrazoxane hydrochloride)* Injection, for emergency oncology intervention, to treat the toxic effects of anthracycline chemotherapy in case of extravasation (drug leakage from the bloodstream into the tissues); and
- **Vibativ®** (*telavancin*) Injection, for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia, as well as complicated skin and skin structure infections.

Cumberland's pipeline of product candidates includes:

- **Hepatoren®** (*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill patients suffering from liver and kidney failure associated with hepatorenal syndrome ("HRS");
- **Boxaban®***(ifetroban)* Oral Capsules, a Phase II candidate for the treatment of asthma patients with aspirin-exacerbated respiratory disease ("AERD");
- **Vasculan®***(ifetroban)* Oral Capsules, a Phase II candidate for the treatment of patients with systemic sclerosis (SSc) a form of autoimmune disease;
- **Portaban®***(ifetroban)* Injection and Oral Capsules, a Phase II candidate for the treatment of patients with portal hypertension associated with liver disease; and
- **RediTrex™** (*methotrexate*) Injection, an approval submission candidate for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as disabling psoriasis.

For more information on Cumberland's approved products, including full prescribing information, please visit the individual product websites, links to which can be found on the Company's website www.cumberlandpharma.com.

About Winhealth Pharma Group

As one of the leading integrated commercialization organizations, Winhealth Pharma Group focuses on introducing leading healthcare products and technologies from all over the world into the Chinese market and providing tailed full-cycle commercialization services covering route-to-market design, product registration and market access, sales and promotional services as well as channel management and distribution services to pharmaceutical and medical device products around the globe. Winhealth's products cover a range of market segments, including cardiovascular, respiratory, antiviral, oncology and dermatology. It currently works with a broad spectrum of pharmaceutical manufacturers including Roche, Pfizer, Boehringer

Ingelheim, Merz, Kyowa-Kirin and so on.

Established in 2006, the Company was founded in Hangzhou and is head-officed in Hong Kong, China.

For more information, please visit http://en.winhealth.hk/.

Forward-Looking Statements

This press release contains forward-looking statements, which are subject to certain risks and reflect Cumberland's current views on future events based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. Forward-looking statements include, among other things, statements regarding our intent, belief or expectations. As with any business, all phases of Cumberland's operations are subject to factors outside of its control, and any one or combination of these factors could materially affect Cumberland's results of operations. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis or failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure and other factors discussed in the Company's most recent Form 10-K and subsequent 10-Q's as filed with the SEC. There can be no assurance that results anticipated by the Company will be realized or that they will have the expected effects. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to publicly revise these statements to reflect events after the date hereof.

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Investor Contact: Erin Gull, Corporate Relations, (615) 255-0068; Media Contact: Jeff Bradford, the Bradford Group, (615) 515-4880