New Study Reveals Superiority Of Vibativ® Over Vancomycin In Select Patients With Bacterial Pneumonia

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NASHVILLE, Tenn., Oct. 15, 2019 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a U.S. specialty pharmaceutical company announces a new publication in *Infectious Diseases and Therapy*, showing numerically superior cure rates of telavancin compared to vancomycin within a subset of patients who were enrolled in phase 3 ATTAIN trials and had hospital-acquired pneumonia caused by bacteria with low susceptibility to vancomycin. Cumberland manufactures and distributes telavancin under the brand name Vibativ®.

Vibativ® (telavancin) is a patented, FDA approved anti-infective for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia. It is also approved for complicated skin and skin structure infections. It addresses a range of gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant.

Hospital-acquired pneumonia and ventilator-associated pneumonia (HAP/VAP) occur in 5 to >20 cases per 1,000 hospital admissions and 2-16 episodes per 1,000 ventilator days, respectively. Alternative treatment options are needed for HAP/VAP patients with *S. aureus* infections that test with high vancomycin minimum inhibitory concentration (MIC) and patients unable to tolerate vancomycin or linezolid.

The study, led by Michael S. Niederman, MD at Weill Cornell Medicine in New York, assessed a subset of the ATTAIN microbiologically evaluable patients with hospital-acquired monomicrobial *S. aureus* infections with vancomycin MIC ≥ 1.0 ug/mL to determine the efficacy and safety of telavancin. Of the 1,503 patients treated in ATTAIN, 194 microbiologically evaluable patients had monomicrobial respiratory *S. aureus* infections with vancomycin MIC ≥ 1.0 ug/mL; 89 patients were treated with telavancin, and 105 with vancomycin. The overall clinical cure rate for telavancin was 85.4% versus 74.3% for vancomycin with a 95% confidence interval 11.1% (- 0.002%, 22.2). In addition, several other sub-group analyses also demonstrated where telavancin was numerical superiority over vancomycin, including patients age ≥ 65, patients with APACHE II ≥ 20, and patients with VAP. Renal function changes and or other AEs were comparable between treatment groups. In settings where organisms with vancomycin MIC ≥ 1.0 ug/mL are prevalent, telavancin is an alternative to vancomycin for empiric or specific coverage of MRSA in patients with HAP/VAP.

About Vibativ®

Vibativ® (telavancin) Injection was discovered in a research program dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus (S. aureus)* and other Gram-positive bacteria, including MRSA and MSSA.

Vibativ is a once-daily, injectable lipoglycopeptide antibiotic with *in vitro* potency, bactericidal activity within six hours, and penetration into target infection sites. The drug is approved in the U.S. for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *S. aureus* when alternative treatments are not suitable. In addition, Vibativ is approved in the U.S. for the treatment of adult patients with complicated skin & skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *S. aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains. The product labeling also describes the use of Vibativ in treating patients whose pneumonia or skin infection is complicated by concurrent bacteremia. The product's proven efficacy against difficult-to-treat Gram-positive infections has been demonstrated in several large, multinational registrational studies, which involved one of the largest cohorts of patients with *S. aureus* infections studied to date. Importantly, these studies demonstrated significantly higher cure rates for Vibativ as compared to vancomycin in HABP/VABP due to any single Gram-positive pathogen or *S. aureus* with vancomycin MIC ≥1 µg/mL. Additionally, there is extensive and well-documented evidence of the drug's *in vitro* potency and *in vivo* activity against a broad collection of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant. For full prescribing information, visit www.vibativ.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;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.

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.

Cumberland has also submitted a New Drug Application for the approval of **RediTrex ™**(*methotrexate*) Injection, for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as disabling psoriasis.

Additionally, the Company has Phase II clinical programs underway evaluating its ifetroban product candidates in patients with cardiomyopathy associated with Duchenne Muscular Dystrophy ("DMD"), Systemic Sclerosis ("SSc") and Aspirin-Exacerbated Respiratory Disease ("AERD").

Cumberland has also completed Phase II clinical programs with ifetroban in patients with Hepatorenal Syndrome ("HRS") and patients with Portal Hypertension ("PH").

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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