



VIBATIV® BACTEREMIA STUDY DATA

NOW AVAILABLE

NASHVILLE, Tenn. (Monday, June 15, 2020) – Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a U.S. specialty pharmaceutical company, announces the availability of the interim analysis data for a study of Vibativ® for patients with *S. aureus* bacteremia.

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.

The study was sponsored by Theravance Biopharma, owners of Vibativ prior to Cumberland’s acquisition of the product. The primary objective of the study was to compare clinical outcomes of patients treated for *S. aureus* bacteremia with telavancin to those treated with standard intravenous therapy. An interim analysis revealed the study to be underpowered as designed, and Theravance decided to close the study due to challenges in recruiting patients and the investment needed to increase the power of the trial. The analysis did not identify any new safety concerns. As a result, subjects already enrolled were allowed to continue the clinical trial to completion as outlined in the protocol. Details of the data collected for the 121 patients enrolled in the study before it closed are now available on www.clinicaltrials.gov under the identifier, NCT02208063.

Further information on the treatment of bacteremia with telavancin can be found in the recently published sub analysis of The Telavancin Observational Use Registry (TOUR™) which reports the real-world outcomes of 132 patients with endocarditis and/or bacteremia with a known or unknown primary source treated with telavancin.¹

1. Reilly, Joseph et al. “Clinical Experience with Telavancin for the Treatment of Patients with Bacteremia and Endocarditis: Real-World Results from the Telavancin Observational Use Registry (TOUR™).” *Drugs - real world outcomes*, 10.1007/s40801-020-00191-x. 5 May. 2020, doi:10.1007/s40801-020-00191-x
<https://link.springer.com/article/10.1007%2Fs40801-020-00191-x>

About Vibativ®

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 $\mu\text{g/mL}$. 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 and gastroenterology market segments. 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;
- **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;
- **RediTrex**[®] (*methotrexate*) Injection, 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.

The Company also has a series of 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"), Hepatorenal Syndrome ("HRS") and 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. 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, natural disasters, public health epidemics, and other events beyond our control, as more fully discussed in the Company's most recent Form 10-K and subsequent 10-Qs 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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