Vibativ® Sustained Potency Confirmed In Two Surveillance Studies

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NASHVILLE, Tenn., May 11, 2020 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a U.S. specialty pharmaceutical company announces two new publications detailing the sustained *in vitro* potency of Vibativ® (telavancin) as part of a 7-year antimicrobial surveillance program. Both publications were part of continued surveillance of telavancin activity since 2011. The first publication tested a global collection of 24,408 Gram-positive clinical isolates, and the second publication tested a U.S. collection of 15,882 *S. aureus* isolates. All isolates were collected from the SENTRY Antimicrobial Surveillance Program.

Vibativ 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 global study published in *Microbial Drug Resistance*[1] reports that since 2011, there has been little or no change in telavancin activity against several important Gram-positive pathogen groups that include MRSA, CoNS, vancomycin-susceptible *E. faecalis*, *S. pneumoniae*, viridans group streptococci, and b-hemolytic streptococci. Telavancin maintained excellent antimicrobial activity against multidrug-resistant subsets of these pathogen groups and against ceftaroline-nonsusceptible (telavancin MIC_{90} value, 0.06 µg/mL; 100% susceptible) and ceftaroline-resistant (telavancin MIC_{90} value, 0.12 µg/mL; 100% susceptible) *S. aureus* isolates. Telavancin exhibited MIC_{90} values of 0.06 mg/mL against the full global set of *S. aureus* isolates and the MRSA subset.

The U.S. study published in the *Journal of Global Antimicrobial Resistance*[2] focused on *S. aureus* isolates. Telavancin antimicrobial activity against MRSA and MDR MRSA isolates ($MIC_{50/90}$ values, 0.03/ 0.06 mg/mL for both subsets) remained unchanged over the surveillance period 2014 - 2016, and all isolates were susceptible to telavancin. Previously published data on MRSA and multidrug-resistant (MDR) MRSA isolates (collected 2011–2013) were merged with the current isolate set to examine longer-term resistance trends. The telavancin results for the MRSA and MDR MRSA subsets were identical to corresponding $MIC_{50/90}$ and susceptibility values reported for isolates collected in 2011–2013.

References:

1. Duncan, Leonard R et al. "Antimicrobial Activity of Telavancin Tested *In Vitro* Against a Global Collection of Gram-Positive Pathogens, Including Multidrug-Resistant Isolates (2015-2017)." *Microbial drug resistance (Larchmont, N.Y.)*, 10.1089/mdr.2019.0104. 12 Feb. 2020, doi:10.1089/mdr.2019.0104 https://www.ncbi.nlm.nih.gov/pubmed/32049591

2. Duncan, Leonard R et al. "Regional analysis of telavancin and comparator antimicrobial activity against multidrug-resistant Staphylococcus aureus collected in the USA 2014-2016." *Journal of global antimicrobial resistance* vol. 20 (2020): 118-123. doi:10.1016/j.jgar.2019.07.007 https://www.ncbi.nlm.nih.gov/pubmed/31325617

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 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 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 ("P.H.").

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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