

## FDA-APPROVED ANTIBIOTIC WITH LIFE-SAVING POTENTIAL LAUNCHES IN PUERTO RICO

March 14, 2022

Vibativ<sup>®</sup> treats patients with pneumonia and serious skin infections

NASHVILLE, Tennessee and EWING, New Jersey (March 14, 2022) – Specialty pharmaceutical companies Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX) and Verity Pharmaceuticals International Ltd. today announced the launch of Cumberland's VIBATIV <sup>®</sup> (telavancin) injection in Puerto Rico. The announcement follows an agreement between the companies providing Verity the rights to introduce the product for patients in that market. VIBATIV can serve as a potentially life-saving treatment in patients with hospital-acquired and ventilator-associated pneumonia resulting from infections including the flu and COVID-19.

VIBATIV is a patented, FDA-approved injectable anti-infective. It is designed to treat serious infections due to *Staphylococcus aureus* (*S. aureus*) and other Gram-positive bacteria, including *Methicillin-resistant Staphylococcus aureus* (*MRSA*) and *Methicillin-sensitive Staphylococcus aureus* (*MSSA*). VIBATIV addresses a range of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant.

Pneumonia caused by secondary bacterial infections is common among patients with viral respiratory infections. The risk of such infections grows as hospitals see more patients with respiratory symptoms due to COVID-19. Research shows that hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP) have historically accounted for 22% of common hospital-acquired infections. Methicillin-sensitive and methicillin-resistant *S. aureus* (MSSA and MRSA) are important disease-causing pathogens in these cases.

"Given the global concern on multidrug resistance organisms, Puerto Rico is in need of a product like VIBATIV. Of note, the island has a high number of elderly citizens and residents living with chronic diseases, like diabetes, that increase the risk of hospitalization and infections," said Howard Glase, CEO and general manager of Verity Pharmaceuticals. "We strongly believe in VIBATIV's efficacy and safety and are honored to provide this potentially life-saving drug for patients in Puerto Rico."

While many recently introduced antibiotics are quickly losing the battle to fight the bacteria they were designed to kill because those bacteria have become drug-resistant, VIBATIV was specifically designed to kill drug-resistant bacteria. The molecule of an existing antibiotic to which bacteria had developed a resistance, vancomycin, was altered by adding a lipophilic (fat-loving) component and a hydrophilic (water-loving) component. The lipophilic addition increases VIBATIV's ability to penetrate the cell wall and inhibits the formation of new cell walls (the development of new and/or additional cell walls is the most common way that bacteria become resistant to drugs). The hydrophilic addition increases VIBATIV's penetration into tissue – so it is able to attack infections that are not reachable by other antibiotics.

In comparison to vancomycin, VIBATIV is 32 times more potent against MRSA strains when tested under in vitro conditions. Further, in clinical trials, VIBATIV demonstrated superior cure rates of patients with hospital-acquired bacterial pneumonia.

Two recently published studies – one that tested over 24,000 clinical isolates and one that tested over 15,000 – show that VIBATIV is just as potent today against difficult-to-treat and multidrug-resistant bacteria as it was when it was introduced 10 years ago.

"I am very happy to have gained access to VIBATIV here in Puerto Rico, especially in times when effective and timely single-dose therapy is needed for my complicated patients." said Dr. Carlos Guzmán, an infectious disease physician in San Juan. Puerto Rico.

VIBATIV is intravenously administered with once-daily dosing and does not require therapeutic drug monitoring, decreasing health care professionals' exposure to the patient.

"Verity has a strong presence in Puerto Rico, which made them a natural fit when we were searching for a partner to introduce VIBATIV to this market," said A.J. Kazimi, CEO of Cumberland Pharmaceuticals. "We are confident that they will ensure the product reaches as many patients within the territory as possible and we look forward to a successful partnership."

Under the terms of the agreement, Cumberland is responsible for product supply and Verity will commercialize and promote the product in the local market. The companies will share in the financial contribution from the product within the territory.

# About VIBATIV®

VIBATIV<sup>®</sup> (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 and 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, including important safety information visit www.vibativ.com.

## **About Verity Pharmaceuticals**

Verity Pharmaceuticals International Ltd. is a specialty pharmaceutical company with a primary focus on therapeutic solutions for genitourinary (GU) diseases.

Verity Pharmaceuticals works with best-in-class global pharmaceutical manufacturing partners to ensure that product quality and availability is a constant deliverable. The company is also committed to supporting programs, initiatives, and organizations that help improve health, expand research opportunities and promote education within the healthcare community. Learn more at <a href="https://www.veritypharma-usa.com">www.veritypharma-usa.com</a>.

#### **About Cumberland Pharmaceuticals**

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high-quality, prescription brands designed to improve patient care. The company develops, acquires, and commercializes products for the hospital acute care, gastroenterology, and rheumatology market segments. The company's portfolio comprises eight FDA-approved brands, including SANCUSO <sup>®</sup>, which Cumberland acquired in December 2021. The company also has a series of Phase II clinical programs underway evaluating its ifetroban product candidate in patients with cardiomyopathy associated with Duchenne Muscular Dystrophy ("DMD"), as well as Systemic Sclerosis ("SSc"), and Aspirin-Exacerbated Respiratory Disease ("AERD").

More information can be found on Cumberland Pharmaceutical's website at www.cumberlandpharma.com.

#### **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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