



## **Clinigen and Theravance Announce Exclusive Commercialization Agreement in the EU for VIBATIV® (telavancin)**

**Burton-on-Trent, UK and South San Francisco, CA – 11<sup>th</sup> March 2013** – Clinigen Group plc (LSE: CLIN) (AIM: CLIN) and Theravance, Inc. (NASDAQ: THRX) today announced that they have entered into an exclusive commercialization agreement in the European Union (EU) and certain other countries located in Europe for VIBATIV® (telavancin) for the treatment of nosocomial pneumonia (hospital-acquired), including ventilator-associated pneumonia, known or suspected to be caused by methicillin resistant *Staphylococcus aureus* (MRSA) when other alternatives are not suitable. VIBATIV® is a bactericidal, once-daily injectable lipoglycopeptide antibacterial agent with a dual mechanism of action against Gram-positive bacteria, including resistant pathogens such as MRSA.

Under the terms of the agreement, Theravance has granted Clinigen exclusive commercialization rights to VIBATIV® in the EU and certain other European countries (including Switzerland and Norway). In exchange, Theravance will receive a \$5 million upfront payment from Clinigen and is entitled to receive tiered royalties on net sales of VIBATIV®, ranging from 20% to 30%. The agreement has a term of at least 15 years, with an option to extend exercisable by Clinigen.

“We are pleased to have Theravance, a leader in antibiotic development, as a license partner,” said Peter George, Chief Executive Officer of Clinigen. “This agreement is of strategic importance to us as it not only strengthens our anti-infective offering with a product that has patent protection into the next decade, but it is an exciting opportunity to commercialize VIBATIV® and Foscavir® while leveraging their operational synergies. VIBATIV® is a second product for Clinigen’s Specialty Pharmaceuticals (SP) portfolio, complementing the division’s anti-viral product, Foscavir®.”

“We are very excited to partner with Clinigen and we believe that its innovative business model and experience in specialty pharmaceuticals provide an ideal platform to maximize the growth opportunity for VIBATIV®,” said Rick E Winningham, Chief Executive Officer of Theravance. “We look forward to working with Clinigen in making VIBATIV® available to patients with nosocomial pneumonia in the EU.”

### **About VIBATIV® (telavancin)**

VIBATIV® is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with a dual mechanism of action whereby VIBATIV® both inhibits bacterial cell wall synthesis and disrupts bacterial cell

membrane function. VIBATIV<sup>®</sup>, discovered and developed by Theravance, is approved in the United States for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains, since 2009. In 2011, the European Commission granted marketing authorization for VIBATIV<sup>®</sup> for the treatment of nosocomial pneumonia (hospital-acquired), including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. In May 2012, the European Commission suspended marketing authorization for VIBATIV<sup>®</sup> because the former VIBATIV<sup>®</sup> drug product supplier, Ben Venue Laboratories, Inc., at that time did not meet current Good Manufacturing Practice requirements for the manufacture of VIBATIV<sup>®</sup>. Theravance is currently working on re-establishing consistent product supply that will meet European Commission requirements.

### **VIBATIV<sup>®</sup> Important Safety Information (US)**

#### **Fetal Risk**

Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV<sup>®</sup>. Avoid use of VIBATIV<sup>®</sup> during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Adverse developmental outcomes observed in three animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans. If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV<sup>®</sup> treatment.

#### **Nephrotoxicity**

New onset or worsening renal impairment occurred in patients who received VIBATIV<sup>®</sup>. Renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction and in patients who received concomitant medications known to affect kidney function. Monitor renal function in all patients receiving VIBATIV<sup>®</sup> prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV<sup>®</sup> versus discontinuing and initiating therapy with an alternative agent should be assessed. Clinical cure rates in telavancin-treated patients were lower in patients with baseline CrCl  $\leq 50$  mL/min compared to those with CrCl  $> 50$  mL/min. Consider these data when selecting antibacterial therapy for use in patients with baseline moderate/severe renal impairment.

#### **Geriatric Use**

Telavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

#### **Infusion Related Reactions**

VIBATIV<sup>®</sup> is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions. Rapid intravenous infusions of the glycopeptide class of antimicrobial agents can cause "Red-man Syndrome" like reactions including: flushing of the upper body, urticaria, pruritus, or rash.

### *Clostridium difficile*-Associated Diarrhea

*Clostridium difficile*-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibiotic use.

### Development of Drug-Resistant Bacteria

Prescribing VIBATIV® in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. As with other antibacterial drugs, use of VIBATIV® may result in overgrowth of nonsusceptible organisms, including fungi.

### QTc Prolongation

Caution is warranted when prescribing VIBATIV® to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV® prolonged the QTc interval. Use of VIBATIV® should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy.

### Coagulation Test Interference

VIBATIV® does not interfere with coagulation, but does interfere with certain tests used to monitor coagulation such as prothrombin time, international normalized ratio, activated partial thromboplastin time, activated clotting time, and coagulation based factor Xa tests. Blood samples for these coagulation tests should be collected as close as possible prior to a patient's next dose of VIBATIV®.

### Adverse Reactions

The most common adverse reactions ( $\geq 10\%$  of patients treated with VIBATIV®) observed in the Phase 3 cSSSI clinical trials were taste disturbance, nausea, vomiting, and foamy urine.

In the Phase 3 cSSSI clinical trials, serious adverse events were reported in 7% of patients treated with VIBATIV® and most commonly included renal, respiratory, or cardiac events. Serious adverse events were reported in 5% of vancomycin-treated patients, and most commonly included cardiac, respiratory, or infectious events.

For full Prescribing Information, including Boxed Warning and Medication Guide in the US, please visit [www.VIBATIV.com](http://www.VIBATIV.com).

### **About Clinigen**

Clinigen is a specialty global pharmaceutical products and services business headquartered in the UK, with offices in the US and Japan. The Group has three operating business; Specialty Pharmaceuticals (SP), Clinical Trials Supply (Clinigen CTS), and Global Access Programs (Clinigen GAP). The SP business focuses on acquiring and in licensing specialist, hospital only medicines worldwide and commercializing them within niche markets. The lead product is the anti-infective,

Foscavir®, acquired from AstraZeneca in 2010. For more information, please visit [www.clinigengroup.com](http://www.clinigengroup.com).

## **About Theravance**

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Theravance's key programs include: RELVAR™ or BREO™ (FF/VI), ANORO™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist program. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit Theravance's web site at [www.theravance.com](http://www.theravance.com).

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VIBATIV® is a registered trademark of Theravance, Inc.

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives and future events. Theravance intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the status and timing of clinical studies, data analysis and communication of results, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates (including, with respect to VIBATIV®, statements regarding any expectation (a) that we will be able to respond fully or adequately to FDA's requests using currently existing clinical data, (b) that the FDA will approve the VIBATIV® nosocomial pneumonia NDA on the basis of existing preclinical and clinical data or at all or (c) regarding the timing of the European Commission releasing the suspended marketing authorization for VIBATIV®), statements concerning the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, statements concerning expectations for the discovery, development and commercialization of product candidates, and projections of revenue, expenses and other financial items. These statements are based on the current estimates and assumptions of the management of Theravance as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance to be materially different from those reflected in its forward-looking statements. Important factors that could cause

actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to delays or difficulties in commencing or completing clinical and non-clinical studies, the potential that results of clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, delays or failure to achieve regulatory approvals for product candidates, risks of relying on third-party manufacturers for the supply of our product and product candidates and risks of collaborating with third parties to discover, develop and commercialize products. These and other risks are described in greater detail under the heading "Risk Factors" contained in Theravance's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 26, 2013 and the risks discussed in our other period filings with SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance assumes no obligation to update its forward-looking statements.

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