

## Theravance Biopharma and SciClone Pharmaceuticals Enter Into Development and Commercialization Agreement for VIBATIV(R) (Telavancin) in China

### Once-Daily, Dual Mechanism Antibiotic Possesses Profile to Play Key Role in Global Fight Against Antimicrobial Resistance

GEORGE TOWN, GRAND CAYMAN and FOSTER CITY, CA -- (Marketwired) -- 05/27/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma"), through an affiliate, and SciClone Pharmaceuticals (NASDAQ: SCLN) ("SciClone"), a U.S.-based, China-focused specialty pharmaceutical company, today announced they have entered into a development and commercialization agreement granting SciClone exclusive development and commercial rights for the antibiotic VIBATIV<sup>®</sup> (telavancin) in China and certain adjacent territories. The companies plan to pursue development and commercialization of VIBATIV in hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP). Additional indications may include complicated skin and skin structure infections (cSSSI), and potentially bacteremia.

VIBATIV is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with *in vitro* potency and a dual mechanism of action whereby telavancin both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. The drug's proven efficacy against difficult-to-treat infections has been demonstrated in several large, multinational registrational studies, which involved one of the largest cohorts of patients with methicillin-resistant *Staphylococcus aureus* (MRSA) infections studied to date. Additionally, there is extensive and well-documented evidence of the drug's *in vitro* potency and *in vivo* activity against a broad collection of bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant.

Under the terms of the agreement, Theravance Biopharma has granted SciClone exclusive development and commercialization rights to VIBATIV in China, as well as the Hong Kong SAR, the Macau SAR, Taiwan and Vietnam. In exchange, Theravance Biopharma will be eligible to receive upfront and regulatory milestone payments totaling \$6 million. SciClone will be responsible for all aspects of development and commercialization in the partnered regions, including pre- and post-launch activities and product registration. Theravance Biopharma will sell to SciClone all clinical and commercial product required to develop and commercialize VIBATIV in China.

"Partnering with SciClone and expanding into the large and growing China market is a key component of Theravance Biopharma's strategy to leverage regional partners to broaden our commercial reach and establish VIBATIV as a valuable global brand," said Frank Pasqualone, Senior Vice President, Development and Operations at Theravance Biopharma. "Our companies share the belief that VIBATIV can play a significant role in combating difficult-to-treat infections. SciClone's proven experience and expertise in navigating the complex regulatory and commercial landscape in China provide us confidence in their ability to obtain regulatory approval of VIBATIV in China and maximize the value of VIBATIV in its licensed regions."

"We believe that VIBATIV is a very valuable addition to our portfolio of high quality, differentiated products, and targets a key, under-appreciated public health concern in China, namely the high level of antibiotic resistance," said Friedhelm Blobel, PhD, Chief Executive Officer of SciClone. "We believe that its many attractive product attributes, including its dual mechanism of action, bactericidal activity and well documented evidence of *in vitro* potency against a broad collection of difficult-to-treat and multi-drug resistant Gram-positive clinical pathogens, including MRSA, can establish VIBATIV as a valuable asset in the antibacterial armamentarium in China for multiple infection types. If VIBATIV is approved in China, we intend to leverage our deep knowledge of the infectious disease segment and our ZADAXIN<sup>®</sup> regulatory and commercial infrastructure to support the market success of this important brand."

#### About VIBATIV<sup>®</sup> (telavancin)

VIBATIV<sup>®</sup> was discovered internally in a research program dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including MRSA. VIBATIV is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with *in vitro* potency and a dual mechanism of action whereby telavancin both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. VIBATIV for injection is approved in the U.S. for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Staphylococcus 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 *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains.

Theravance Biopharma plans to market VIBATIV in markets outside the United States where the drug is approved through a network of partners. To date, the company has secured partners for VIBATIV in the following geographies -- Europe, Canada, Middle East, North Africa, Israel, Russia and China.

## **VIBATIV<sup>®</sup> Important Safety Information (U.S.)**

### **Mortality**

Patients with pre-existing moderate/severe renal impairment (CrCl  $\leq$ 50 mL/min) who were treated with VIBATIV<sup>®</sup> for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia had increased mortality observed versus vancomycin. Use of VIBATIV in patients with pre-existing moderate/severe renal impairment (CrCl  $\leq$ 50 mL/min) should be considered only when the anticipated benefit to the patient outweighs the potential risk.

### **Nephrotoxicity**

New onset or worsening renal impairment occurred in patients who received VIBATIV. 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 prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV versus discontinuing and initiating therapy with an alternative agent should be assessed.

### **Fetal Risk**

Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV. Avoid use of VIBATIV 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 treatment.

### **Contraindication**

Intravenous unfractionated heparin sodium is contraindicated with VIBATIV administration due to artificially prolonged activated partial thromboplastin time (aPTT) test results for up to 18 hours after VIBATIV administration.

VIBATIV is contraindicated in patients with a known hypersensitivity to the drug.

### **Hypersensitivity Reactions**

Serious and potentially fatal hypersensitivity reactions, including anaphylactic reactions, may occur after first or subsequent doses. VIBATIV should be used with caution in patients with known hypersensitivity to vancomycin.

### **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 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.

### **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.

### **Most Common Adverse Reactions**

The most common adverse reactions (greater than or equal to 10% of patients treated with VIBATIV) were diarrhea, taste disturbance, nausea, vomiting, and foamy urine.

Full Prescribing Information, including Boxed Warning and Medication Guide in the U.S., is available at [www.VIBATIV.com](http://www.VIBATIV.com).

### **About Theravance Biopharma**

The mission of Theravance Biopharma (NASDAQ: TBPH) is to create value from a unique and diverse set of assets: an approved product; a development pipeline of late-stage assets; and a productive research platform designed for long-term growth.

Our pipeline of internally discovered product candidates includes potential best-in-class opportunities in underserved markets in the acute care setting, representing multiple opportunities for value creation. VIBATIV<sup>®</sup> (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S. and Europe for certain difficult-to-treat infections. TD-4208 is an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for COPD. Axelopran (TD-1211) is an investigational potential once-daily, oral treatment for opioid-induced constipation (OIC). Our earlier-stage clinical assets represent novel approaches for potentially treating diseases of the lung and gastrointestinal tract and infectious disease. In addition, we have an economic interest in future payments that may be made by GSK pursuant to its agreements with Theravance, Inc. relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (or the "Closed Triple").

With our successful drug discovery and development track record, commercial infrastructure, experienced management team and efficient corporate structure, we believe that we are well positioned to create value for our shareholders and make a difference in the lives of patients.

For more information, please visit [www.theravance.com](http://www.theravance.com).

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### **Theravance Biopharma Forward-Looking Statements**

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 Biopharma 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 Company's strategies, plans and objectives, the Company's regulatory strategies and timing of clinical studies, the potential benefits and mechanisms of action of the Company's product and product candidates, the Company's expectations for product candidates through development and commercialization (including their potential as components of combination therapies). These statements are based on the current estimates and assumptions of the management of Theravance Biopharma as of the date of the press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance Biopharma to be materially different from those reflected in the 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 studies, the potential that results from clinical or non-clinical studies indicate the Company's product candidates are unsafe or ineffective (including when our product candidates are studied in combination with other compounds), the feasibility of undertaking future clinical trials for our product candidates based on FDA policies and feedback, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with third parties to discover, develop and commercialize products and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure. Other risks affecting Theravance Biopharma are described under the heading "Risk Factors" contained in Theravance Biopharma's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 13, 2015. In addition to the risks described above and in Theravance Biopharma's other filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance Biopharma assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

### **About SciClone**

SciClone Pharmaceuticals is a revenue-generating, specialty pharmaceutical company with a substantial commercial business

in China and a product portfolio spanning major therapeutic markets including oncology, infectious diseases and cardiovascular disorders. SciClone's proprietary lead product, ZADAXIN<sup>®</sup> (thymalfasin), is approved in over 30 countries and may be used for the treatment of hepatitis B (HBV), hepatitis C (HCV), and certain cancers, and as a vaccine adjuvant, according to the local regulatory approvals. The Company has successfully in-licensed and commercialized products with the potential to become future market leaders and to drive the Company's long-term growth, including DC Bead<sup>®</sup>, a novel treatment for liver cancer. Through its promotion business with pharmaceutical partners, SciClone also markets multiple branded products in China which are therapeutically differentiated. SciClone is a publicly-held corporation based in Foster City, California, and trades on the NASDAQ Global Select Market under the symbol SCLN. For additional information, please visit [www.sciclone.com](http://www.sciclone.com).

### ***SciClone Forward-Looking Statements***

This press release contains forward-looking statements regarding the prospects for VIBATIV in China and certain adjacent territories and other matters. Readers are urged to consider statements that include the words "may," "will," "would," "could," "should," "might," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," "unaudited," "approximately" or the negative of those words or other comparable words to be uncertain and forward-looking. These statements are subject to risks and uncertainties that are difficult to predict and actual outcomes may differ materially. These include but are not limited to risks relating to the product development and clinical trial process, including uncertainties regarding the time and costs related thereto, and risks relating to performance by us and by Theravance of obligations under the agreement with Theravance Biopharma, as well as risks and uncertainties relating to: the course, cost and outcome of regulatory matters, including regulatory approvals and future pricing decisions by authorities in China; the on-going regulatory investigations and expenses related thereto, including potential fines and/or other remedies; Additional factors that could cause actual results to differ materially from those anticipated by our forward-looking statements are described under "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 on file with the Securities and Exchange Commission and in subsequent Securities and Exchange Commission filings. All forward-looking statements are based on information currently available to SciClone and SciClone assumes no obligation to update any such forward-looking statements.

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