

## **Takeda Licenses Global Rights to Theravance Biopharma's TD-8954, a Novel 5-HT4 Agonist and Motility Agent for Gastrointestinal Motility Disorders**

### **Deal Provides Takeda Global Rights to Selective 5-HT4 Agonist; Highlights Takeda's Commitment to Gastroenterology as a Core Therapeutic Area**

DUBLIN, IRELAND and OSAKA, JAPAN -- (Marketwired) -- 06/08/16 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") and Takeda Pharmaceutical Company Limited (TSE: 4502) ("Takeda") today announced that the companies have entered into a global license, development and commercialization agreement for TD-8954, a selective 5-HT4 receptor agonist being investigated for potential use in the treatment of gastrointestinal motility disorders, including enteral feeding intolerance ("EFI").

TD-8954 is being developed for the short-term use with EFI to achieve early nutritional adequacy in critically ill patients at high nutritional risk, an indication for which the compound received U.S. Food and Drug Administration (FDA) Fast Track Designation. Theravance Biopharma has most recently completed a study evaluating the safety, tolerability and pharmacodynamics of a single dose of the compound administered intravenously compared to metoclopramide in critically ill patients with EFI.

"The addition of TD-8954 to our portfolio highlights Takeda's commitment to the development of treatments to improve the health of patients with gastroenterological disorders," said Asit Parikh, M.D., Ph.D., Head, Gastroenterology Therapeutic Area Unit, Takeda. "As a leader in gastroenterology, Takeda has a history of bringing innovative treatments to patients where there is significant unmet need. We believe that TD-8954 has the potential to deliver therapeutic benefit to patients with gastrointestinal motility disorders, including EFI. Today EFI impacts approximately one million Americans and there are currently no FDA-approved treatment options available."

"This is an important licensing deal for Theravance Biopharma as it provides a path forward for the development of this much-needed treatment option. Our single-dose study of TD-8954 in critically ill patients with EFI provided early confidence in the potential for TD-8954 to improve gastric emptying time. This is important as delayed gastric emptying makes it more difficult to feed patients in the ICU, slowing their recovery time, extending their stay in the ICU and increasing the risk of ICU-related complications," said Rick E. Winningham, Chairman and Chief Executive Officer of Theravance Biopharma. "Takeda is an industry leader in the development of treatments for gastrointestinal disorders, which we believe makes the company an ideal partner to drive the continued advancement of TD-8954."

Theravance Biopharma will receive an upfront cash payment of \$15 million and will be eligible to receive success based development and sales milestone payments as well as double digit royalties on worldwide net sales by Takeda. The first \$110 million of potential milestones are associated with the development, regulatory and commercial launch milestones for EFI or other intravenously dosed indications. The transaction is expected to close during the second calendar quarter of 2016, and is subject to customary closing conditions and clearance under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act").

#### **About Takeda**

Takeda Pharmaceutical Company Limited (TSE: 4502) is a global, R&D-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its research efforts on oncology, gastroenterology and central nervous system therapeutic areas. It also has specific development programs in specialty cardiovascular diseases as well as late-stage candidates for vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology, central nervous system and gastroenterology, as well as its presence in emerging markets, fuel the growth of Takeda. More than 30,000 Takeda employees are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit <http://www.takeda.com/news>.

#### **About Theravance Biopharma**

Theravance Biopharma is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in the lives of patients suffering from serious illness. Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions

primarily in the acute care setting. VIBATIV<sup>®</sup> (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Our neprilysin (NEP) inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop GI-targeted pan-Janus kinase (JAK) inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

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

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### ***Takeda's Forward-Looking Statements***

This press release contains "forward-looking statements." Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future, statements regarding the expected timing of filings and approvals relating to the transaction, the expected timing of the completion of the transaction, the ability to complete the transaction or to satisfy the various closing conditions, future revenues and profitability from or growth or any assumptions underlying any of the foregoing. Statements made in the future tense, and words such as "anticipate," "expect," "project," "continue," "believe," "plan," "estimate," "pro forma," "intend," "potential," "target," "forecast," "guidance," "outlook," "seek," "assume," "will," "may," "should," and similar expressions are intended to qualify as forward-looking statements. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to: required regulatory approvals for the transaction may not be obtained in a timely manner, if at all; the conditions to closing of the transaction may not be satisfied; competitive pressures and developments; applicable laws and regulations; the success or failure of product development programs; actions of regulatory authorities and the timing thereof; changes in exchange rates; and claims or concerns regarding the safety or efficacy of marketed products or product candidates in development.

The forward-looking statements contained in this press release speak only as of the date of this press release, and neither Theravance Biopharma nor Takeda undertakes any obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If one or more of these statements is updated or corrected, investors and others should not conclude that additional updates or corrections will be made.

### ***Theravance Biopharma's 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 and results of clinical studies, the potential benefits and mechanisms of action of the Company's product and product candidates and the Company's expectations for product candidates through development and commercialization. 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, 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. 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 10, 2016. 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.

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