Theravance Biopharma
Medicines That Make a Difference
September 10, 2015

Theravance Biopharma Presents Positive Clinical Data on Fixed-Dose Combination (FDC) of Axelopran (TD-1211) and Oxycodone at PAINWeek(R) 2015

FDC Designed to Offer Pain Relief Without Opioid-Induced Constipation (OIC); Study Results Demonstrate Bioequivalence of Oxycodone From FDC Compared to Individual Components With No Significant Impact on Systemic Oxycodone Exposure

DUBLIN, IRELAND -- (Marketwired) -- 09/10/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced additional positive data from a Phase 1 study of its fixed-dose combination (FDC) of axelopran (TD-1211) and controlled-release oxycodone. The study showed oxycodone from the FDC was bioequivalent to the two components co-administered as individual tablets. Importantly, findings demonstrated that axelopran does not significantly alter systemic exposure to oxycodone when delivered as a FDC relative to when co-administered as individual tablets. Additionally, axelopran from the FDC and the components co-administered as individual tablets were bioequivalent by area under the concentration-time curve comparison. These results suggest that Theravance Biopharma's axelopran/oxycodone FDC has the potential to be developed as a single abuse-deterrent tablet designed to provide pain relief without opioid-induced constipation (OIC). Study findings were delivered in a poster presentation this week at PAINWeek® 2015 being held September 8-12 in Las Vegas, Nevada.

Theravance Biopharma researchers enrolled 28 healthy subjects in an open-label, randomized, four-period crossover study to determine the effect of axelopran on oxycodone exposure. Subjects received either axelopran alone, oxycodone alone, axelopran and oxycodone co-administered as two separate tablets, or the FDC, consisting of a spray-coat application of axelopran onto oxycodone. The relative bioavailability of oxycodone met criteria for bioequivalence between all treatments, demonstrating no interaction of axelopran or the FDC formulation on oxycodone pharmacokinetics. Furthermore, axelopran relative bioavailability also met area under the concentration-time curve bioequivalence criteria between the FDC and the co-administration of the individual treatments. Oxycodone and axelopran bioequivalence was demonstrated for all statistically powered comparisons between treatments.

"We are very pleased to see clinical data showing that our fixed-dose combination of axelopran and oxycodone is behaving in a similar fashion to those two agents co-administered as individual tablets, and specifically that axelopran does not impact the levels of oxycodone in the body," said Brett Haumann, Senior Vice President, Clinical Development of Theravance Biopharma. "We believe that there is a large and underserved market for a treatment that is able to offer the proven pain relief of an opioid without the opioid-induced constipation. This fixed-dose combination not only appears to have the potential to address this market but could do so in a single abuse-deterrent pill, providing an important benefit for patients."

Axelopran (TD-1211) is a potentially best-in-class, once-daily, oral peripherally active mu opioid receptor antagonist being developed by Theravance Biopharma for the treatment of OIC and related gastrointestinal symptoms associated with constipation. The drug candidate, which has completed long term toxicology studies, is intended to normalize bowel function without impacting analgesia. As a stand-alone treatment, axelopran has been successfully advanced through Phase 2 studies, demonstrating a rapid restoration of normal bowel function followed by maintenance in OIC patients compared to placebo. Phase 2 study data also shows statistically significant improvements in a range of gastrointestinal symptoms in OIC patients for axelopran as compared to placebo. Theravance Biopharma believes that the therapy has a number of important competitive advantages and has developed a patient reported outcome (PRO) measure designed to evaluate relief of additional patient symptoms associated with the long term use of opioid analgesics in an effort to differentiate axelopran from potential competitors. While the company is currently refining its development and commercial strategy for axelopran, the PRO is ready for use in a Phase 3 registrational program.

Concurrently, Theravance Biopharma is developing its FDC of axelopran and oxycodone as a single, once-daily, abuse-deterrent pill for the combined treatment of pain and OIC. This treatment is based on the company's proprietary spray-coating formulation which allows oxycodone to be coated with axelopran in a single pill without any modification of oxycodone, its activity or abuse-deterrent characteristics. Based on its work to date, the company believes this spray-coating technology is applicable to a broad range of opioids, allowing for a potential FDC platform.

Based upon market research, Theravance Biopharma estimates that approximately 11 million patients in the U.S. currently use chronic opioids to deal with a range of chronic disease, lower back pain and several forms of arthritis. Of those patients, nearly 70 percent, or more than 7 million, are reporting constipation associated with their opioid use. Current treatment options for OIC are fairly limited with a significant portion of patients unable to achieve relief with over-the-counter laxatives. Theravance

Biopharma believes that axelopran and its axelopran/oxycodone FDC are well positioned to address this significant unmet need in the treatment of OIC.

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® (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 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 GlaxoSmithKline plc pursuant to its agreements with Theravance, Inc. relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium and vilanterol (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.

About PAINWeek

PAINWeek is the largest US pain conference for frontline practitioners with an interest in pain management. Convening at The Cosmopolitan of Las Vegas for its 9th year on September 8-12, 2015, PAINWeek expects to welcome over 2100 physicians, nurses, pharmacists, and other healthcare professionals for a comprehensive program of course offerings, satellite events, and exhibits. Over 120 hours of continuing medical education activities will be presented. To learn more and register for PAINWeek 2015, visit www.painweek.org.

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, risks of collaborating with third parties to discover, develop and commercialize product and product candidates and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate 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 August 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.

Contact Information:

Renee Gala
Chief Financial Officer
650-808-4045
investor.relations@theravance.com

Tim Brons
Vida Strategic Partners (media)
646-319-8981
tbrons@vidasp.com

Source: Theravance Biopharma