THERAVANCE, INC.
A ROYALTY MANAGEMENT COMPANY

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Theravance Announces Positive Topline Results From TD-1211 Phase 2b Study 0084 for the Treatment of Opioid-Induced Constipation

All Doses Met Primary Efficacy Endpoint and Resulted in Significant Improvements in Patient's Global Impression of Change

SOUTH SAN FRANCISCO, Calif., July 10, 2012 (GLOBE NEWSWIRE) -- Theravance, Inc. (Nasdaq:THRX) today announced positive topline results from 0084, the key study in the Phase 2b program evaluating TD-1211 as a potential treatment for chronic, non-cancer pain patients with opioid-induced constipation (OIC). TD-1211 is an investigational, orally administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed with the goal of alleviating gastrointestinal side effects of opioid therapy without affecting analgesia. These positive clinical results support progression into Phase 3 development for the treatment of patients with opioid-induced constipation.

The Phase 2b program consists of three studies (0074, 0076 and 0084) designed to evaluate doses and dosing regimens for Phase 3. The key study in this program is 0084, a 5-week, randomized, double-blind, parallel-group, dose-ranging study evaluating 5 mg, 10 mg, and 15 mg doses of TD-1211 versus placebo. This study randomized 217 patients with OIC. During the 2-week baseline period, patients had on average 0.1 to 0.3 complete spontaneous bowel movements (CSBMs) per week. All patients randomized into a TD-1211 arm received 5 mg for the first four days of dosing. On Day 5, these patients either remained at 5 mg or were dose-escalated to 10 mg or 15 mg for the remainder of the 5-week treatment period. Patients randomized into the placebo arm received placebo for all five weeks.

The primary efficacy endpoint was the change from baseline in average CSBMs per week over the last four weeks of treatment for the three doses of TD-1211 and placebo in the Efficacy Analysis (EA) population. Study 0084 achieved the primary efficacy endpoint for all doses of TD-1211.

EA Population

		TD-1211		
	Placebo (n=52)	**5 mg (n=53)**	**10 mg (n=49)**	**15 mg (n=47)**
Baseline	0.2	0.1	0.3	0.2
Treatment Period (Weeks 2 — 5)	1.0	1.6	3.0	2.7
Least Squares (LS) Mean Differences from Placebo		0.97	1.61	1.79
p-value		p=0.0413	p=0.0010	p=0.0003

A key secondary endpoint was the change from baseline in average spontaneous bowel movements (SBMs) per week over the last four weeks of treatment for the three doses of TD-1211 and placebo in the EA population.

EA Population

		TD-1211		
	Placebo (n=52)	**5 mg (n=53)**	**10 mg (n=49)**	**15 mg (n=47)**
Baseline	1.2	1.2	1.1	1.2
Treatment Period (Weeks 2 — 5)	3.1	3.9	4.5	4.9
LS Mean Differences from Placebo		0.88	1.46	1.83
p-value		p=0.0739	p=0.0038	p=0.0003

In a pre-specified responder analysis, defined as at least three SBMs per week and an increase of at least one SBM per week from baseline for at least three of the last four weeks of the treatment period, patients on TD-1211 demonstrated a response of 59% (5 mg), 61% (10 mg) and 70% (15 mg) compared to 39% in the placebo group. The 5 mg (p=0.0401), 10 mg (p=0.0222) and the 15 mg (p=0.0016) responder rates were statistically significantly higher than placebo. An identical analysis using CSBMs was statistically significant at the 10 mg and 15 mg doses.

In another secondary endpoint, 66% of patients in the 15 mg TD-1211 group reported that their constipation was *better* or *much better* on a 7-point global impression of change scale after five weeks of treatment, which was significantly higher than the 21% of patients in the placebo arm ($p < 0.0001$). Results from patients on 5 mg and 10 mg treatment arms also achieved statistical significance versus placebo.

TD-1211 was generally well tolerated in patients. The percentage of patients with a treatment-emergent adverse event was 44% for placebo compared to 39%-55% for TD-1211. The most common adverse events reported were abdominal pain (13.0% for TD-1211 vs. 11.1% for placebo), nausea (9.3% vs. 3.7%), diarrhea (8.7% vs. 0%), and headache (5.0% vs. 5.6%). A majority of treatment-related gastrointestinal (GI) adverse events were associated with initiation of treatment, resolved within a few days and were mild or moderate. There was no evidence of CNS opioid withdrawal or analgesic interference based on the Clinician Opioid Withdrawal Score, daily opioid use or the assessment of daily pain scores. Four patients experienced serious adverse events, none of which were treatment-related.

"We are impressed with the durability of response through Week 5 particularly for the 10 mg and 15 mg dose strengths," said Mathai Mammen, MD, PhD, Senior Vice President of Research and Early Clinical Development. "In a measure of satisfaction with treatment, over 90% of patients on 15 mg reported that they would be likely to use the medication again if offered by a physician after FDA approval."

"The results from Study 0084 are very encouraging and support progression into Phase 3 development," said Rick E Winningham, Chief Executive Officer. "Over 6 million Americans are on opioid therapy for chronic pain with a significant percentage of them suffering from OIC despite use of current treatments. Our goal with this program is to restore normal bowel function in OIC patients."

About the Phase 2b Program

The Phase 2b program consists of three studies: 0074, 0076 and 0084. The key clinical study (0084) was a randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study in the US that randomized 217 patients. Patients were eligible to enroll in the study if they experienced five or fewer SBMs and at least one additional symptom of constipation during the 2-week baseline period.

Study 0074 was a randomized, double-blind, placebo-controlled, dose-escalation study to assess the safety, tolerability, and clinical activity of dose-to-effect regimens of TD-1211 in approximately 69 randomized patients with OIC. The primary endpoint of this study was measurement of frequency and severity of treatment-emergent adverse events in patients with OIC. Study 0076 is an open-label, single-blind, dose escalation pilot study to assess the safety and tolerability of TD-1211 in approximately 95 patients with OIC, and is near completion.Data reviewed to date support further development of TD-1211. Detailed results from all three studies will be presented at future medical conferences.

About TD-1211

TD-1211 was discovered by Theravance using the application of multivalent drug design in a research program dedicated to finding new treatments for GI motility disorders/pain. TD-1211 is an investigational, once-daily, orally administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed with the goal of alleviating gastrointestinal side effects of opioid therapy without affecting analgesia.

About Opioid-Induced Constipation

Opioid analgesic medications are widely used in the treatment of acute and chronic pain. Opioid-induced constipation (OIC) is a highly prevalent and well recognized complication among the millions of patients on chronic opioid therapy. OIC has a significant impact on the quality of life of patients, and is currently poorly treated with laxatives. Consisting of constipation, delayed gastric emptying, abdominal discomfort and nausea, OIC can be debilitating in patients. Theravance believes that there remains a major unmet medical need for an oral therapy that is efficacious and well tolerated in OIC patients.

Conference Call and Webcast Information

Theravance has scheduled an analyst conference call to discuss this announcement today at 5:00 p.m. Eastern Daylight Time. Analysts who wish to participate in the live call by telephone, please dial (877) 837-3908 from the U.S., or (973) 890-8166 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting Theravance's web site at www.theravance.com. To listen to the live call and to download the slide presentation, please go to Theravance's web site 15 minutes prior to its start to register, download, and install any necessary audio software.

A replay of the conference call will be available on Theravance's web site for 30 days through August 9, 2012. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on July 17, 2012 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 99539228.

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: RELOVAIR™, LAMA/LABA (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist (PμMA) 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.

This press release contains and the conference call will contain 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 Exchange Act 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, statements concerning enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, statements concerning expectations for product candidates through development and commercialization 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 the conference call 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 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 develop and commercialize products. These and other risks are described in greater detail under the heading "Risk Factors" contained in Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 2, 2012 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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