Theravance Biopharma, Inc. Reports Second Quarter 2019 Financial Results and Provides Business Update

July 31, 2019

- Late-stage clinical studies of TD-1473 and ampreloxetine progressing

- Phase 1 results including biomarker data in asthmatics for lung-selective inhaled pan-JAK inhibitor TD-8236 expected in September 2019

- Strong customer acceptance and brand performance of YUPELRI® (revefenacin) inhalation solution advancing in partnership with Mylan

- Arbitration against Innoviva ongoing; resolution expected in Q3 2019

DUBLIN, July 31, 2019 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today reported financial results for the second quarter ended June 30, 2019. Revenue for the second quarter of 2019 was $26.2 million. Second quarter operating loss was $42.5 million or $31.2 million excluding share-based compensation expense. Cash, cash equivalents, and marketable securities totaled $396.1 million as of June 30, 2019.

Rick E Winningham, Chief Executive Officer, commented: "2019 is a critical year of progress that sets the stage for what we believe will be an extraordinary year of data-driven, value-creating milestones in 2020.

"TD-1473, our gut-selective pan-JAK inhibitor, is moving forward in a Phase 2b/3 study in ulcerative colitis and a Phase 2 study in Crohn's disease. Ampreloxetine, our norepinephrine reuptake inhibitor, is advancing in a Phase 3 registrational program in symptomatic nOH. New data from the Phase 2 study of ampreloxetine presented at recent scientific meetings demonstrated consistent and durable improvements in both symptom severity and daily activity performance in patients with nOH treated with ampreloxetine for 20 weeks. These data further support the potential of this therapy to provide patients with greater durability of effect. The Phase 1 study of TD-8236, our lung-selective inhaled pan-JAK inhibitor, in healthy volunteers and asthmatics is ongoing, and we anticipate results in September 2019.

"The YUPELRI U.S. launch is progressing well in partnership with Mylan and we are pleased by our progress against key performance metrics. Additionally, we were excited to announce the expansion of our development and commercialization agreement with Mylan for nebulized revefenacin to include China. Lastly, sales of GSK's TRELEGY ELLIPTA for COPD continue to grow, supported by product approvals and launches in additional geographies. We expect GSK to submit regulatory submissions in support of an asthma indication in the second half of this year, following the completion of the Phase 3 CAPTAIN study of TRELEGY ELLIPTA in patients with asthma.

"We are well capitalized and enter the second half of the year in a strong position to continue to drive our key programs toward meaningful inflection points. We are proud of our ability to advance a rich pipeline of differentiated assets that can yield a broad line-up of important milestones and catalysts over the next 12 to 18 months as our later-stage trials mature, earlier-stage programs advance to the clinic, and our commercial efforts gain traction. We look forward to the near-term resolution of the dispute with Innoviva to ensure we retain our economics related to TRELEGY ELLIPTA," concluded Mr. Winningham.

Program Updates

TD-1473 (gut-selective pan-Janus kinase (JAK) inhibitor):

- Supplemental data from the four-week exploratory Phase 1b study of TD-1473 in patients with ulcerative colitis shared in an oral presentation at Digestive Disease Week (DDW) in May 2019
  - Study designed to measure signals of localized biologic activity, and with little to no systemic exposure or immunosuppression
  - Data were positive across a variety of measures, including disease activity, including rectal bleeding and endoscopic improvement, as well as biomarker changes confirming target engagement
- Registrational Phase 2b/3 induction and maintenance study in ulcerative colitis (RHEA) and Phase 2 induction study in Crohn's disease (DIONE) progressing
- Data from the Phase 2b portion of the ulcerative colitis and Phase 2 Crohn's disease studies planned late-2020

Ampreloxetine (TD-9855, norepinephrine reuptake inhibitor (NRI)):

- New 20-week data from the Phase 2 study in patients with neurogenic orthostatic hypotension (nOH) presented at the

International Association of Parkinsonism and Related Disorders (IAPRD) in June 2019 and in an oral presentation at the 32nd European Neurology Congress (ENC) in July 2019
    - Consistent and durable improvements in both symptom severity and daily activity performance in patients with nOH were sustained through 20 weeks of ampreloxetine therapy
    - Following withdrawal of ampreloxetine treatment, patients' symptom severity and daily activity scores returned to pre-treatment baseline levels
- Ongoing registrational program in symptomatic nOH comprised of two studies:
    - Phase 3 4-week treatment study (SEQUOIA), with data expected in 2H 2020
    - Phase 3 4-month open label study followed by a 6-week randomized withdrawal phase (REDWOOD) to demonstrate durability of response

TD-8236 (novel, lung-selective inhaled pan-JAK inhibitor for serious respiratory diseases):

- Phase 1 data expected in September 2019; study designed to evaluate safety and provide biomarker data of TD-8236 in healthy volunteers and asthmatic patients
    - Program goal in asthma is the prevention of exacerbations and the improvement of symptoms in patients uncontrolled by steroids despite compliance
    - TD-8236 shown to potently inhibit targeted mediators of Th2-high and Th2-low asthma in human cells in preclinical studies

YUPELRI® (revefenacin) inhalation solution (lung-selective nebulized long-acting muscarinic antagonist (LAMA)):

- First and only once-daily, nebulized bronchodilator approved in the US for the maintenance treatment of patients with COPD
- Launch underway with partner Mylan; continued strong customer acceptance and brand performance across key market metrics; combined sales infrastructures covering the hospital, hospital discharge, and home health settings
- Development and commercialization agreement with Mylan for nebulized revefenacin expanded to include China and certain adjacent geographies

TRELEGY ELLIPTA (first once-daily single inhaler triple therapy for COPD)[1]:

- Q2 2019 net sales of $151.4 million; Theravance Biopharma entitled to approximately 5.5% to 8.5% (tiered) of worldwide net sales of the product
- Supplemental NDA submitted to FDA supporting revised labelling for TRELEGY ELLIPTA on reduction in risk of all-cause mortality compared with ANORO ELLIPTA in patients with COPD
- Phase 3 CAPTAIN study in asthma met primary endpoint demonstrating statistically significant improvement in lung function compared with RELVAR/BREO; regulatory submissions planned for 2H 2019
- Product now launched in 36 countries, including Japan; approval in China expected in Q4 2019

Notes:
[1] As reported by Glaxo Group Limited or one of its affiliates (GSK); reported sales converted to USD; economic interest related to TRELEGY ELLIPTA (the combination of fluticasone furoate, aclidinium, and vilanterol, (FF/UMEC/VI), jointly developed by GSK and Innoviva, Inc.) entitles Company to upward tiering payments equal to approximately 5.5% to 8.5% on worldwide net sales of the product (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used in TRC over the next four fiscal quarters). RELVAR/BREO ELLIPTA (FF/VI). ANORO ELLIPTA (UMEC/VI).

Second Quarter Financial Results

Revenue

Total revenue for the second quarter of 2019 was $26.2 million compared to $23.5 million in the same period in 2018. The increase was primarily due to licensing revenue of $18.5 million recognized in the second quarter of 2019 related to the upfront from Mylan for rights to nebulized revefenacin in China and adjacent geographies. The increase was partially offset by a decrease in product sales which resulted from the sale of VIBATIV® to Cumberland Pharmaceuticals in late-2018 and a one-time opt-in received from Alfasigma for velusetrag (TD-5108) in the second quarter of 2018.

Research and Development (R&D) Expenses

R&D expenses for the second quarter of 2019 were $46.4 million, compared to $48.6 million in the same period in 2018. The decrease was primarily due to lower employee-related costs associated with the reduction in force announced in the first quarter of 2019 as well as a decrease in share-based compensation which was partially offset by an increase in external expenses related to the progression of our key programs. Second quarter R&D expenses included non-cash share-based compensation of $5.7 million.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses for the second quarter of 2019 were $22.2 million, compared to $25.0 million in the same period in 2018. The decrease was primarily due to lower VIBATIV-related external expenses due to the sale of VIBATIV to Cumberland in late-2018 as well as a decrease in share-based compensation which was partially offset by higher collaboration expenses associated with the commercial launch of YUPELRI. Second quarter SG&A expenses included non-cash share-based compensation of $5.6 million.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities, excluding restricted cash, totaled $396.1 million as of June 30, 2019. The quarter ending cash balance include proceeds from the upfront payment received from Mylan for rights to nebulized revefenacin in China and adjacent territories.

2019 Financial Guidance

The Company's guidance on operating loss excluding non-cash share-based compensation for the full year of 2019 remains unchanged at $210.0 million to $230.0 million. Operating loss guidance does not include royalty income for TRELEGY ELLIPTA which the Company recognizes as non-operating income. The Company's share of U.S. profits and losses related to the commercialization of YUPELRI, potential future business development collaborations as well as the timing and cost of clinical studies associated with its key programs, among other factors, could impact the Company's financial guidance.

Arbitration Against Innoviva

In May 2019, the Company announced that it had initiated arbitration against Innoviva, Inc. ("Innoviva") in connection with Innoviva's failure to disburse certain royalties to Theravance Biopharma. Innoviva had caused Theravance Respiratory Company, LLC ("TRC LLC") to not make any distributions to Theravance Biopharma with respect to Theravance Biopharma's 85% economic interest in TRC LLC for the quarter ended December 31, 2018. Those distributions were due March 31, 2019. Additionally, Innoviva stated that it intended to cause TRC LLC to withhold making further cash distributions through calendar year 2019. The arbitration hearing commenced on July 23, 2019. Resolution of the arbitration should occur in the third quarter of 2019.

Conference Call and Live Webcast Today at 8:00 am ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 8:00 am ET. To participate in the live call by telephone, please dial (855) 296-9648 from the US, or (920) 663-6266 for international callers, and use the confirmation code 2445969. Those interested in listening to the conference call live via the internet may do so by visiting Theravance Biopharma's website at www.theravance.com, under the Investor Relations section, Presentations and Events. Please go to the website 15 minutes prior to the start of the call to register, download, and install any necessary audio software.

A replay of the conference call will be available on Theravance Biopharma's website for 30 days through August 30, 2019. An audio replay will also be available through 11:00 am ET on August 7, 2019 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 2445969.

About Theravance Biopharma

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including FDA-approved YUPELRI® (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have an economic interest in potential future payments from Glaxo Group or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including TRELEGY ELLIPTA.

For more information, please visit 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, expectations 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 current dispute with Innoviva and TRC LLC, the Company's strategies, plans and objectives, the Company's regulatory strategies and timing of clinical studies (including the data therefrom), the potential characteristics, benefits and mechanisms of action of the Company's product and product candidates, the potential that the Company's research programs will progress product candidates into the clinic, the Company's expectations for product candidates through development, potential regulatory approval and commercialization (including their differentiation from other products or potential products), product sales or profit share revenue and the Company's expectations for its 2019 operating loss, excluding share-based compensation. 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 the conference call 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: the nature of the current dispute with Innoviva and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result involving the current dispute could be adverse to the Company, delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's compounds or product candidates are unsafe or ineffective, risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates based on policies and feedback from regulatory authorities, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with

or relying on third parties to discover, develop, manufacture 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 Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 10, 2019 and Theravance Biopharma's other filings with the SEC. In addition to the risks described above and in Theravance Biopharma's 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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THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	$ -	$ 5,361	$ -	$ 9,040
Collaboration revenue	7,650	18,115	12,988	22,755
Licensing revenue	18,500	-	18,500	-
Total revenue	26,150	23,476	31,488	31,795
Costs and expenses:				
Cost of goods sold	-	(1,448)	-	(622)
Research and development [1]	46,399	48,621	100,217	96,386
Selling, general and administrative [1]	22,227	25,007	47,413	49,711
Total costs and expenses	68,626	72,180	147,630	145,475
Loss from operations	(42,476)	(48,704)	(116,142)	(113,680)
Income from investment in TRC, LLC	8,366	1,949	14,595	2,635
Interest expense	(7,901)	(2,137)	(15,759)	(4,274)
Interest and other income, net	2,374	1,284	5,169	2,768
Loss before income taxes	(39,637)	(47,608)	(112,137)	(112,551)
Provision for income tax (expense) benefit	(201)	6,790	(281)	6,646
Net loss	$ (39,838)	$ (40,818)	$ (112,418)	$ (105,905)
Net loss per share:				
Basic and diluted net loss per share	$ (0.72)	$ (0.76)	$ (2.04)	$ (1.98)
Shares used to compute basic and diluted net loss per share	55,529	53,799	55,235	53,529

[1] Amounts include share-based compensation expense as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2019	2018	2019	2018
Research and development	$ 5,720	$ 6,904	$ 11,880	$ 13,463
Selling, general and administrative	5,578	6,951	11,639	14,390
Total share-based compensation expense	$ 11,298	$ 13,855	$ 23,519	$ 27,853

THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	June 30, 2019	December 31, 2018
Assets	**(Unaudited)**	**(1)**
Current assets:		
Cash and cash equivalents and short-term marketable securities	$ 396,072	$ 505,276
Receivables from collaborative arrangements	979	10,053
Other prepaid and current assets	28,987	17,494
Total current assets	426,038	532,823
Property and equipment, net	12,662	13,176
Long-term marketable securities	-	11,869
Operating lease assets	47,831	-
Restricted cash	833	833
Other assets	5,083	1,534
Total assets	$ 492,447	$ 560,235
Liabilities and Shareholders' Deficit		
Current liabilities	$ 110,136	$ 98,554
Convertible senior notes due 2023, net	225,354	224,818
Non-recourse notes due 2033, net	217,715	229,535
Long-term operating lease liabilities	48,565	-
Other long-term liabilities	27,901	58,917
Shareholders' deficit	(137,224)	(51,589)
Total liabilities and shareholders' deficit	$ 492,447	$ 560,235

(1) The condensed consolidated balance sheet as of December 31, 2018 has been derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

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