# Theravance Biopharma, Inc.

(NASDAQ: TBPH)

First Quarter 2019 Financial Results and Business Update May 7, 2019

# Theravance Biopharma

Medicines That Make a Difference®

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#### **Forward Looking Statements**

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company are subject to risks and uncertainties that may cause actual results to differ materially from the forward-looking statements or projections.

Examples of forward-looking statements in this presentation may include the current dispute with Innoviva, Inc. and TRC LLC, statements relating to 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.

The company's forward-looking statements are based on the estimates and assumptions of management as of the date of this presentation and are subject to risks and uncertainties that may cause the actual results to be materially different than those projected, such as 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 or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective (including when our product candidates are studied in combination with other compounds), delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with third parties to discover, develop and commercialize products, risks associated with establishing and maintaining sales, marketing and distribution capabilities.

Other risks affecting the company are described under the heading "Risk Factors" and elsewhere in the company's Form 10-K filed with the Securities and Exchange Commission (SEC) on February 28, 2019, and other periodic reports filed with the SEC.



## Focus on Strategic Priorities COMMITMENT TO CREATING TRANSFORMATIONAL MEDICINES

Opportunities to Create Transformational Medicines	YUPELRI®	Nebulized LAMA in COPD <ul> <li>Formal commercial launch underway</li> </ul>
	TD-1473	<ul> <li>Intestinally-restricted JAKi for inflammatory intestinal diseases</li> <li>Phase 2 DIONE study in Crohn's disease underway</li> <li>Phase 2b/3 RHEA study in ulcerative colitis underway</li> <li>Supplemental Phase 1b data to be shared in oral presentation at DDW</li> </ul>
	Ampreloxetine	<ul> <li>NRI in symptomatic neurogenic orthostatic hypotension</li> <li>Registrational Phase 3 program progressing</li> <li>5-month data from Phase 2 in nOH to be shared at IAPRD and ENC</li> </ul>
	TD-8236	<ul> <li>Lung-selective inhaled pan-JAK inhibitor for serious respiratory diseases</li> <li>Safety and biomarker data from Phase 1 study in healthy volunteers and asthmatic patients expected 3Q19</li> </ul>
Economic Interest	TRELEGY ELLIPTA <sup>1</sup>	<ul> <li>(FF/UMEC/VI) Single inhaler triple therapy in COPD</li> <li>Product launched in 30 markets, including Japan; additional geographies expected throughout 2019 (incl. China)</li> <li>Positive results from Phase 3 CAPTAIN study in patients with asthma recently announced</li> <li>Potential sNDA in 2H 2019</li> </ul>

#### Significant existing cash resources to fund strategic priorities<sup>2</sup>



<sup>1</sup> TBPH holds 85% economic interest in upward-tiering royalty stream of 6.5% – 10% payable by GSK (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). All statements based on publically available information.

<sup>2</sup> Cash of approximately \$434M as of March 31, 2019 (cash, cash equivalents, and marketable securities)

## **GSK's TRELEGY ELLIPTA** FIRST AND ONLY ONCE-DAILY SINGLE INHALER TRIPLE THERAPY

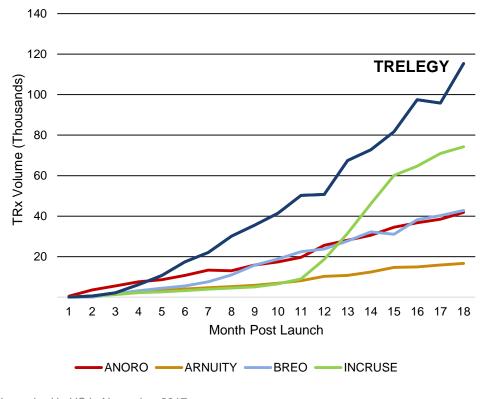
#### **Economic interest in TRELEGY ELLIPTA**

- Upward-tiering royalty of ~5.5% 8.5% of worldwide net sales<sup>1</sup>
- Passive economic interest; no product cost obligations

#### Growth continues after first full year on market

- Available in 30 markets, including recent Japan launch
- Additional geographies expected in 2019; potential for China approval and launch later this year
- Phase 3 asthma study met primary endpoint; data to be submitted for regulatory review once full dataset available

#### Strongest US ELLIPTA Launch to Date



#### Launched in US in November 2017

Source: GSK, IQVIA NPA weekly TRx data. This information is an estimate derived from the use of information under license from the following IQVIA information service: NPA for the time period Sept 2013 through March 2019. IQVIA expressly reserves all rights, including rights of copying, distribution, & republication.

TRELEGY ELLIPTA is FF/UMEC/VI or fluticasone furoate/umeclidinium/vilanterol; comprised of ICS, LAMA, and LABA, active components of Breo (FF/VI) and Anoro (UMEC/VI).

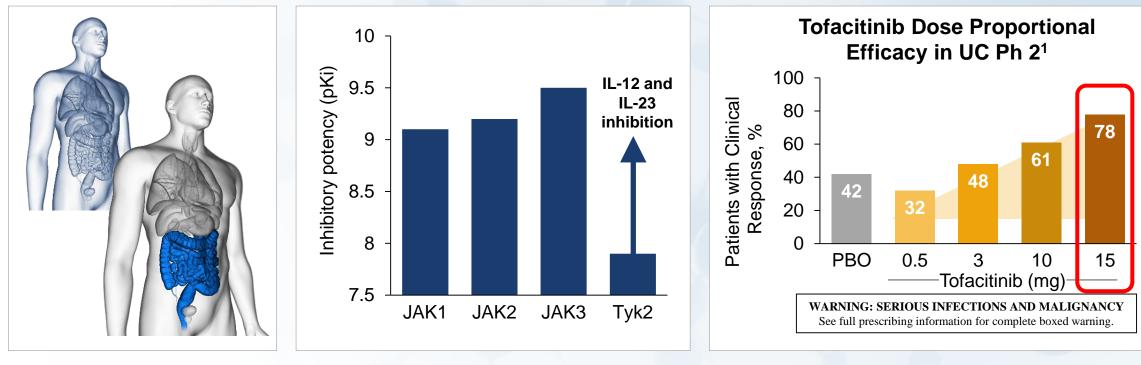
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## **TD-1473 Research Vision** ORAL GUT-SELECTIVE PAN-JAK INHIBITOR



Treat disease at site to maximize efficacy

Optimize pharmacology to include potent inhibition of Tyk2

Improve upon the efficacy of a clinically validated target

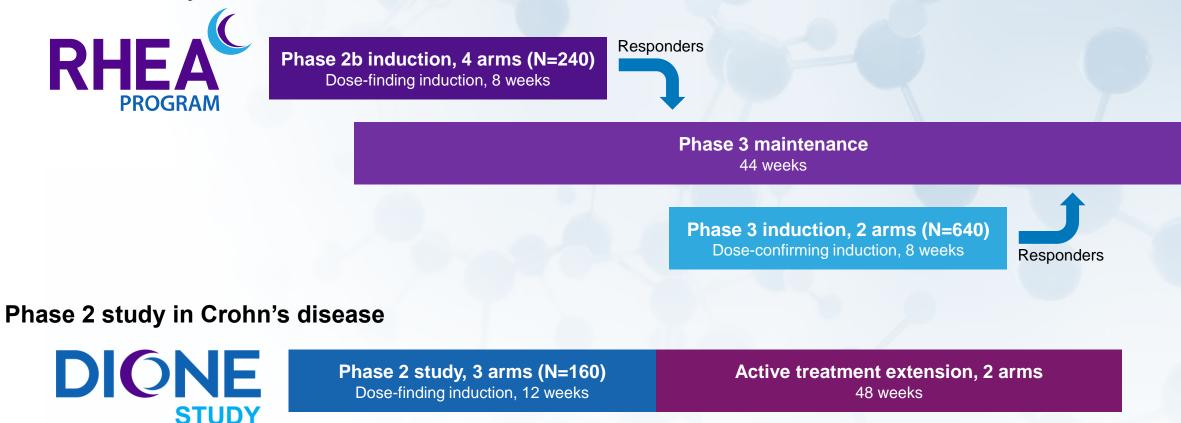
TD-1473 advancing in Phase 2 study in Crohn's disease and Phase 2b/3 study in ulcerative colitis



<sup>1</sup> Sandborn WJ, et al. N EnglJ Med 2012;367:616-24

## TD-1473 Clinical Program LATE STAGE STUDIES IN ULCERATIVE COLITIS AND CROHN'S DISEASE

#### Phase 2b/3 study in ulcerative colitis





## Organ-selective Approach COMPOUNDS DESIGNED TO FULLY HARNESS INTENDED BIOLOGY

#### Conventional Systemic Compound

- Often unable to achieve maximal efficacy due to dose limiting safety
- Narrow therapeutic index

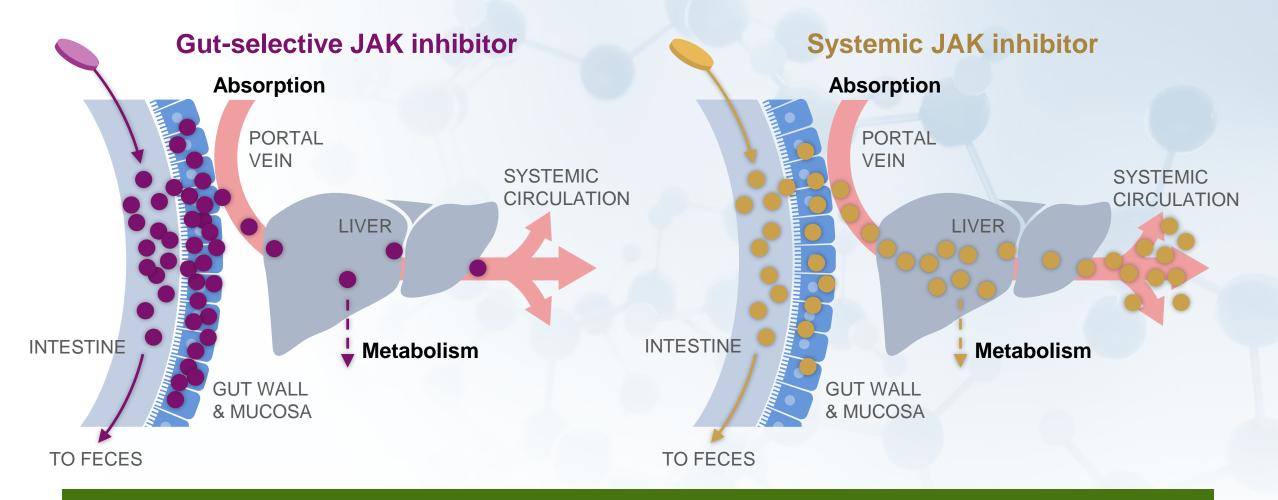
### Theravance Biopharma Organ-selective Compound

- Opportunity to increase dose for improved efficacy, without cost of systemic safety risk
- Expanded therapeutic index





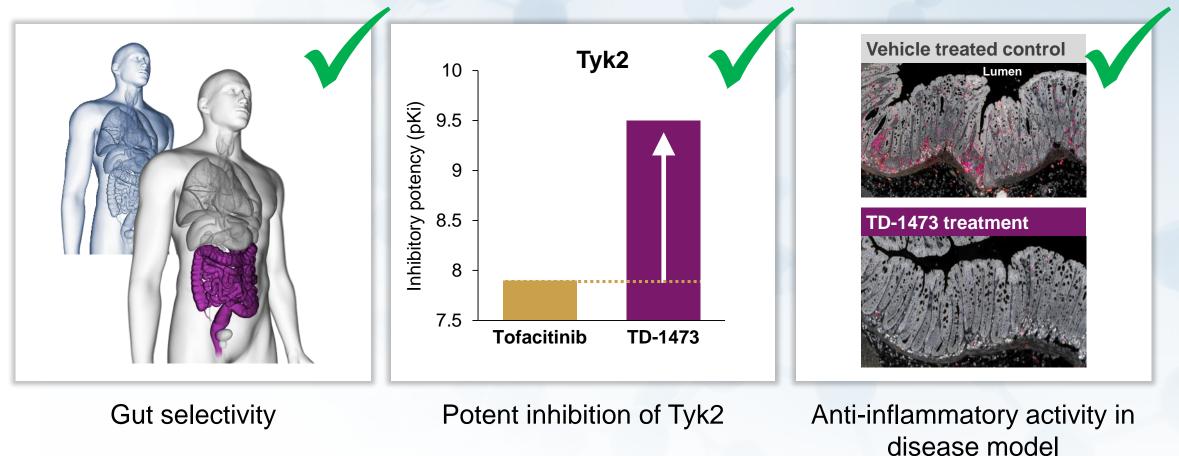
## **Gut-selective Design** INFLAMMATION TREATED AT THE TISSUE OF INTEREST



Systemically available drug eliminated by the liver via first pass metabolism



## **TD-1473: Innovative Approach in Treating IBD** COMPELLING PRECLINICAL PACKAGE AND ENCOURAGING PHASE 1B DATA



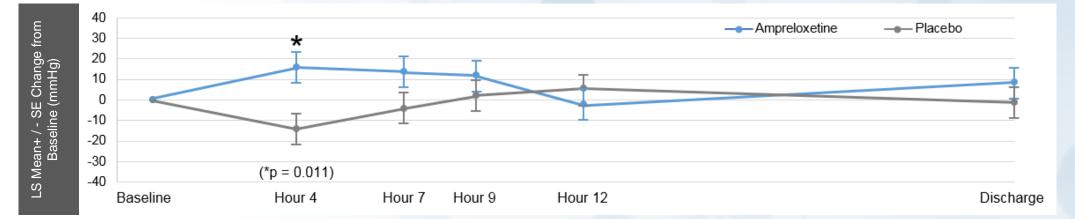
## Ampreloxetine: Top-line Phase 2 Results in nOH PART B and C: VERSUS PLACEBO AND REPEAT DOSE EXTENSION PHASE

#### Part B: Change from baseline SBP

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#### Part C: Durability of effect observed in repeat-dose open-label extension phase

- Reductions in symptom severity, with most pronounced benefit in patients with symptomatic nOH
  - Mean reduction in OHSA #1 = 2.4 at four weeks (n=16)
  - 13 completers had OHSA #1 > 4 at baseline; mean reduction in this group = 3.8 at four weeks

## Positive results including durability of effect provide basis for registrational Phase 3 program in symptomatic nOH

SBP = systolic blood pressure. OHSA = orthostatic hypotension symptom assessment. OHSA #1 is a measurement of dizziness, a cardinal symptom of nOH. <sup>1</sup> Symptomatic defined as OHSA #1 > 4. Durability of effect observed at four weeks and five months in the completed Phase 2 trial of ampreloxetine in patients with nOH

## Ampreloxetine Clinical Program PHASE 3 REGISTRATIONAL PROGRAM IN SYMPTOMATIC NOH

#### Study 0169 4 weeks (N=188)

Randomized, double blind, placebo-controlled, parallel group study

De Novo

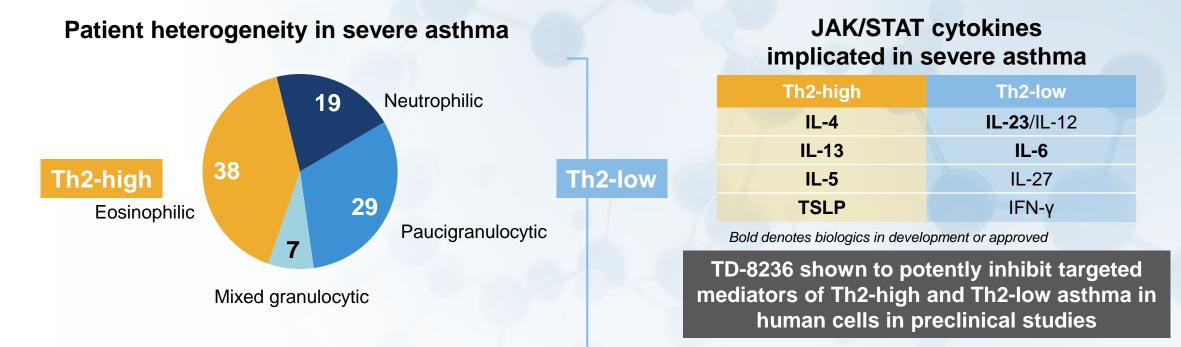
#### Study 0170 22 weeks (N=258)

Randomized 6-week withdrawal phase (preceded by 4-month open label)

Supportive 5-month treatment data from Phase 2 study to be presented at IAPRD and ENC



## **TD-8236: Lung-selective pan-JAK Inhibitor** POTENTIAL TO ADDRESS PATIENTS NEEDS REGARDLESS OF TH2 PHENOTYPE



- Novel approved biologics address only Th2-high asthma
- Key treatment needs: Prevention of exacerbations and symptom control for patients regardless of Th2 phenotype

Phase 1 study data in healthy volunteers and asthmatic patients (including biomarker measures) expected 3Q19

Simpson JL, et al. Resp 2006;11:54-61

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## YUPELRI®: Formal Commercial Launch Underway FDA-APPROVED FOR THE MAINTENANCE TREATMENT OF COPD

- First and only once-daily bronchodilator delivered in a nebulizer
- Higher of two doses approved: 175 mcg once daily, for use with any standard jet nebulizer

#### Unmet need for nebulized LAMA therapy

- Once-daily LAMAs are first-line therapy for moderate to severe COPD<sup>1</sup>
- No once-daily nebulized LAMAs available previously; only available in handheld devices
- Nebulized therapy associated with reduced hospital readmissions in low PIFR patients<sup>2</sup>





YUPELRI<sup>®</sup> (revefenacin) inhalation solution. Approved for the maintenance treatment of patients with COPD. COPD = Chronic Obstructive Pulmonary Disease. <sup>1</sup> Global Strategy for Diagnosis, Management, and Prevention of COPD. <sup>2</sup> Suboptimal Inspiratory Flow Rates Are Associated with COPD and All Cause Readmissions. Loh et al., Annals of ATS 2017.

# Partnership with Mylan Provides Commercial Strength in Nebulized Opportunity

Combined sales infrastructures to cover Hospital, Hospital Discharge and Home Health settings



#### Enduring patient niche and significant market opportunity

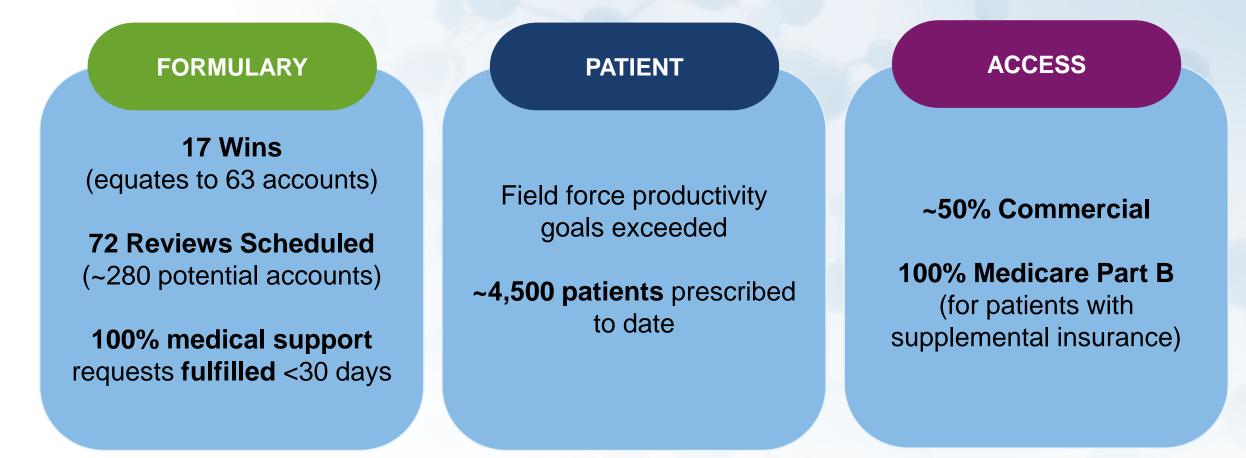
- >100M patient treatment days in nebulized COPD segment<sup>1</sup>
- 9% of COPD patients currently use nebulizers for ongoing maintenance therapy<sup>2</sup>
- 41% of COPD patients use nebulizers at least occasionally for bronchodilator therapy<sup>2</sup>



HD = hospital

<sup>1</sup> IMS Health information service: NSP for period MAT May, 2015. Excludes nebulized SABAs. IMS expressly reserves all rights, including rights of copying, distribution and republication. <sup>2</sup> TBPH market research (N = 160 physicians); refers to US COPD patients.

## YUPELRI® Launch Update ENCOURAGING INITIAL MARKET RESPONSE





## **First Quarter 2019 Financial Highlights**

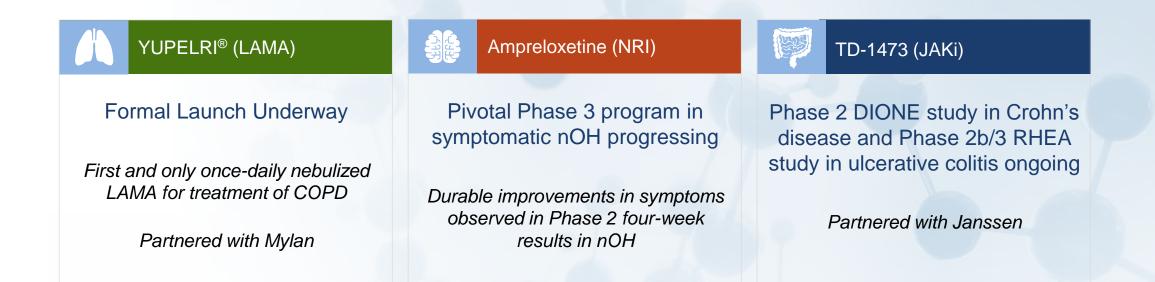
	Three Months Ended, March 31,	
(\$, in thousands)	2019	2018
	(Unaudited)	
Product sales	Sec	3,679
Collaboration revenue	5,338	4,640
Total revenue	5,338	8,319
Cost of goods sold	11	826
Research and development <sup>1</sup>	53,818	47,765
Selling, general and administrative <sup>1</sup>	25,186	24,704
Total costs and expenses	79,004	73,295
Loss from operations	(73,666)	(64,976)
Share-based compensation expense		
Research and development	6,159	6,559
Selling, general and administrative	6,061	7,439
Total share-based compensation expense	12,220	13,998
Operating loss excluding share-based compensation	(61,446)	(50,978)

#### Strong financial position with \$434M in cash as of the end of the first quarter<sup>2</sup>



<sup>1</sup>Amounts include share-based compensation <sup>2</sup>Cash, cash equivalents, and short-term marketable securities

## **Strategic Focus with Inflection Points Near- and Long-term**



- Differentiated organ-selective projects advancing to clinical development
- Economic interest in TRELEGY ELLIPTA serves as an important strategic asset<sup>1</sup>
  - Strong launch following approvals in US and EU in late 2017

YUPELRI<sup>®</sup>, ampreloxetine, and TD-1473 each internally discovered and developed by R&D engine which serves as important driver of long-term value

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YUPELRI® (revefenacin) inhalation solution. Approved for the maintenance treatment of patients with COPD. NRI: norepinephrine reuptake inhibitor. LAMA: long-acting muscarinic antagonist. JAKi: Janus kinase inhibitor.