

## Theravance Biopharma, Inc. (NASDAQ: TBPH)

4Q and Full Year 2017 Financial Results and Business Update February 27, 2018

# Cautionary Statement Regarding 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 include statements relating to the company's business plans and objectives, including financial and operating results, potential partnering transactions and sales targets, 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 (including their potential as components of combination therapies).

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 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-Q filed with the Securities and Exchange Commission (SEC) on November 8, 2017, and other periodic reports filed with the SEC.

# Advancing Multiple Opportunities for Value Creation

## Programs in Focus in 2018

#### **Managed by Theravance Biopharma:**

#### TD-1473

Intestinally restricted JAK inhibitor

- Initiation of Ph 2b/3 induction and maintenance study in ulcerative colitis (UC)
- Initiation of Phase 2 induction study in Crohn's disease

## TD-9855

NSRI in nOH

- Phase 2a results in symptomatic neurogenic orthostatic hypotension (nOH)
- Seeking an expedited development pathway

# Revefenacin (TD-4208) Nebulized LAMA in COPD

Potential FDA approval (PDUFA date November 13, 2018)<sup>1</sup>

## Velusetrag (TD-5108) 5HT4 agonist in gastroparesis

Interactions with regulatory agencies in first half of 2018

# Inhaled JAK inhibitor Serious respiratory diseases

Progressing into the clinic in late 2018 or early 2019

#### Managed by GSK and Innoviva<sup>2</sup>:

# Trelegy Ellipta (FF/UMEC/VI) Single inhaler triple therapy

- Potential inclusion of IMPACT data in label (sNDA filed November 2017)
- Completion of Phase 3 study in asthma (CAPTAIN)

<sup>&</sup>lt;sup>1</sup> PDUFA = Prescription Drug User Fee Act. <sup>2</sup> Economic interest. Regulatory and clinical milestones as reported by GlaxoSmithKline. Trelegy Ellipta previously referred to as the Closed Triple. FF/UMEC/VI= Fluticasone Furoate/Umeclidinium/Vilanterol. Approved for the treatment of appropriate patients with COPD. Innoviva formerly Theravance, Inc. JAK = Janus kinase; NSRI = norepinephrine serotonin reuptake inhibitor; LAMA = long acting muscarinic antagonist Submissions, filings, and approvals are subject to preclinical and clinical data and regulatory interactions.

# TD-1473 in Development with Janssen Biotech

Potential to maximize value of TD-1473 for Theravance Biopharma





- Shared belief in TD-1473 as a localized medicine with potential to transform the treatment landscape in inflammatory intestinal diseases
- Meaningful program enhancements for TD-1473
  - Accelerate clinical development; plan to advance UC and Crohn's in parallel
  - Apply Janssen expertise in IBD to optimize clinical strategy and execution
  - Maximize worldwide commercial opportunity of TD-1473
- Attractive deal economics reducing overall financial risk

Collaboration represents important milestone for TD-1473, the value of our internally discovered pipeline, and our strategy to design localized medicines to make a difference for patients



# TD-9855: Phase 2a Study in nOH in Progress, Results Expected 1H 2018

- Purpose: Exploratory study to evaluate the effect of TD-9855 in improving symptoms of orthostatic intolerance
- Understanding totality of symptoms encompasses tests of stand-up time, orthostatic hypotension status, and other measures
  - Interest in patients who fail to accomplish 10-minute standing time at baseline

## Part A Part B Part C (Extension)

## Part A: Single ascending dose portion

Continue to observe emerging signals of potential benefits to patients in Part A

Part B: Single dose (response dose) or placebo

## Part C: Multiple dose portion to assess durability of response

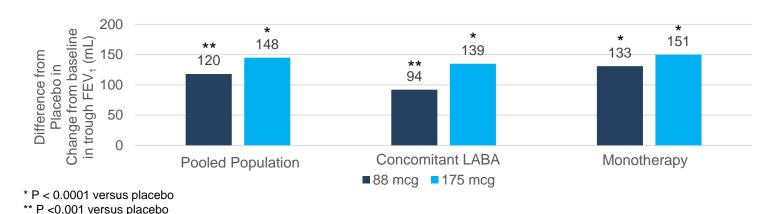
- Enrolling patients in open label design
- Up to 24 weeks (20 weeks dosing, 4 week wash out)
- Primary endpoint at 4 weeks

Intention to seek expedited development path



# Revefenacin: NDA for Treatment of COPD in FDA Review, PDUFA Date November 13, 2018

- NDA supported by Phase 3 efficacy and safety studies
- Primary endpoint achieved for both doses in both replicate efficacy studies
  - Robust and sustained improvements in FEV<sub>1</sub>
  - Effective as monotherapy and as add-on to LABA or LABA/ICS
  - Generally well tolerated



- Generally well tolerated in 12-month safety study
  - No new safety issues identified
  - Rates of adverse events low and comparable to standard of treatment



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