



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

Investor Presentation  
May 2017

# Cautionary Statement Regarding Forward-Looking Statements

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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.

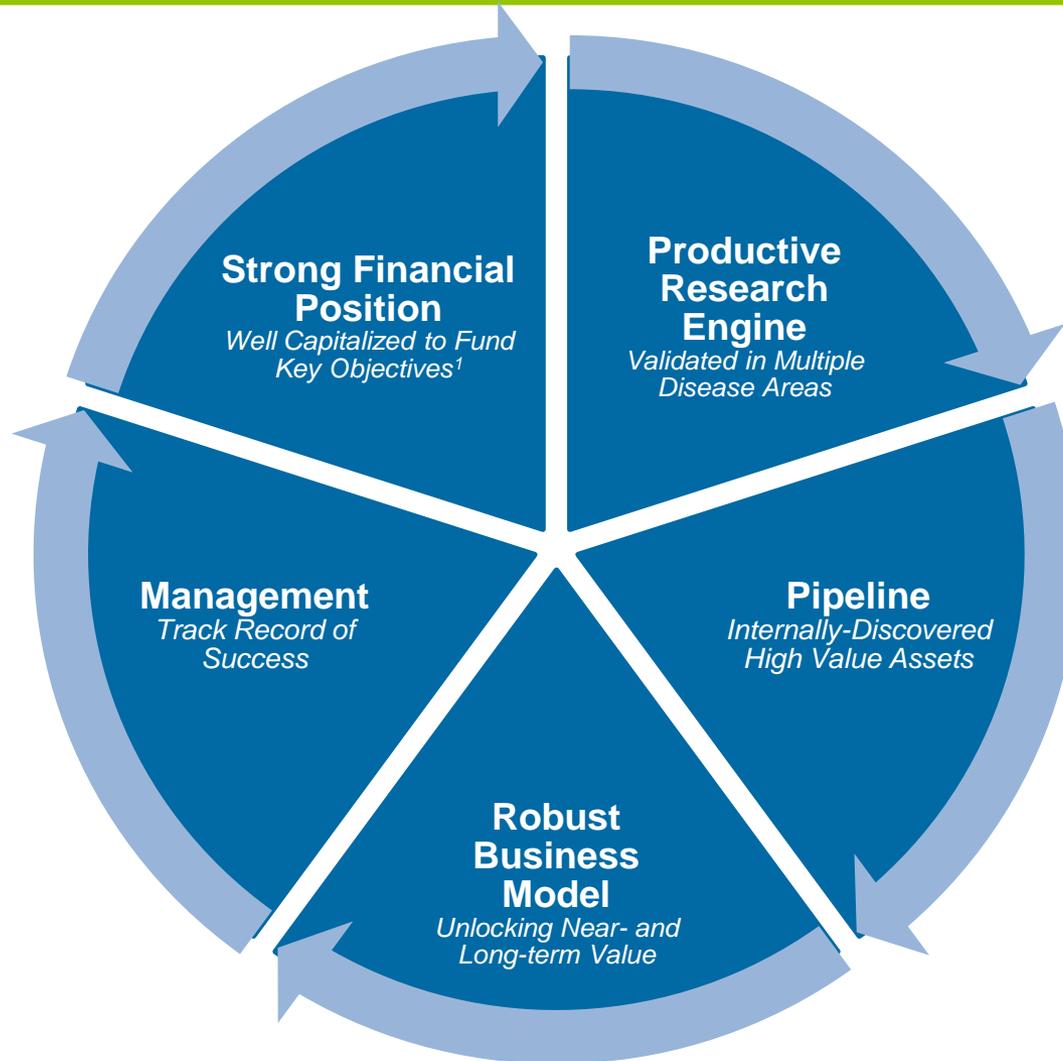
Examples of forward-looking statements in this presentation include statements relating to the company's business plans and objectives, including financial and operating results, potential partnering transactions and sales targets, the company's regulatory strategies and timing and results of clinical 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-K filed with the Securities and Exchange Commission (SEC) on March 1, 2017, and other periodic reports filed with the SEC.

# Theravance Biopharma Investment Highlights

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# Upcoming Milestones

## *Multiple Opportunities for Value Creation in 2017 and 2018*

Program	Milestone	Target
TD-1439 (NEP inhibitor)	Phase 1a SAD/MAD results in healthy volunteers	1H 2017
TD-1473 (JAK inhibitor)	Phase 1b results in UC patients	Mid 2017
Velusetrag (TD-5108)	Phase 2b results in Gastroparesis patients	Mid 2017
Revefenacin (TD-4208)	Phase 3 long-term safety results in COPD patients	Mid 2017
Revefenacin (TD-4208)	NDA submission in US*	2017
TD-9855 (NSRI)	Phase 2a results in nOH patients	2017
VIBATIV® (telavancin)	Patient registry study data (TOUR™)	2017
Closed Triple (FF/UMEC/VI) <sup>1</sup>	Phase 3 IMPACT study completion	2017
Closed Triple (FF/UMEC/VI) <sup>1</sup>	Potential regulatory approval in US and EU for COPD*	2017
Revefenacin (TD-4208)	Phase 3b study results in COPD patients with low PIFR <sup>2</sup>	Early 2018
VIBATIV® (telavancin)	Phase 3 study results in Bacteremia patients	2018
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<sup>1</sup> Economic interests. Regulatory and clinical milestones as reported by GlaxoSmithKline

<sup>2</sup> Peak inspiratory flow rate

\* Submissions, filings, and approvals are subject to preclinical and clinical data and regulatory interactions



## **JAK Inhibitor Program**

*Oral intestinally-restricted pan-Janus kinase (JAK) inhibitors for ulcerative colitis and other inflammatory intestinal diseases*

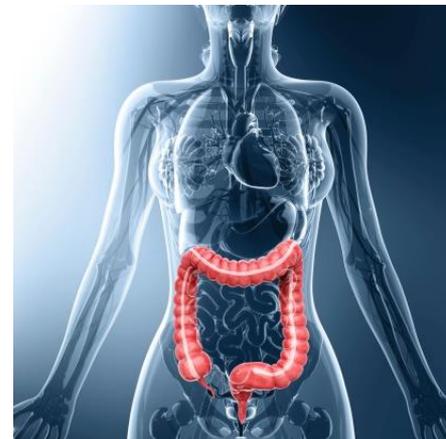
# Intestinally Restricted JAK Program Represents a Potential Breakthrough Approach to Treating IBD

## **TD-1473:** An oral pan-JAK inhibitor designed to be **intestinally restricted**

- Proof of concept: MOA is validated in ulcerative colitis<sup>1</sup>
- SAD/MAD study complete, Phase 1b in patients underway
- Potential utility in other IBD indications: Crohn's disease, checkpoint inhibitor-induced colitis

### Program objectives:

- Selective distribution to intestinal tract
- Reduction in UC disease activity score comparable to best in class therapy, but without corresponding systemic immunosuppression
- High affinity for JAK1/2/3 and TYK2



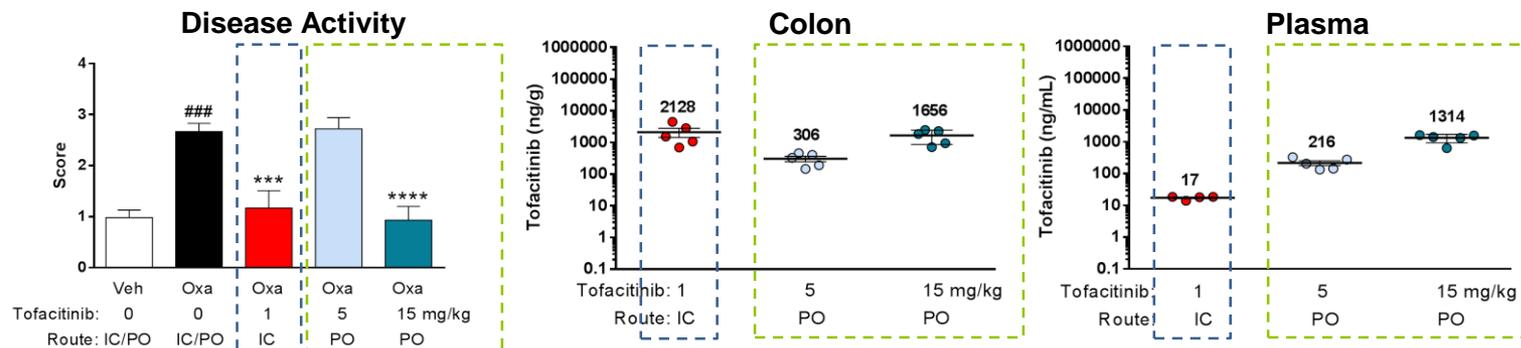
## **TD-3504:** An innovative prodrug of tofacitinib which provides chemically distinct secondary strategy for intestinally-restricted JAK inhibition

Differentiated program designed for maximal local anti-inflammatory efficacy with minimal systemic exposure and immunosuppressive effects

<sup>1</sup> Tofacitinib (Xeljanz®) - an oral, systemically available, JAK inhibitor, which has demonstrated efficacy in treating moderate to severe ulcerative colitis patients. Estimated to be 900K cases of ulcerative colitis in 2017 in the US. Source: Ulcerative Colitis Epidemiology, November 2016

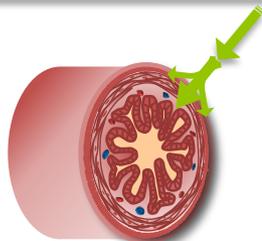
# Preclinical Evidence Validates Locally Restrictive Concept in JAK Inhibition

- Efficacy of tofacitinib in rodent colitis model driven by local exposure in the colon<sup>1</sup>
  - Intracecal (direct to colon) delivery (IC) versus oral delivery (PO) of tofacitinib<sup>2</sup>: IC results in equivalent efficacy of PO, **with 15-fold lower dose, similar colon concentration, and 80-fold lower plasma concentration** (PO relies on systemic delivery of tofacitinib to the colon)



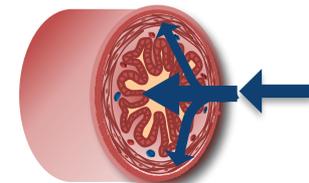
## Tofacitinib Oral

Systemically-delivered, from the “outside-in”



## Tofacitinib Intracecal (mimics TD-1473 Oral)

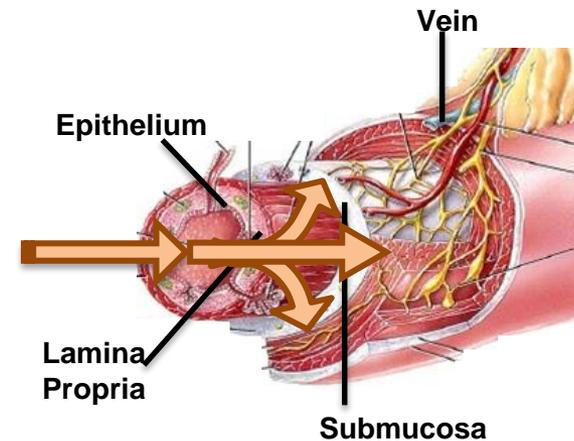
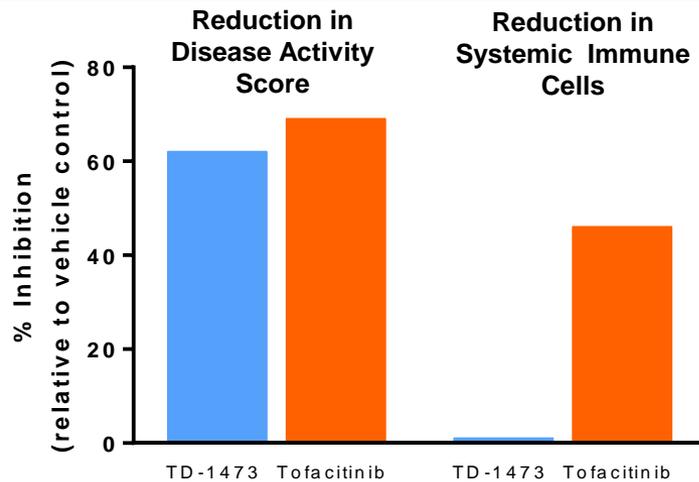
Intestinally-restricted, from the “inside-out”



# TD-1473: Designed to Maximize Local Anti-Inflammatory Efficacy and Minimize Systemic Exposure

TD-1473 is Active in Rodent Colitis Model without Systemic Effects

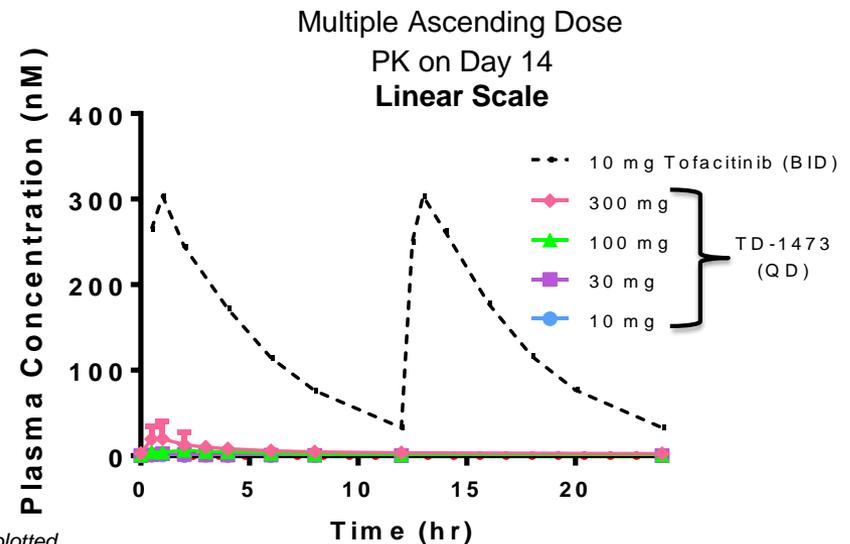
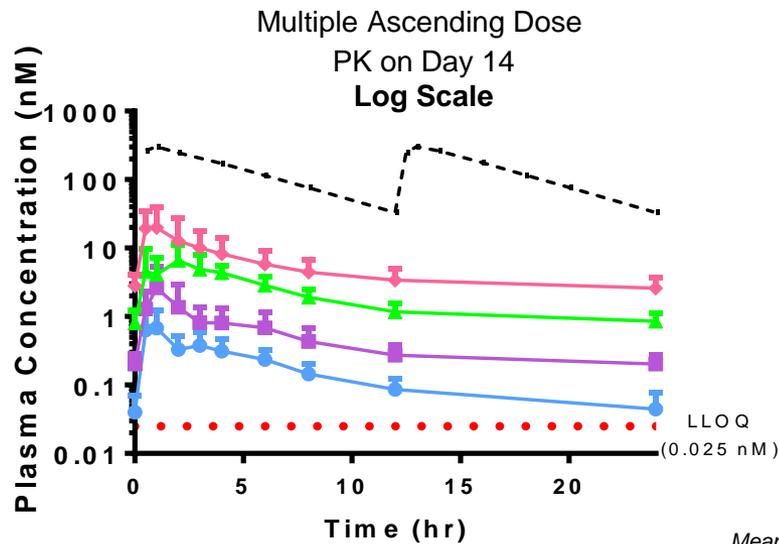
TD-1473 Penetrates Intestinal Wall to Act Directly at the Site of Inflammation



- Preclinical findings to date indicate potential breakthrough approach in UC
  - ✓ Selective distribution of TD-1473 to tissues in the GI tract, with reduction in UC disease activity score comparable to systemically delivered JAK inhibitor therapy
  - ✓ No dose-related immunosuppression activity within the systemic circulation
  - ✓ Slow absorption throughout intestinal tract
  - ✓ Penetration of the GI tissue to act directly at the site of inflammation

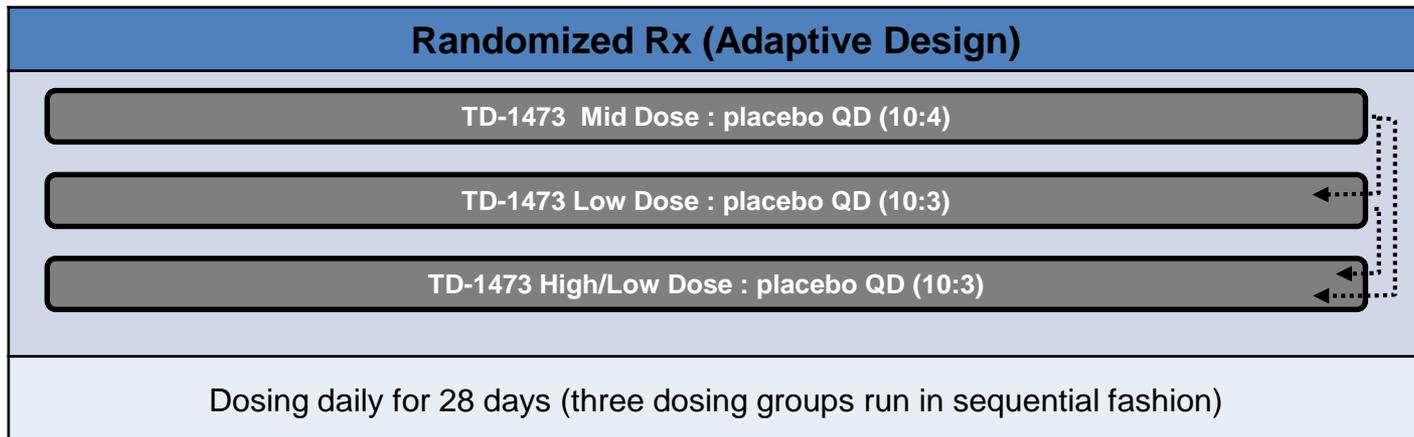
# TD-1473: Phase 1 Clinical Data Support Progression into Phase 1b Trial in Ulcerative Colitis Patients

- Phase 1 study of TD-1473 in healthy subjects met target objectives:
  - ✓ Data suggest slow absorption of TD-1473 throughout intestinal tract
  - ✓ Minimal levels of TD-1473 in systemic circulation
  - ✓ High levels of TD-1473 in stool<sup>1</sup>
  - ✓ Well tolerated at all dose levels
- PK findings consistent with positive preclinical models



# TD-1473: Phase 1b Study in Ulcerative Colitis Patients Underway; Data Expected Mid-2017

- Phase 1b designed to evaluate safety, tolerability, PK and PD of TD-1473 in moderately-to-severely active ulcerative colitis patients over 28 days
  - Secondary/exploratory objectives to demonstrate biologic effect through biomarker analysis and clinical, endoscopic and histologic assessments



Adaptive design to provide flexibility in dosing and inform future development of TD-1473

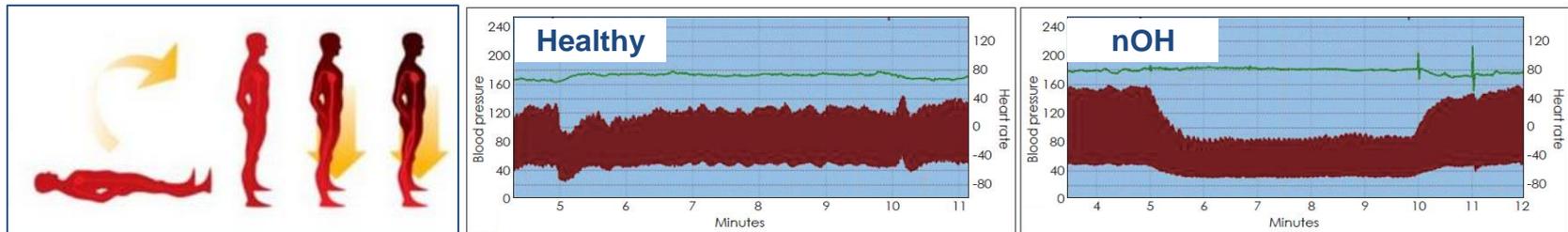


## **TD-9855**

*Dual norepinephrine and serotonin reuptake inhibitor (NSRI) for neurogenic orthostatic hypotension (nOH)*

# Neurogenic Orthostatic Hypotension (nOH) Represents a Significant Unmet Need

nOH is characterized by a **sustained drop in blood pressure** that occurs **upon standing up** and is associated with the **nervous system**, specifically due to the body producing **insufficient levels of norepinephrine**



- Associated with several autonomic disorders, including Multiple System Atrophy (MSA), Parkinson's Disease (PD), and Pure Autonomic Failure (PAF)
- Orphan indication with <200k patients in US
- Symptoms include dizziness, fainting, blurred vision and weakness
- Significant impacts to QoL for both patients and family members
  - Patients limited in routine daily functions and prone to injury from falling
  - In severe cases, patients become bedridden and require caregiver support

# Current Approved Therapies in Neurogenic Orthostatic Hypotension (nOH) Have Limitations

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## **Current therapies limited in safety, efficacy, and/or dosing**

- Only Northera (droxidopa) and midodrine (generic) are FDA approved for nOH
- Both impact disease by increasing vascular tone
- Significant unmet need remains due to limitations of current therapies
  - Supine hypertension (high blood pressure while lying down)
  - Require dosing three times a day
  - Patients<sup>1</sup> may become refractory over time or discontinue due to AEs

## **Opportunity exists for effective, well tolerated nOH therapies**

- No evidence of other new therapeutic agents in development for nOH

Successful nOH therapy would target reduction in symptoms and offer meaningful improvements in quality of life for patients

# TD-9855: Potential Best in Class Therapy for Neurogenic Orthostatic Hypotension (nOH)

## Reasons to Pursue TD-9855 in nOH

- ✓ Designed to restore deficits in noradrenergic function
- ✓ Norepinephrine dominance confirmed in human PET study<sup>1</sup>
- ✓ QD dosing and long half-life may offer improved patient outcomes
- ✓ ADME studies suggest low probability of DDIs
- ✓ Favorable safety and tolerability profile established in >500 subjects<sup>2</sup>

### Phase 2a Study of TD-9855 in nOH

Encouraging responses to date in single ascending dose portion of study

Key endpoints include change from placebo in sitting and standing blood pressure, symptom reduction, and safety/tolerability in nOH

**Intention to seek orphan designation and expedited development path**

**Phase 2a results for TD-9855 in nOH expected in 2017**



## **Velusetrag (TD-5108)**

*Highly selective 5-HT<sub>4</sub> agonist for gastroparesis*

# Velusetrag has Demonstrated Gastrointestinal Motility Effect with Favorable Safety Profile

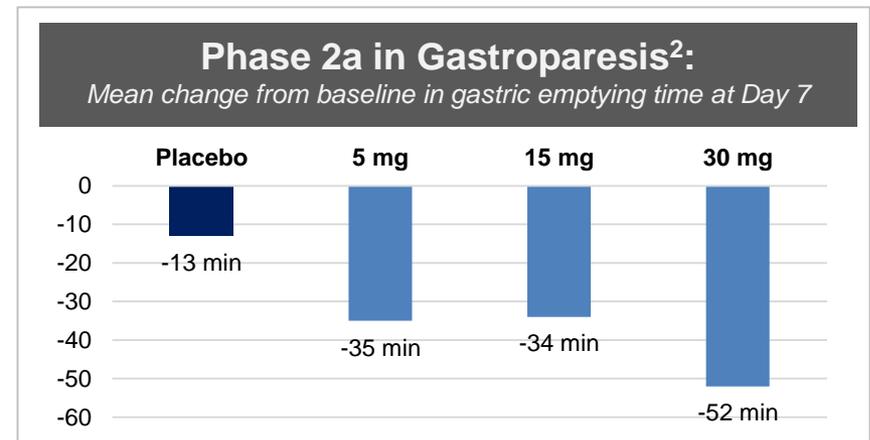
## Large Market Opportunity

### Gastroparesis is a severe disease with few treatment options

- Delayed gastric emptying with symptoms of nausea, vomiting, postprandial fullness or abdominal pain
- Estimated 6M gastroparesis patients in US<sup>1</sup>
- Velusetrag is being evaluated in both idiopathic and diabetic cases
- Fast Track designation granted by FDA in December 2016
- Partnered ex-U.S. with Alfa Wassermann<sup>3</sup>

## Supportive Results To Date

- Multiple positive Phase 2a studies completed (chronic constipation and gastroparesis)
- Long term toxicity studies completed
- Well-tolerated in >600 subjects exposed



Enrollment complete in Phase 2b study in idiopathic and diabetic gastroparesis patients (n=~200), results expected mid-2017

<sup>1</sup> Rey et al., Prevalence of Hidden Gastroparesis in the Community: The Gastroparesis "Iceberg." J. Neurogastroenterol. Motil., 2012; 18:34-42.

<sup>2</sup> N= 34 patients; similar treatment effect with velusetrag observed in both diabetic and idiopathic patient groups

<sup>3</sup> Velusetrag is being developed by TBPH in collaboration with AW. AW holds an exclusive option to certain ex-U.S. markets. TBPH retains all U.S. rights.

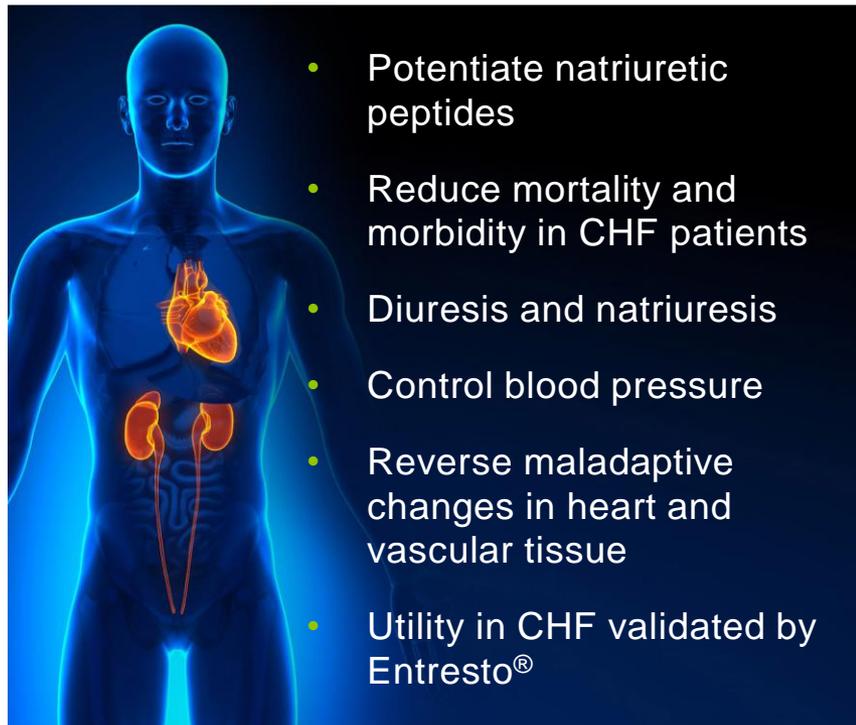


## **Neprilysin Inhibitor (NEPi) Program**

*Potential Best-in-Class Therapeutic for Cardiovascular and Renal Disease*

# Best-in-Class NEPi Could Improve Treatment Regimens for Cardiovascular & Renal Diseases

## Utility of NEP Inhibitors (NEPi)



## Large Market Opportunities

Neprilysin  
Inhibitor  
(NEPi)

Chronic Kidney Disease  
26 million people

Acute Heart Failure  
(AHF)  
1 million hospitalizations  
annually

Chronic Heart Failure  
(CHF)  
6 million patients  
diagnosed

- Significant opportunity remains for a next-generation NEP inhibitor for treatment of CHF patients with chronic kidney disease and in indications beyond CHF offering once-daily dosing, combination flexibility and enhanced tolerability

# NEPi Program: Differentiated & Versatile Platform with Multiple Development Candidates Advancing

## Potential Applications for NEPi

IV NEPi  
AHF  
Monotherapy

ARB  
Combination  
(ARNI)  
Optimized for  
CHF and/or  
CKD

Non-ARB  
Combinations  
PDE5, PDE9,  
sGC, MRA...

Range of Cardiovascular and Renal Indications

## Theravance NEP Inhibitor Target Product Profile

- ✓ Sustained 24-hour target engagement
  - ✓ Non-renal clearance
  - ✓ Favorable safety and tolerability
  - Flexible administration (oral or IV)
- ✓ = demonstrated in TD-0714 Phase 1 study

### TD-0714:

- Phase 1 SAD/MAD results support further compound development

### TD-1439:

- Phase 1 SAD results supportive of target profile, MAD data expected 1H 2017

Positioned to progress either TD-0714 or TD-1439 into patient studies in 2017<sup>1</sup>

## **Late Stage & Commercial Assets, Acute Care**

Revefenacin (TD-4208): *Nebulized Long-Acting Muscarinic Antagonist (LAMA)*

VIBATIV<sup>®</sup> (telavancin): *Commercial, Once-Daily, Dual Mechanism Antibiotic*

# Acute Care Commercial Infrastructure Positioned to Support VIBATIV<sup>®</sup> and Future Products

## Label Expansion Strategy for VIBATIV Growth

### Potential for broadest set of indications of any branded anti-MRSA antibiotic

- ✓ Approval in cSSSI and HABP/VABP<sup>1</sup>
- ✓ Expanded label describes use in cSSSI and HABP/VABP with concurrent bacteremia

### Phase 3 registrational study in bacteremia

- ~250 patients in ~70 sites in US & ROW
- Expected to complete in 2018
- Potential sNDA submission

### TOUR<sup>™</sup> patient registry study fully enrolled

- Generating “real world” data in 1,000-patient study
- Largest enrollment seen in cSSSI, osteomyelitis, bacteremia, and pneumonia
- Results to inform additional potential indications

## Complementary Products to Optimize the Acute Care Organization

### Opportunity to target large, addressable patient populations

- Overlap in sales calls with pulmonologists and respiratory care physicians for VIBATIV and revefenacin
- Acute care setting provides an important inflection point in patient identification
- Revefenacin collaboration with Mylan includes co-promote and profit split in the US
  - Profit split: 65% Mylan, 35% Theravance
- Combined sales infrastructures to cover hospital, outpatient and home health treatment settings
- Phase 3b PIFR (peak inspiratory flow rate) study with revefenacin planned to support commercialization

<sup>1</sup> VIBATIV is approved in the US for treatment of the following infections in adult patients caused by designated susceptible bacteria: complicated skin and skin structure infections (cSSSI), hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable.

# Compelling Need for Once-Daily Nebulized LAMA

## *Enduring Patient Niche and Significant Market Opportunity*

### Unmet Need for Nebulized LAMA Therapy

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

### Enduring Patient Niche

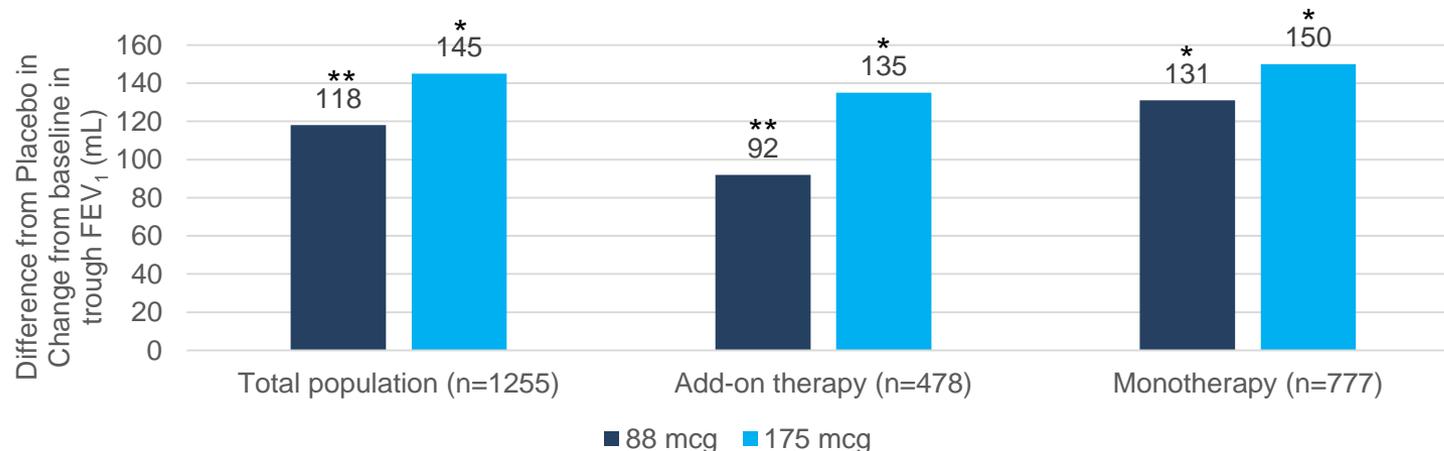
- **>100M patient treatment days** in nebulized COPD segment<sup>3</sup>
- **9%** of COPD patients currently use nebulizers for ongoing maintenance therapy<sup>4</sup>
- **41%** of COPD patients use nebulizers at least occasionally for bronchodilator therapy<sup>4</sup>
- Pricing in branded LA nebulized segment ~ 2x handheld Spiriva<sup>3</sup>

### Significant Market Opportunity

- Revefenacin may be **complementary to existing nebulized LABA** treatments
- Mylan partnership brings commercial strength in nebulized segment

# Revefenacin: Pivotal Phase 3 Studies Met Primary Endpoints; Long-term Safety Study Underway

- 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



\* P < 0.0001 versus placebo

\*\* P < 0.001 versus placebo

Results from single 12-month safety study expected in mid-2017; NDA filing expected late 2017



## Opportunities for Value Creation

*Economic Interests and Upcoming Milestones*

# Economic Interest in GSK Respiratory Programs

## *Royalties from Closed Triple Expected as Early as 2018*

- TBPH holds an 85% economic interest in future payments made by GSK related to the Closed Triple, MABA and MABA/ICS<sup>1</sup>
- Total GSK royalty rates and potential milestone obligations noted below
- Programs jointly managed by GSK and Innoviva<sup>2</sup>; fully funded by GSK

### “Closed Triple” (FF/UMEC/VI)

- Active components of BREO<sup>®</sup> and ANORO<sup>®</sup>
- Positive top-line results reported from Phase 3 FULFIL study (~1,800 COPD patients)
- Potential for regulatory approvals of COPD in both US and EU in 2017
- Upward-tiering royalty 6.5% - 10% of annual global net sales
- Phase 3 IMPACT study ongoing in ~10,000 COPD patients; data expected 2017
- Phase 3 study in asthma initiated in 2016, with US NDA filing planned 2018

### MABA, MABA/ICS (batefenterol, batefenterol/FF)

- Single molecule bifunctional bronchodilator
- Phase 2 studies of single- and combo-agent in COPD patients completed
- Upward-tiering royalty of 10% to 20% of annual global net sales up to \$3.5 billion, and 7.5% above \$3.5 billion for single agent and 70% of those amounts for combo
- Development and commercialization milestones up to \$125 million for single agent and \$250 million for both single- and combo-agent<sup>3</sup>

<sup>1</sup> TBPH holds economic interest in future payments that may be made by GSK relating to certain programs, including “Closed Triple” (FF/UMEC/VI), MABA/FF, MABA monotherapy and other future products that may be combined with VI or MABA. All statements based on publically available information. FF/UMEC/VI= Fluticasone Furoate/Umeclidinium/Vilanterol. MABA= Inhaled Bifunctional Muscarinic Antagonist -Beta2 Agonist. <sup>2</sup> Formerly Theravance, Inc. <sup>3</sup> Certain payments related to MABA program already received by Theravance, Inc.

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# About VIBATIV<sup>®</sup> (telavancin)

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VIBATIV was discovered internally in a research program dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including MRSA. VIBATIV is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with in vitro potency and a dual mechanism of action whereby telavancin both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function.

VIBATIV for injection is approved in the U.S. for the treatment of adult patients for complicated skin & skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains. In addition, VIBATIV telavancin is approved in the U.S. for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable. In addition, VIBATIV is approved in the U.S. for the treatment of adult patients with complicated skin & skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *S. aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains. The product labeling also describes the use of VIBATIV in treating patients with concurrent bacteremia (in addition to either skin infection or pneumonia).

VIBATIV is indicated in Canada and Russia for complicated skin & skin structure infections and HAP/VAP caused by Gram-positive bacteria, including MRSA.

VIBATIV is indicated in the European Union for the treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia (VAP), known or suspected to be caused by methicillin resistant *Staphylococcus aureus* (MRSA) and should be used only in situations where it is known or suspected that other alternatives are not suitable.

# VIBATIV<sup>®</sup> (telavancin)

## Important Safety Information (US)

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### **Mortality**

Patients with pre-existing moderate/severe renal impairment (CrCl  $\leq$ 50 mL/min) who were treated with VIBATIV<sup>®</sup> for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia had increased mortality observed versus vancomycin. Use of VIBATIV in patients with pre-existing moderate/severe renal impairment (CrCl  $\leq$ 50 mL/min) should be considered only when the anticipated benefit to the patient outweighs the potential risk.

### **Nephrotoxicity**

New onset or worsening renal impairment occurred in patients who received VIBATIV. Renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction and in patients who received concomitant medications known to affect kidney function. Monitor renal function in all patients receiving VIBATIV prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV versus discontinuing and initiating therapy with an alternative agent should be assessed.

### **Fetal Risk**

Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV. Avoid use of VIBATIV during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Adverse developmental outcomes observed in three animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans. If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV treatment.

### **Contraindication**

Intravenous unfractionated heparin sodium is contraindicated with VIBATIV administration due to artificially prolonged activated partial thromboplastin time (aPTT) test results for up to 18 hours after VIBATIV administration.

VIBATIV is contraindicated in patients with a known hypersensitivity to the drug.

### **Hypersensitivity Reactions**

Serious and potentially fatal hypersensitivity reactions, including anaphylactic reactions, may occur after first or subsequent doses. VIBATIV should be used with caution in patients with known hypersensitivity to vancomycin.

### **Geriatric Use**

Telavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

### **Infusion Related Reactions**

VIBATIV is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions. Rapid intravenous infusions of the glycopeptide class of antimicrobial agents can cause "Red-man Syndrome" like reactions including: flushing of the upper body, urticaria, pruritus, or rash.

### **QTc Prolongation**

Caution is warranted when prescribing VIBATIV to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV prolonged the QTc interval. Use of VIBATIV should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy.

### **Most Common Adverse Reactions**

The most common adverse reactions (greater than or equal to 10% of patients treated with VIBATIV) were diarrhea, taste disturbance, nausea, vomiting, and foamy urine. Full Prescribing Information, including Boxed Warning and Medication Guide in the U.S., is available at [www.VIBATIV.com](http://www.VIBATIV.com).