



NASDAQ: TENX

September 2019

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This presentation contains certain forward-looking statements by the Company that involve risks and uncertainties and reflect the Company's judgment as of the date of this release. The forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to matters beyond the Company's control that could lead to delays in the clinical study, new product introductions and customer acceptance of these new products; matters beyond the Company's control that could impact the Company's continued compliance with Nasdaq listing requirements; the impact of management changes on the Company's business and unanticipated charges, costs and expenditures not currently contemplated that may occur as a result of management changes; and other risks and uncertainties as described in the Company's filings with the Securities and Exchange Commission, including in its annual report on Form 10-K filed on April 1, 2019, its quarterly report on Form 10-Q filed on August 14, 2019, as well as its other filings with the SEC. The Company disclaims any intent or obligation to update these forward-looking statements beyond the date of this release. Statements in this press release regarding management's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

Mission Statement



Specialty pharmaceutical company focused on identifying and developing therapeutics that address diseases with high unmet medical need with an initial therapeutic focus on Cardio-Pulmonary diseases

Investment Highlights

- **Levosimendan**

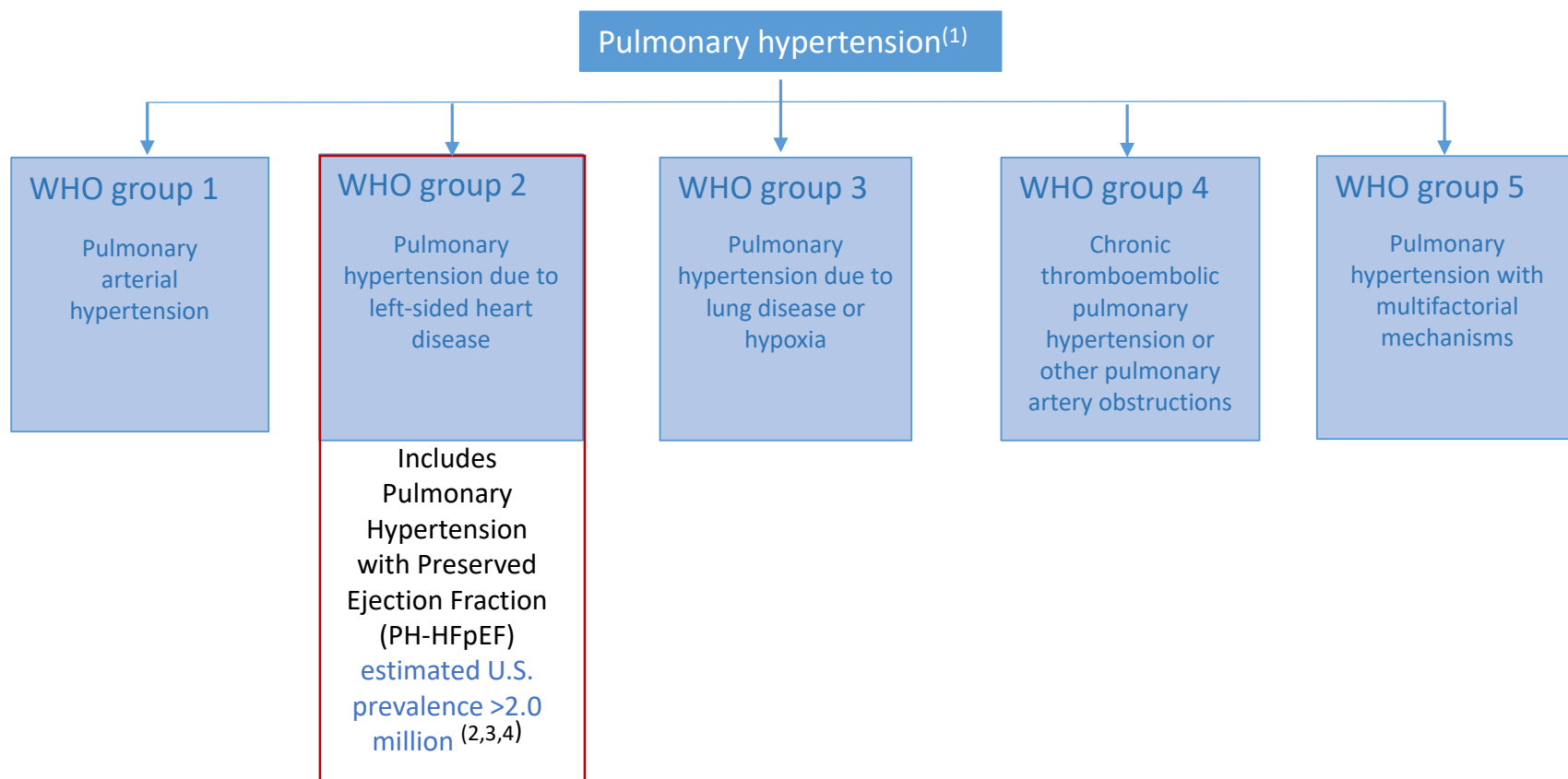
- Novel, first in class calcium sensitizer/K-ATP activator with unique triple mechanism of action
- Approved in over 60 countries acute decompensated heart failure
 - >1000 PubMed publication citations
- Hold US and Canada development and commercialization rights

- **Phase 2 trial for PH-HFpEF underway**

- 12 of 15 leading research centers in the US activated
- Currently enrolling with 8 of targeted 36 patients enrolled
- Enrollment on track to completed year end 2019
- Top line data expected first 2020

Pulmonary Hypertension WHO Classification

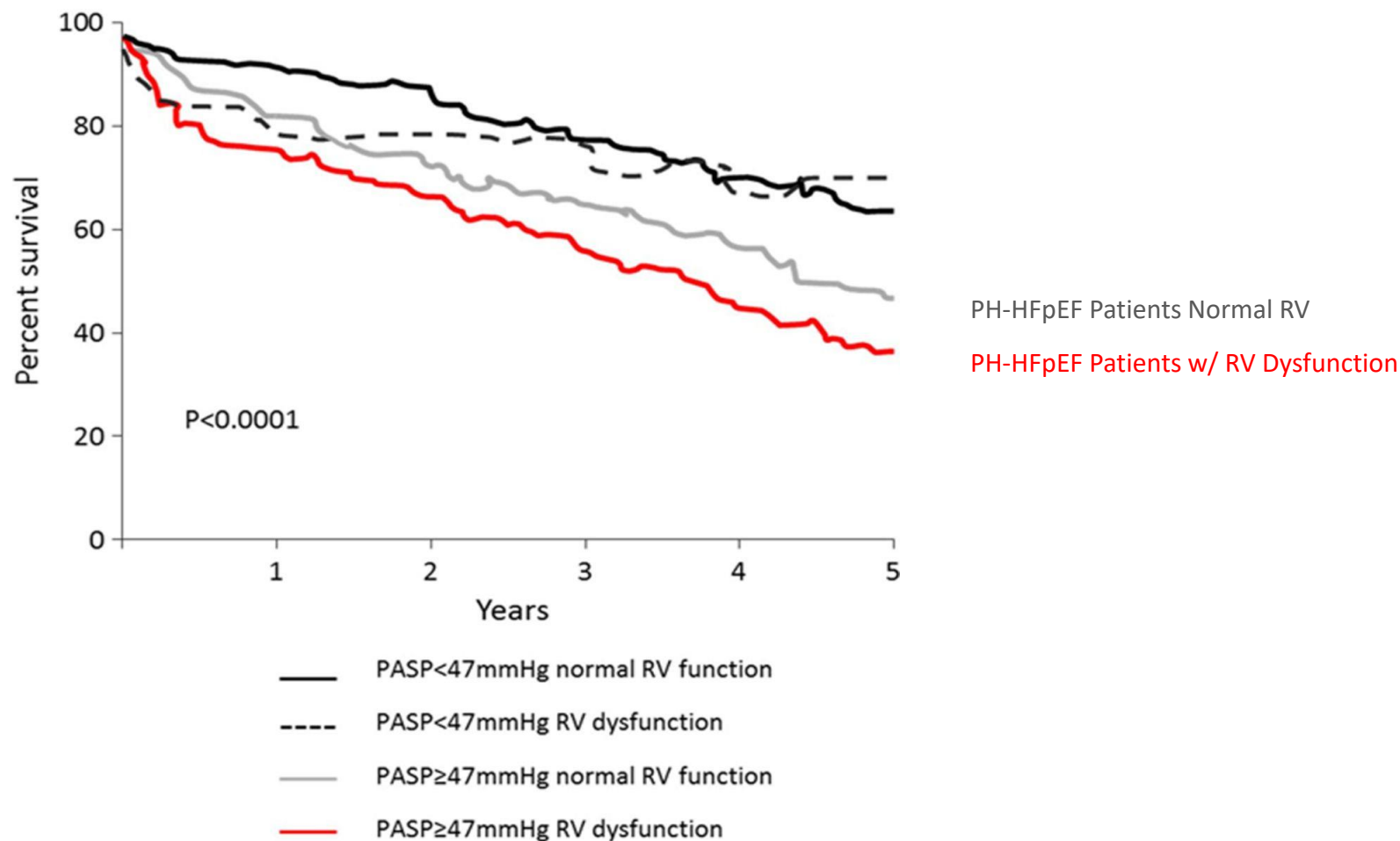
Levosimendan Development Focused on Group 2



- 1) Hoeper, Marius M., et al. "A global view of pulmonary hypertension." *The Lancet Respiratory Medicine* 4.4 (2016): 306-322
- 2) Dixon, Debra D., Amar Trivedi, and Sanjiv J. Shah. "Combined post-and pre-capillary pulmonary hypertension in heart failure with preserved ejection fraction." *Heart failure reviews* 21.3 (2016): 285-297. (Estimates 2.2M PH-HFpEF patients)
- 3) Guazzi, Marco. "Pulmonary hypertension in heart failure preserved ejection fraction: prevalence, pathophysiology, and clinical perspectives." *Circulation: Heart Failure* 7.2 (2014): 367-377. (PH-HFpEF ≈ 50% of all US HFpEF patients)
- 4) Global Data epidemiological estimates

Poor PH-HFpEF Patients Outcomes

PH-HFpEF + Right Ventricle Dysfunction
Associated with Highest Mortality



Levosimendan

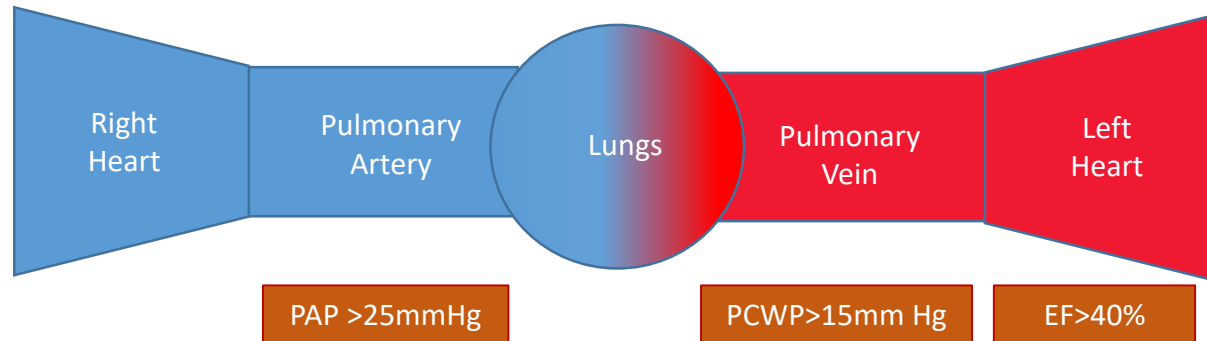
Mechanism of Action

	Molecular targets	Mechanisms of action	Pharmacological effects	Therapeutic effects
1.	<u>Selective binding to the calcium-saturated form of cardiac troponin C</u>	Calcium sensitization	Positive inotropic Positive lusitropic	<ul style="list-style-type: none"> Increased ejection fraction Decreased left ventricular filling pressures
2.	Opening of sarcolemma <u>K_{ATP}</u> channels on <u>smooth-muscle</u> cells in vasculature	Hyperpolarization	Vasodilation in all vascular beds (also coronary and peripheral circulation)	<ul style="list-style-type: none"> Lowered pre- and after-load Anti-ischemic Better tissue perfusion Normalization of neurohormones
3.	Opening of mitochondrial <u>K_{ATP}</u> channels in <u>cardiomyocytes</u>	Protection of mitochondria in ischemia-reperfusion	Preconditioning, anti-stunning anti-apoptotic	<ul style="list-style-type: none"> Cardioprotection Anti-ischemic

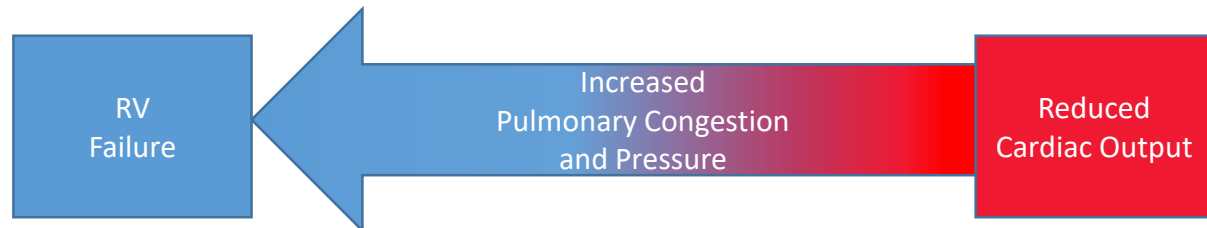
Parissis, John T., et al. "Levosimendan: from basic science to clinical practice." *Heart failure reviews* 14.4 (2009): 265.

Mechanistic Rationale for Levosimendan in PH-HFpEF – More than just a Vasodilator

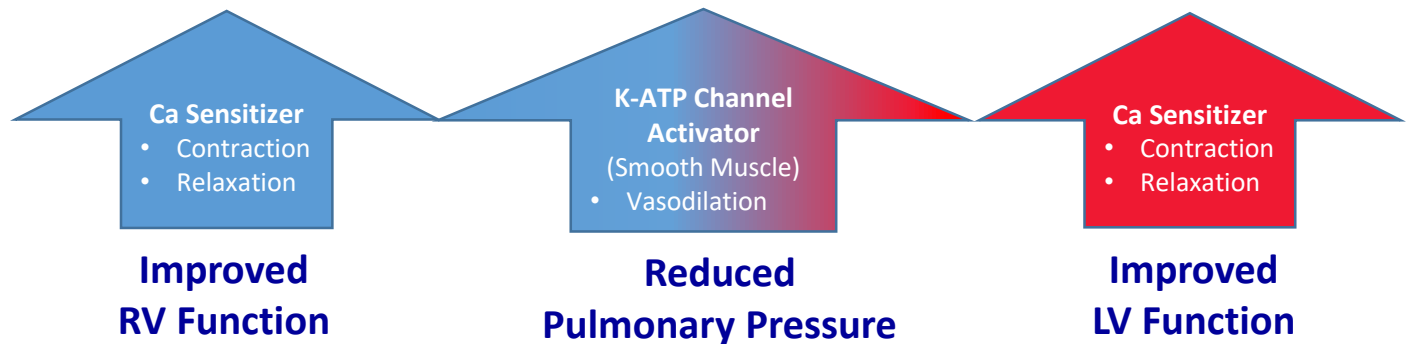
Cardio-Pulmonary System



Problem



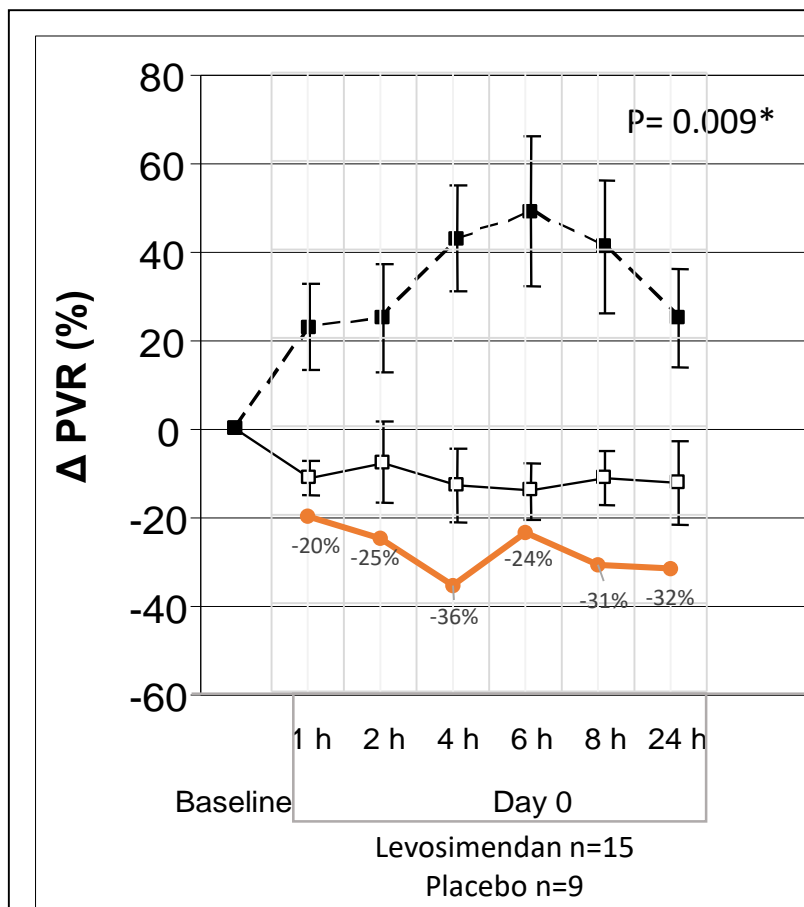
Levosimendan MOA



Potential Benefits

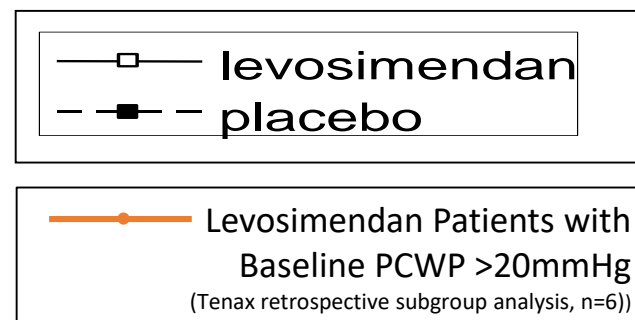
Levosimendan in Pulmonary Hypertension

Change in PVR (mean \pm SEM)
during 24-hour infusion



**Multicenter, Randomized,
Placebo Controlled, Pilot Study
of Levosimendan in Pulmonary
Hypertension Patients**

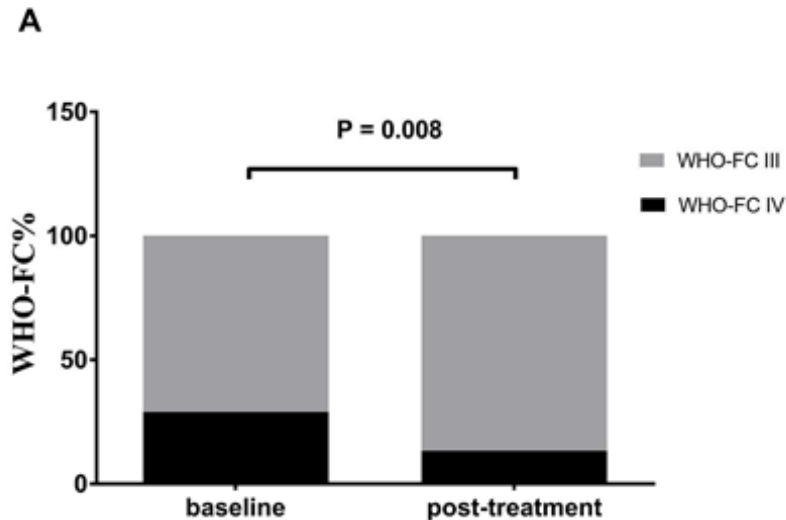
***Primary Endpoint: Change in PVR at end
of initial 24-hour infusion**



Levosimendan in Pulmonary Hypertension Patients with Right Heart Failure

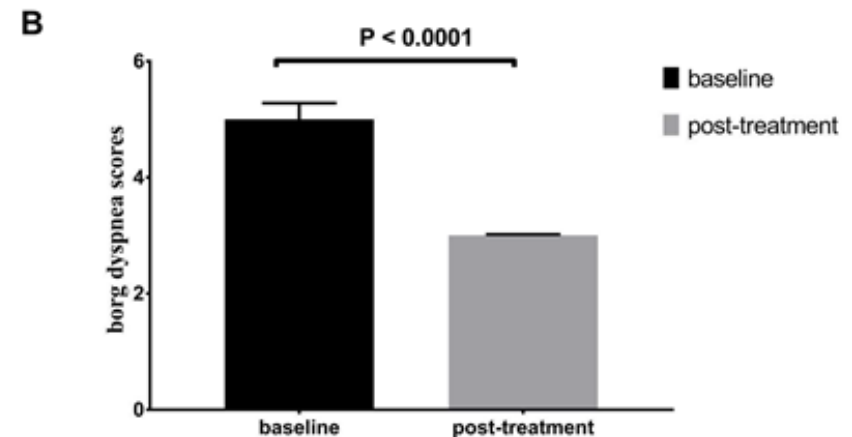
(Prospective Observational Study- September 2017)

Primary Endpoint: Change in WHO Functional Class



A. Change in WHO-FC after infusion of levosimendan from baseline to post-treatment. World Health Organization Function Class: WHO-FC.

Primary Endpoint: Change in Dyspnea Scores



B. Change in Borg dyspnoea scores from baseline to post-treatment

Levosimendan Phase 2 for PH-HFpEF

- **Multi-center, double-blind placebo-controlled study**
- **Enroll 36 evaluable patients at 12-15 sites**
 - PAP ≥ 35 , PCWP ≥ 20 , NYHA Class IIb/III, LVEF $\geq 40\%$
- **Primary Endpoints:**
 - Change from baseline PCWP with bicycle exercise (25Watts) at Week 6
 - 80% power to detect a ≥ 4.8 mmHg change in PCWP from baseline
- **Secondary Endpoints:**
 - Change in Cardiac Index at rest and with exercise
 - Change in PVR effect at rest and with exercise
 - Change in PCWP when supine and legs elevated
 - Patient global assessment
 - Exercise duration via 6 minute walk test
 - Physician's assessment of functional class
 - Clinical events: death and hospitalizations

Levosimendan Phase 2 for in PH-HFpEF Study Design

Open-Label Lead-In

24 hours
(0.1 µg/kg/min)

Levosimendan
enrolled patients

Responders

n=36

Non-Responders

Chronic Phase

5 weeks

Levosimendan
n=18

weekly infusion
through Week 5

Placebo
n=18

Week 6

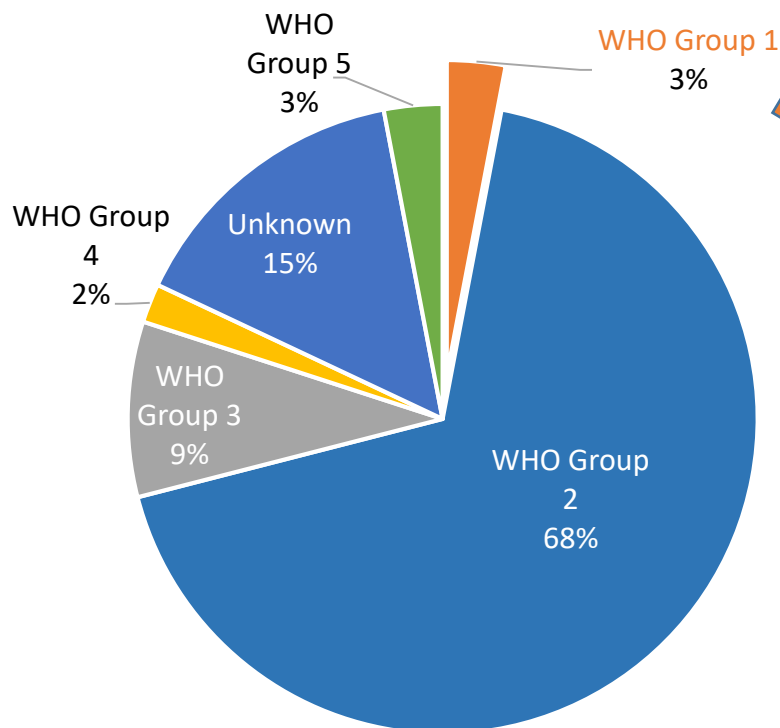
Final Evaluation

Attractive Commercial Opportunity

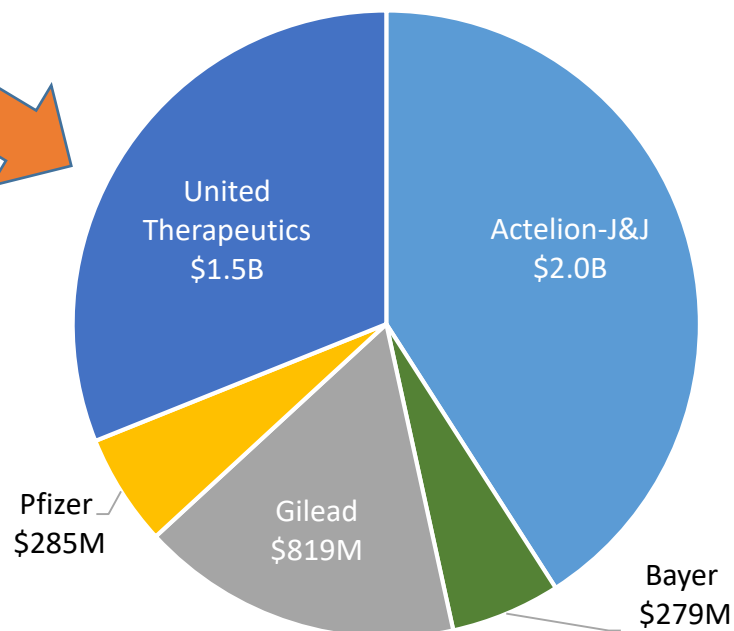
- **Large unmet medical need**
 - High mortality (up to 50% at 5 years)
 - Poor quality of life (poor exercise capacity)
 - No approved therapies
 - Large potential market
 - Estimated PH-HFpEF prevalence in the US >2,000,000
 - High value
 - Chronic therapy that addresses a large unmet medical need
- **IV levosimendan exclusivity as NCE**

Pulmonary Hypertension Prevalence and Market Size

Estimated Prevalence by WHO Group



Pharmaceutical Sales >\$5 billion in 2016
(primarily in Group 1)

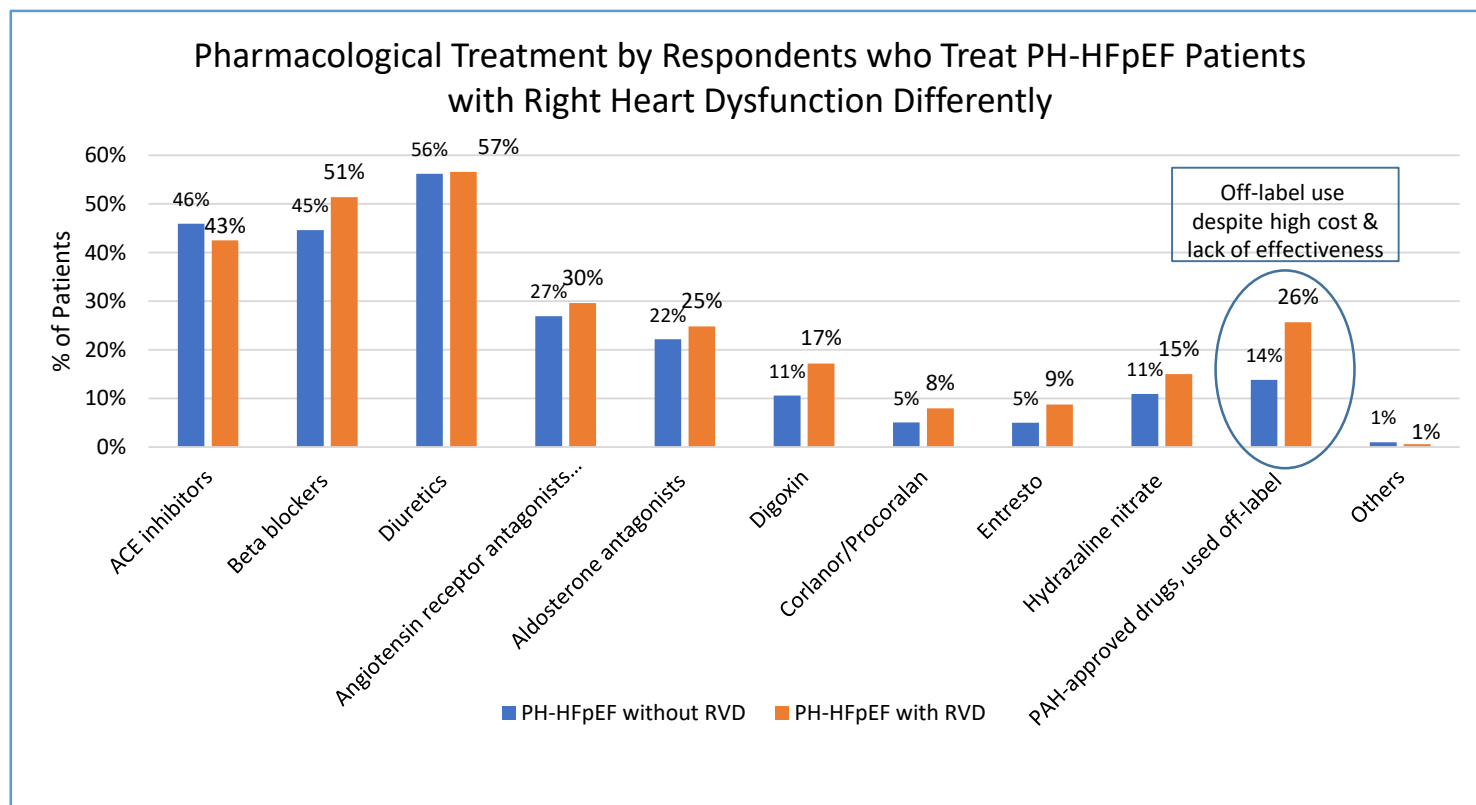


Source: Pulmonary Hypertension Association Strange G, et al. Heart. 2012;98(24):1805-11

Source: Company Annual Reports

PH-HFpEF Pharmacologic Treatment in Right Heart Failure

55% of surveyed physicians indicate that they treat their PH-HFpEF patients with right heart dysfunction differently than those without it. Common treatments are those used to more broadly treat HF - diuretics, beta blockers, and ACE inhibitors



Q. Do you treat PH-HFpEF patients with right heart dysfunction pharmacologically DIFFERENTLY than you PH-HFpEF patients who do NOT have right heart dysfunction?

Q. Of your diagnosed PH-HFpEF patients receiving pharmacological treatment, what percentages received the following drugs in 2017? Please provide your best estimates to the nearest whole number. If they were not treated with a particular therapy, please enter 0. Please note that the columns must equal at least 100 and will exceed 100% if multiple drugs are used.

PH-HFpEF Unmet Need

Approved WHO Group 1 Drugs are **not Approved or Effective** in Group 2 Patients

Drug Class	Pulmonary Hypertension WHO Group 1 (PAH)	Pulmonary Hypertension WHO Group 2 (HFpEF)
PDE5 Inhibitors	FDA Approved	Efficacy not established (Hoendermis et al 2015-Negative)
Endothelin Receptor Antagonists	FDA Approved	Efficacy not established (MELODY Trial-Negative)
Soluble Guanylate Cyclase Stimulators	FDA Approved	Efficacy not established (DILATE Trial-Negative)
Prostacyclins (IV/SC/Inhaled/Oral)	FDA Approved	Efficacy not established (SOUTHPAW Trial - Ongoing)

Management

Anthony DiTonno
CEO

- 40 years of experience in increasing levels of responsibility at life sciences companies
- Aventis Medical Systems: CEO
- NeurogesX: President and Chief Executive Officer
- MBA from Drexel University; BA from St. Joseph University



Michael Jebson
President, CFO

- >15 years of financial and accounting experience
- Grant Thornton, LLP: Auditor
- RTI International: Chief Ethics Officer, Senior Internal Auditor
- MS in Accounting from East Carolina University
- CPA licensed in North Carolina



Doug Randall
EVP, Commercial Business and Operations

- >33 years of pharmaceutical executive experience
- Phyxius Pharma: Co-founder, CCO
- The Medicines Company: VP of Commercial Operations
- Sanofi-Aventis Pharmaceuticals: VP of US Diabetes Marketing
- Aventis: VP of Sales



Doug Hay
EVP, Regulatory Affairs

- >29 years of pharmaceutical regulatory experience
- Phyxius Pharma: Co-founder, VP of Regulatory Affairs
- The Medicines Company, Shire Pharmaceuticals: Regulatory Affairs
- Bristol Myers Squibb: VP, Global Regulatory Sciences
- PhD from Northern Arizona University



Scientific Advisory Board

PH-HFpEF Development Plan Guided by World Recognized Experts in Pulmonary Hypertension and HFpEF

Stuart Rich, MD

- Professor of Medicine, Northwestern University Feinberg School of Medicine
- Director, Pulmonary Vascular Disease Program, Bluhm Cardiovascular Institute
- Previous FDA Cardio-Renal Advisory Committee Member
- Recognized Global Pulmonary Hypertension Expert

Northwestern Medicine
Feinberg School of Medicine

Daniel Burkhoff, MD, PhD

- Director Heart Failure, Hemodynamics and MCS Research at the Cardiovascular Research Foundation
- Adjunct Associate Professor of Medicine, Columbia University

 **Cardiovascular
Research Foundation**



Sanjiv Shah, MD, FAHA, FACC, FASE

- Professor of Medicine, Northwestern University Feinberg School of Medicine
- Director, T1 Center for Cardiovascular Therapeutics
- Director, Northwestern HFpEF Program, Division of Cardiology, Dept of Medicine, Northwestern University Feinberg School of Medicine

Northwestern Medicine
Feinberg School of Medicine

Summary:

The Opportunity for Levosimendan in PH-HFpEF

- **Area of high unmet medical need**
 - High mortality (up to 50% at 5 years)
 - Poor quality of life (poor exercise capacity)
 - No approved therapies in PH-HFpEF
- **Commercially attractive market**
 - Large potential market - Estimated PH-HFpEF prevalence in the US >2,000,000
 - High value chronic therapy that addresses a large unmet need
- **Mechanistic rationale for Levosimendan in PH-HFpEF**
 - Including mechanisms directed at right heart failure
- **Phase 2 trial is almost 25% enrolled**
- **IV Levosimendan exclusivity as NCE**
- **Sub Q patent filed**