



Corporate
Presentation
July 2018

Safe Harbor Statement

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 2, 2018, its quarterly report on Form 10-Q filed on May 15, 2018, 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 drugs that address diseases with high unmet medical need with an initial therapeutic focus on Cardio-Pulmonary diseases.

Investment Highlights

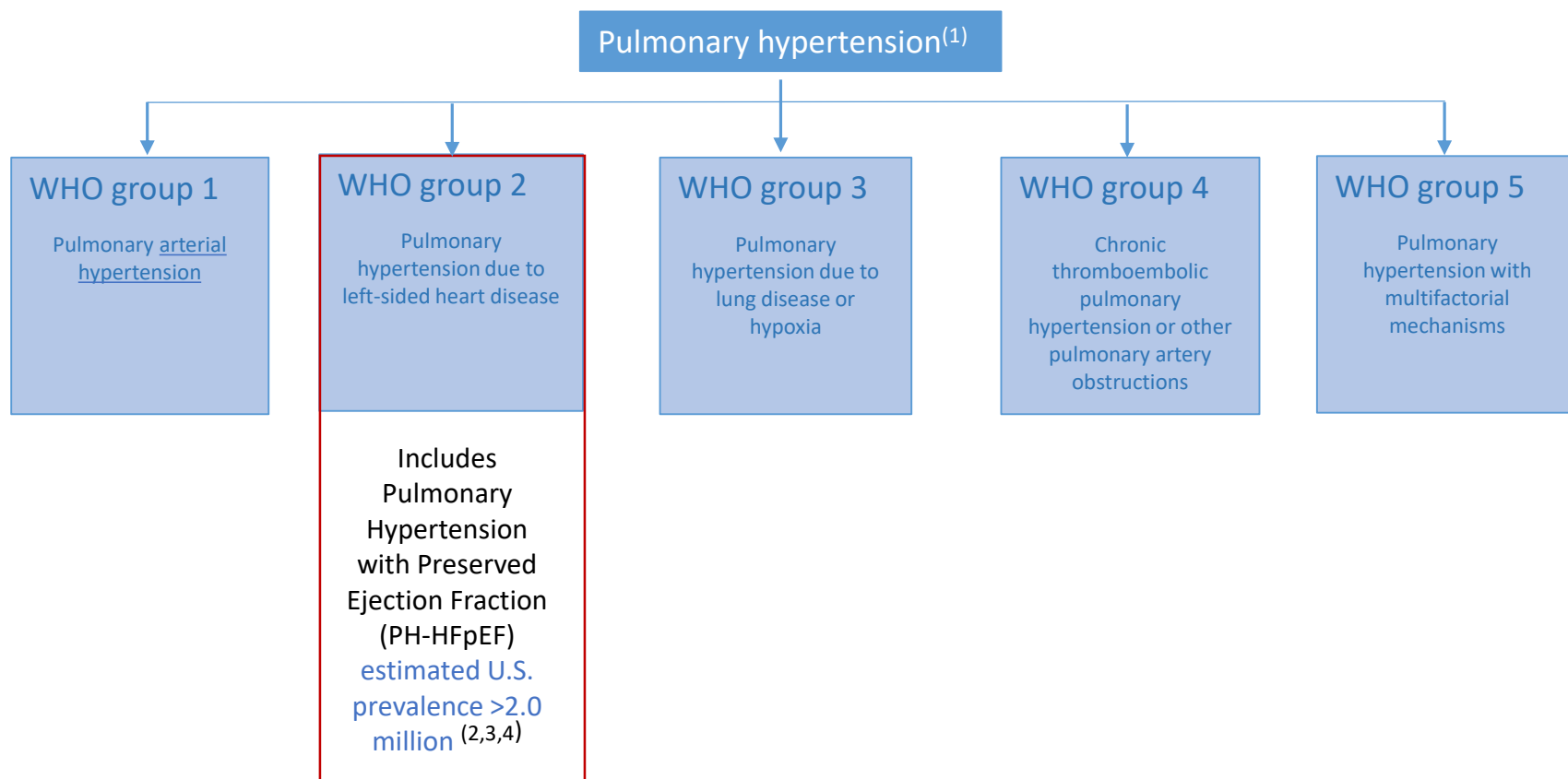
- **Levosimendan**
 - Novel, first in class calcium sensitizer/K-ATP activator with unique triple mechanism of action
 - Approved in over 60 countries acutely decompensated heart failure
 - Hold US and Canadian development and commercialized rights
- **Poised to commence Phase 2 trial for PH-HFpEF**
 - Significant unmet medical need with no approved therapies
 - Positive preclinical and clinical data support moving forward in Pulmonary Hypertension
 - Open-label lead in phase to identify responders ahead of randomization
 - On track to initiate in 3Q18
- **Management and SAB with proven track record in drug development**

Rationale for Development of Levosimendan in PH-HFpEF

- Mechanistic rationale for Levosimendan in PH-HFpEF
 - Including mechanisms directed at right heart failure
- Leverage positive levosimendan clinical study data
 - Positive Phase 2 pulmonary hypertension study data
 - Positive right heart failure data
- Capitalize on PH-HFpEF advisors expertise and advocacy
 - Validate clinical development strategy with PH-HFpEF experts
- Efficient and timely Phase 2 trial planned
- Commercially attractive market with 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
 - High mortality (up to 50% at 5 years) and poor quality of life (poor exercise capacity)
 - Potential IV levosimendan exclusivity as NCE

Pulmonary Hypertension WHO Classification

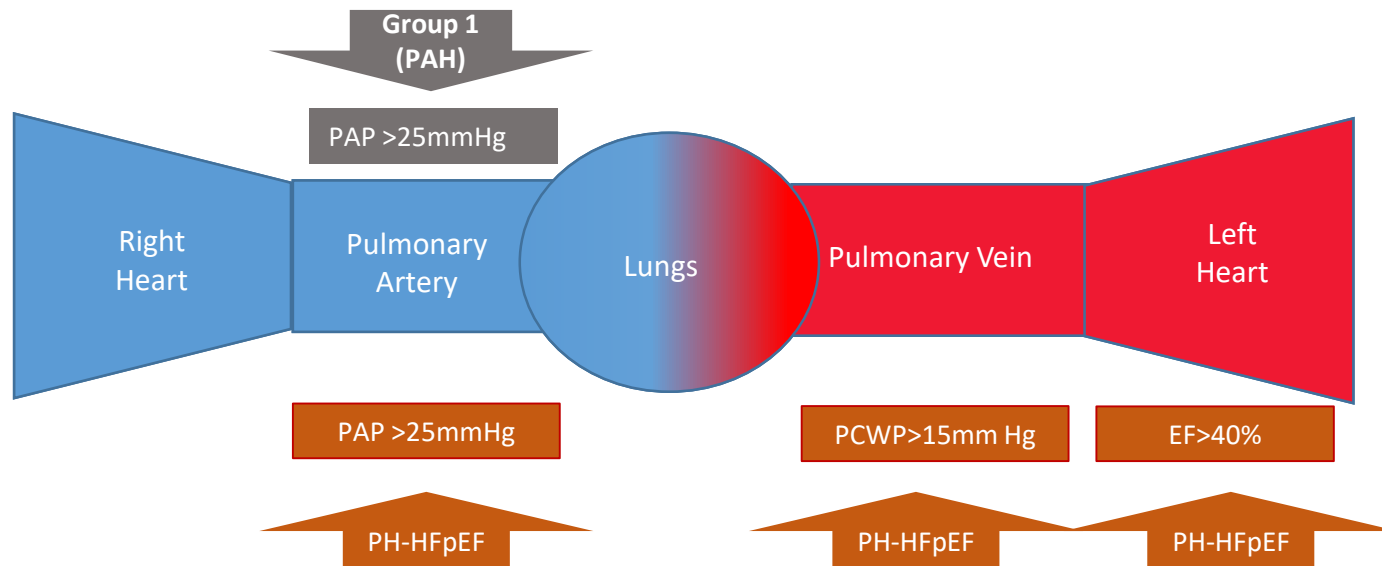
Levosimendan Development Focused on Group 2



- 1) Hoepfer, 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-HFpEFpatients)
- 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

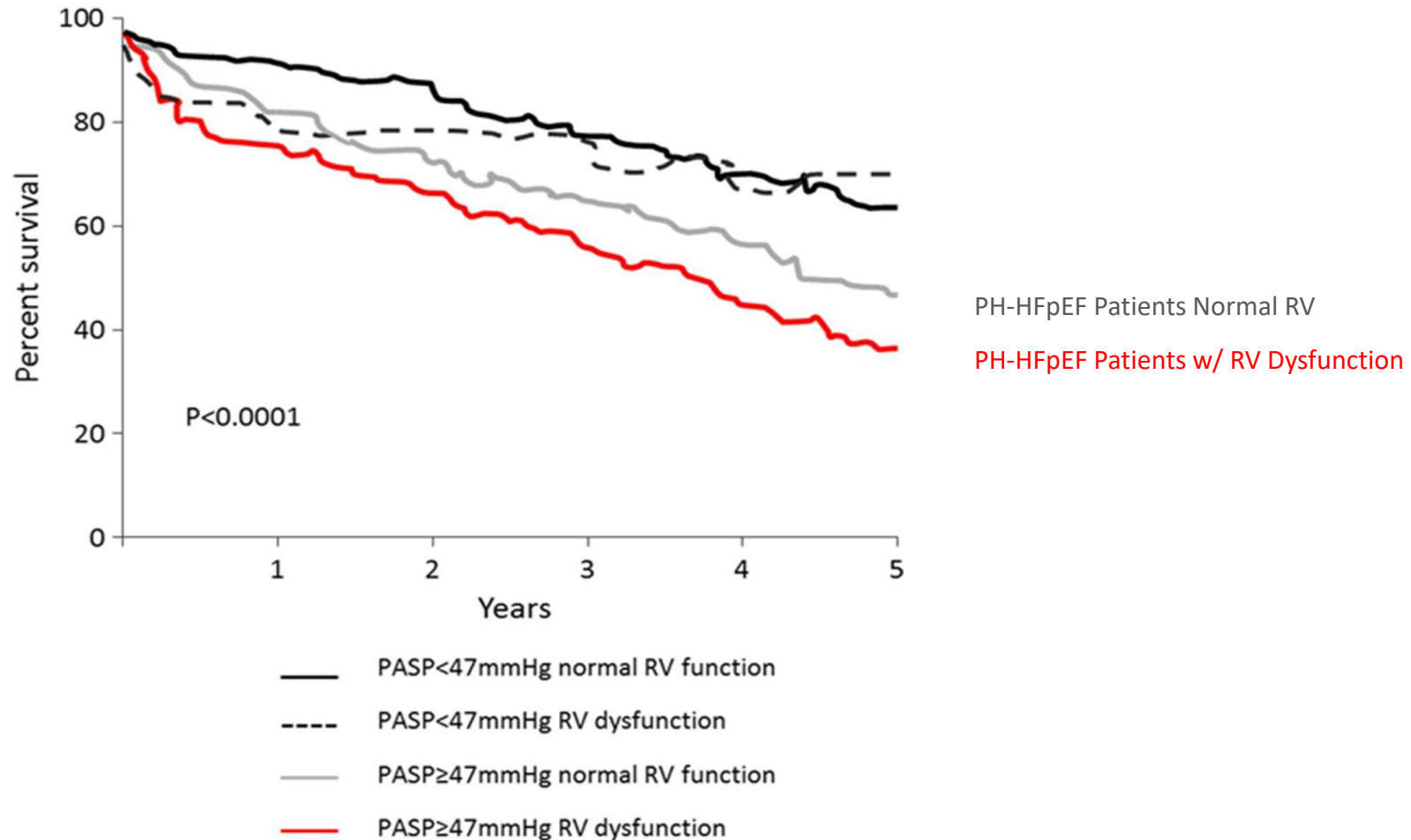
Pulmonary Hypertension and PH-HFpEF Overview

- **Pulmonary Hypertension associated with Heart Failure and preserved Ejection Fraction (PH-HFpEF)**
 - Heart failure with impaired relaxation and stiffened myocardium, EF>40%
 - Pulmonary capillary wedge pressure (PCWP) >15 mm Hg
 - Pulmonary artery pressure (PAP) >25 mm Hg
 - Sustained backward hemodynamic transmission leads to right ventricle dysfunction

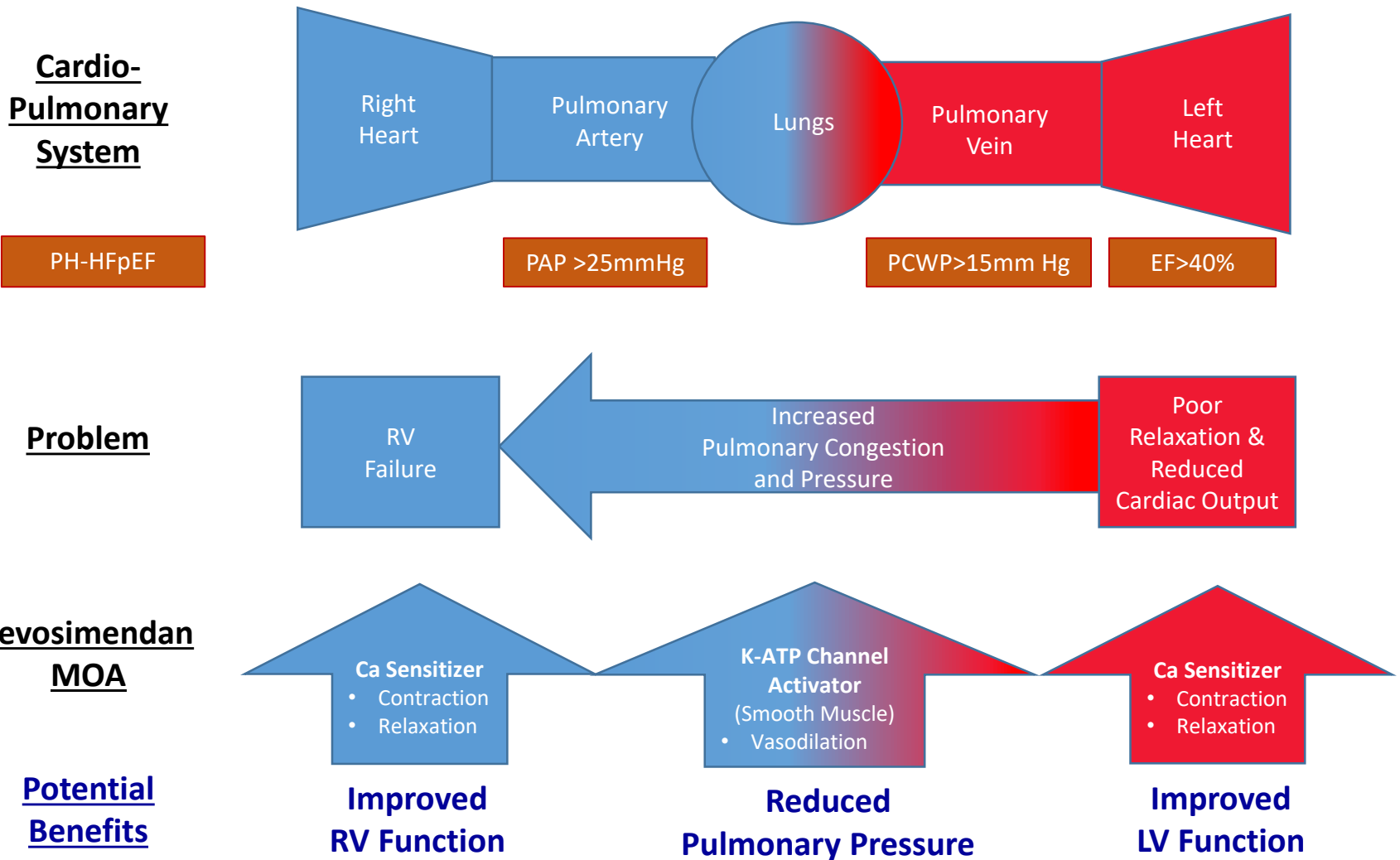


Poor PH-HFpEF Patients Outcomes

PH-HFpEF + Right Ventricle Dysfunction
Associated with Highest Mortality

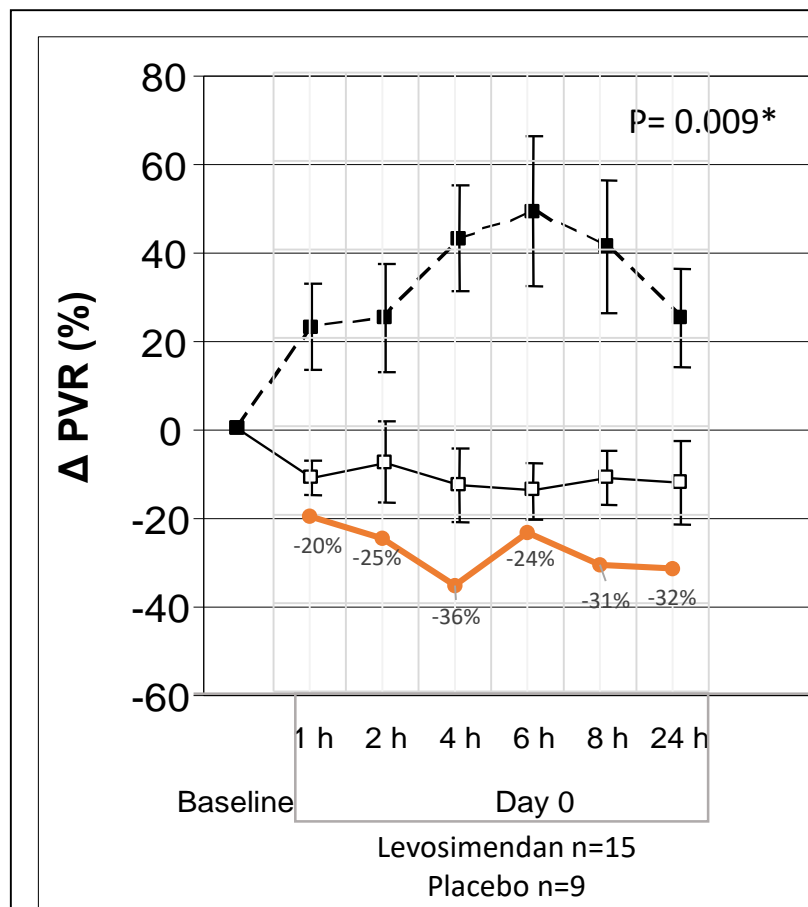


Mechanistic Rationale for Levosimendan in PH-HFpEF – More than just a Vasodilator



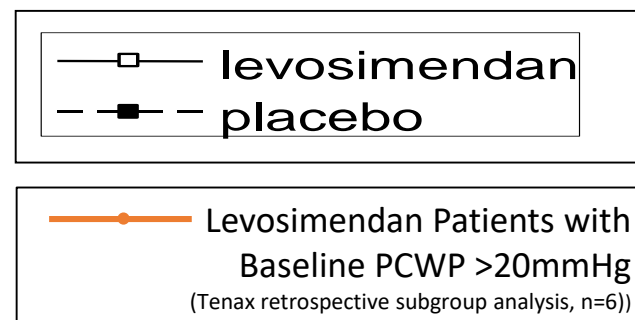
Levosimendan in Pulmonary Hypertension

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



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

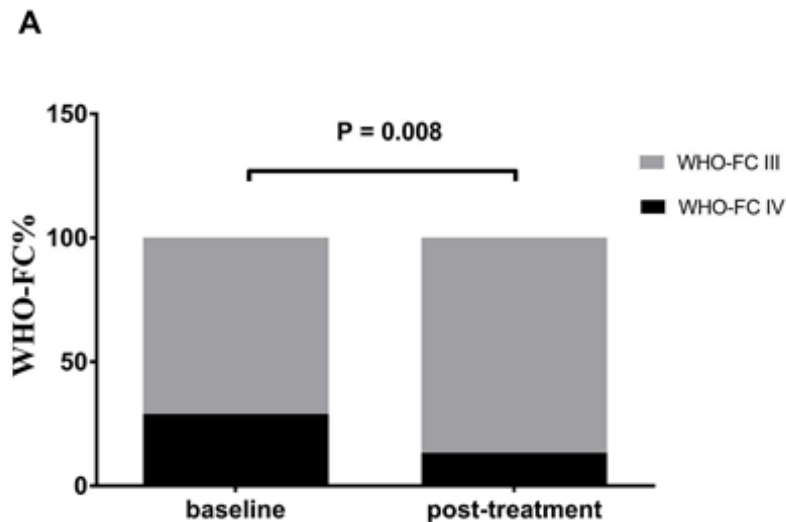
***Primary Endpoint: Change in PVR at end of initial 24-hour infusion**



Levosimendan in Pulmonary Hypertension Patients with Right Heart Failure

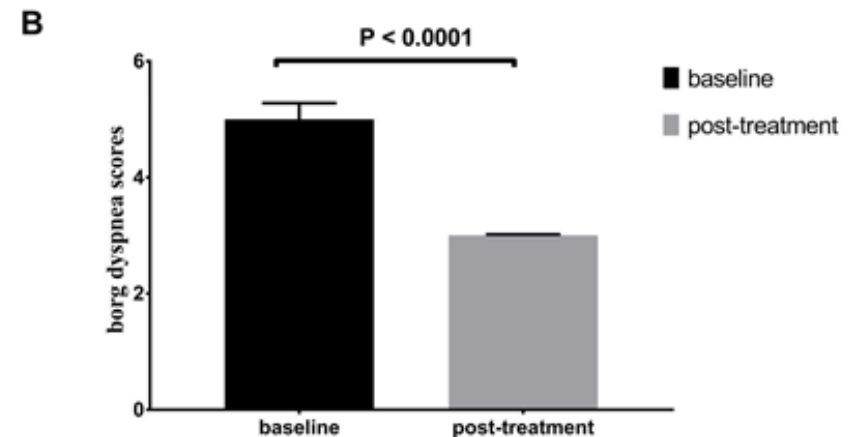
(Prospective Observational Study- September 2017)

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

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**

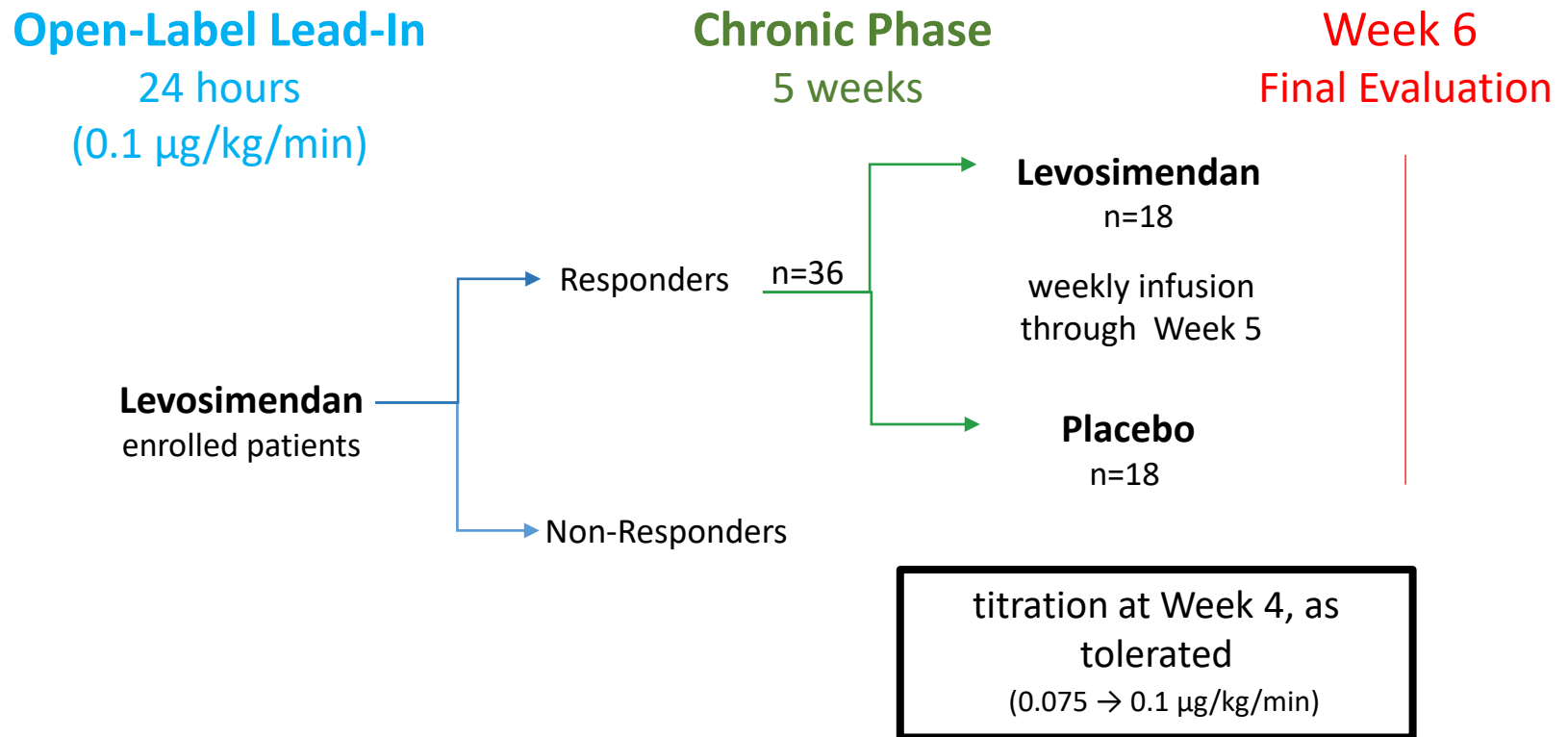
- Professor of Medicine, Northwestern University Feinberg School of Medicine
- Director, T1 Center for Cardiovascular Therapeutics
- Director, Northwestern HFpEF Program, Division of Cardiology, Dept of Medicine, Northwestern University Feinberg School of Medicine

Northwestern Medicine
Feinberg School of Medicine

Levosimendan Phase 2 for PH-HFpEF

- Multi-center, double-blind placebo controlled study
- Enroll 36 evaluable patients at 20 to 25 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

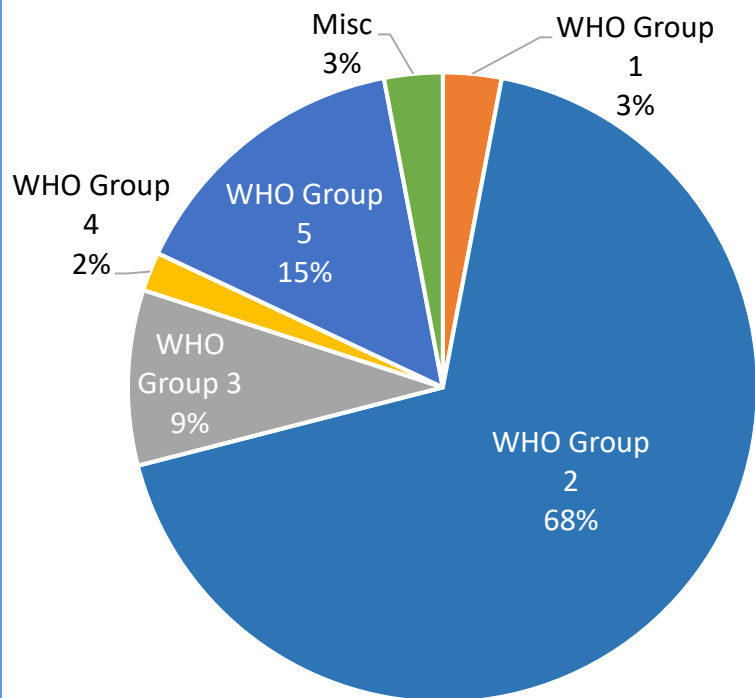


Rationale for Development of Levosimendan in PH-HFpEF

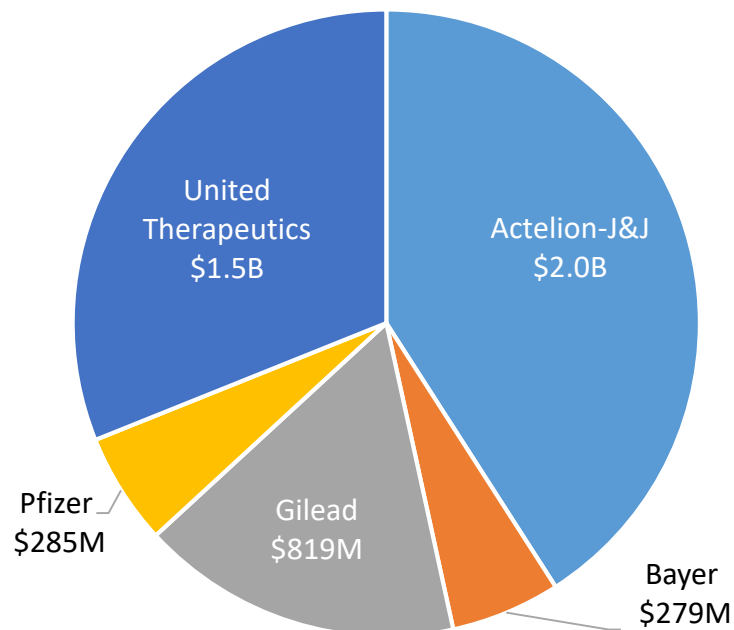
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Pulmonary Hypertension Prevalence and Market Size

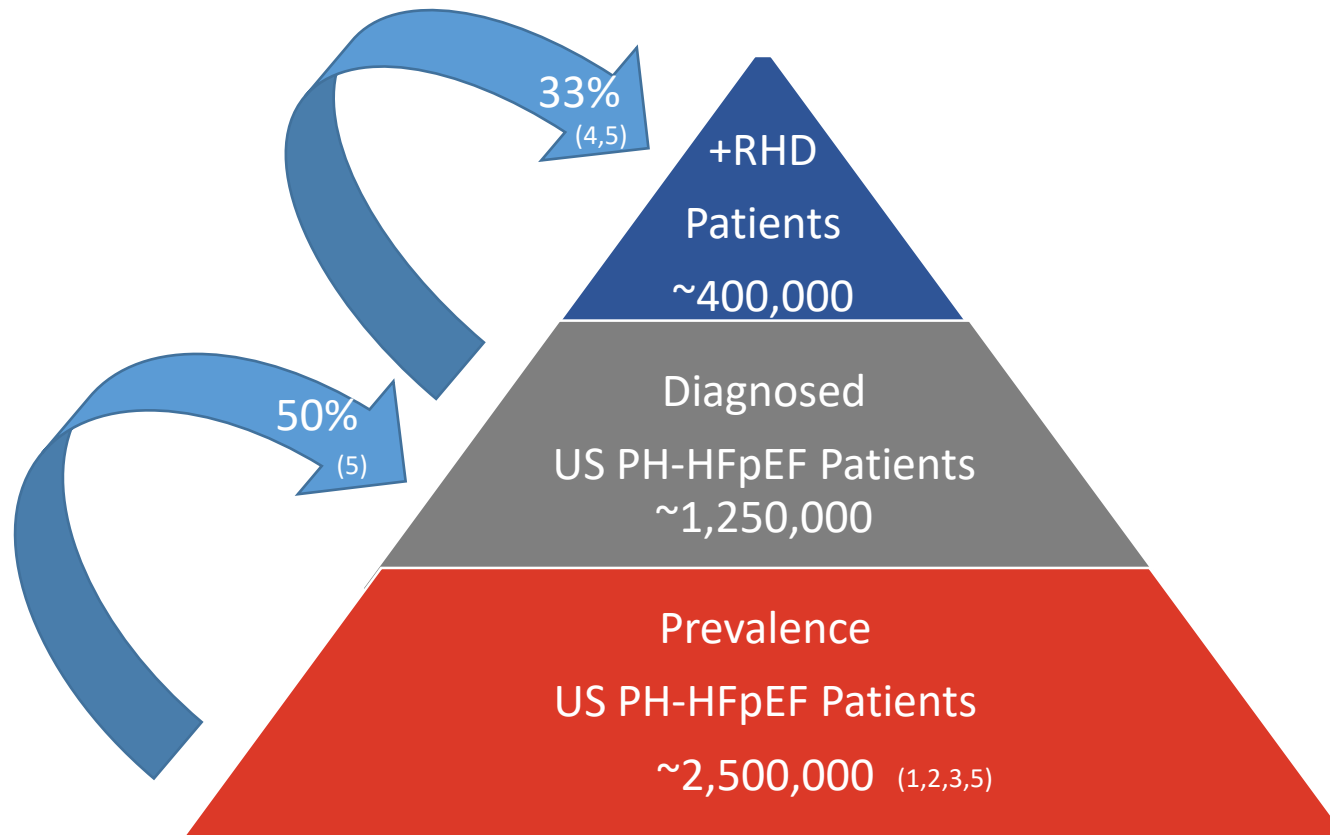
Estimated Prevalence by WHO Group



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



PH-HFpEF with Right Heart Dysfunction (RHD): Large Target Market with Very High Needs



Estimates based on :

- 1) Benjamin, Emelia J., et al. "Heart disease and stroke statistics—2017 update: a report from the American Heart Association." *Circulation* 135.10 (2017): e146-e603.
- 2) Lam CS, Roger VL, Rodeheffer RJ, Borlaug BA, Enders FT, Redfield MM. Pulmonary hypertension in heart failure with preserved ejection fraction: a community-based study. *J Am Coll Cardiol.* 2009;53:1119–1126.
- 3) 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)
- 4) Guazzi, Marco. "Pulmonary hypertension in heart failure preserved ejection fraction: prevalence, pathophysiology, and clinical perspectives." *Circulation: Heart Failure* 7.2 (2014): 367-377.
- 5) Global Data Epidemiologic Analysis and Primary Market Research May 2018

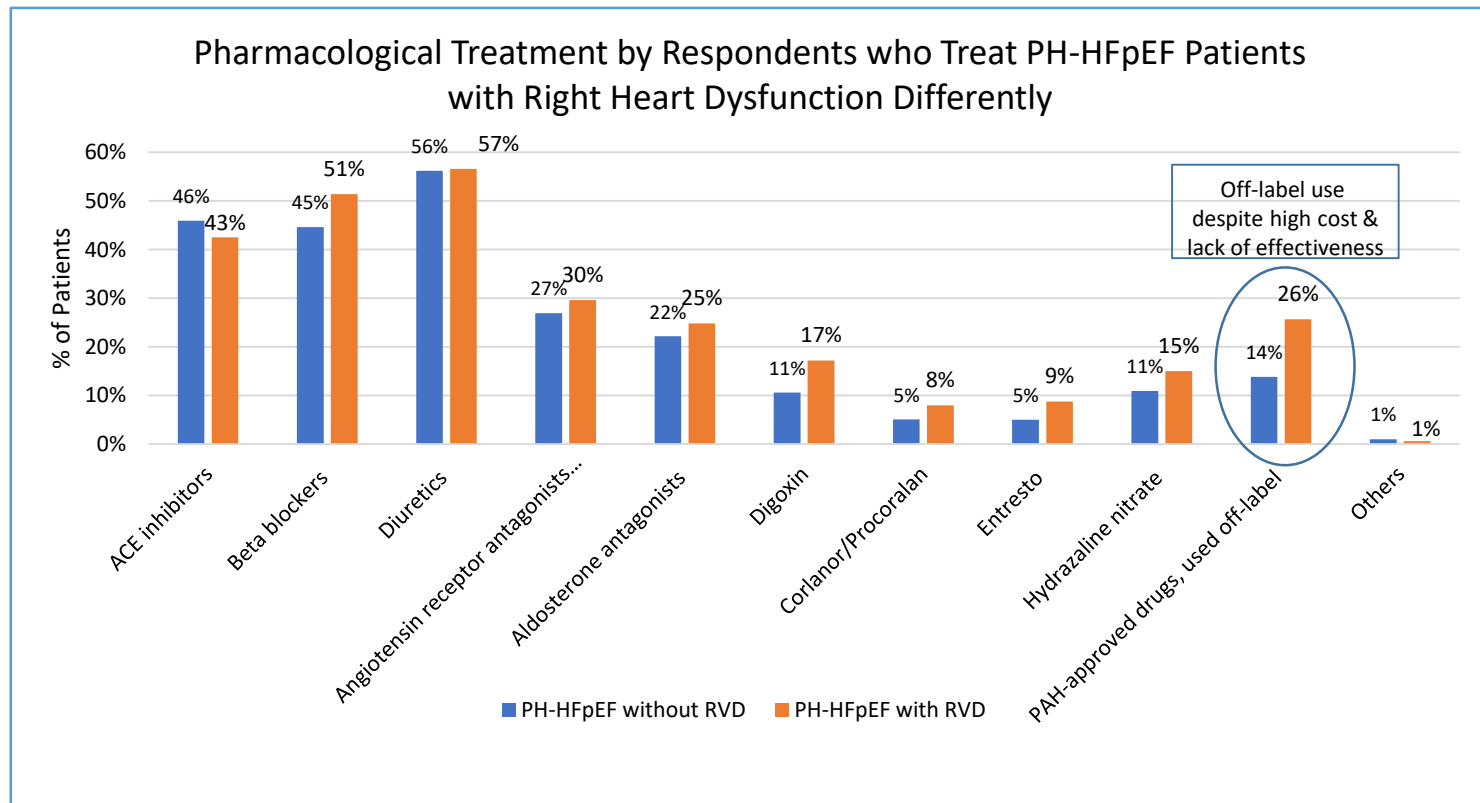
PH-HFpEF Unmet Need

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)

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.

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



Board of Directors

Ronald Blanck, DO
Chairman

- Martin, Blanck & Associates: Chairman
- Retired Surgeon General of the Army
- University of North Texas Health Science Center: President
- Walter Reed Medical Center: Commander



Chris Rallis

- Pappas Capital: Executive-in-Residence
- ImmunoBiosciences: President and Chief Executive Officer
- Triangle Pharmaceuticals, Inc.: President, COO
- Aeolus Pharmaceuticals, Fennec Pharmaceuticals: Audit Committee Chairman



Gerry Proehl

- Dermata Therapeutics, LLC: Founder, President, CEO and Director
- Santarus, Inc.: President, Chief Executive Officer, Director
- HMR: Vice President of Global Marketing
- Sophiris Bio Inc., Ritter Pharmaceuticals, Inc., Kinetek Sports, Patara Pharma LLC, and MD Rejuvena, Inc: Director



Jim Mitchum

- NephroGenex Inc.: Director
- Heart to Heart International: CEO
- Americas for EUSA Pharma: President
- Enturia, Inc.: President, CEO
- Sanofi-Aventis Group and Aventis Pharma UK: President and CEO



Gregory Pepin

- Melixia SA: Senior Vice President
- Vatea Fund: Managing Director
- EOS Investment, Ltd.: Co-founder
- Independent Wealth Management, SA: Co-founder, analyst



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
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- Existing preliminary positive Phase 2 clinical data in Pulmonary Hypertension
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- IV Levosimendan exclusivity as NCE