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# Windtree Therapeutics and Istaroxime Highlights



Biopharmaceutical company with advanced clinical focused on significant acute CV markets with high unmet needs and with supportive regulatory paths and designations (NASDAQ: WINT)



Through three Phase 2 global studies, lead asset istaroxime has consistently demonstrated a highly unique and attractive profile

 It is the only acute heart failure or shock drug that has demonstrated both significant improvement in cardiac function of a failing heart, as well as rapid and significant improvement in blood pressure, with what so far has been a differentiating safety profile (avoiding many of the use-limiting side effects of existing therapies)



Recent positive Phase 2 study with istaroxime in early cardiogenic shock (ECS) paves the way for what we believe is a relatively fast and less expensive developmental and regulatory pathway

- Precedent shows blood pressure response can be acceptable as the primary endpoint in a pivotal shock study. Additionally, istaroxime is demonstrating significant other benefits that we plan to build upon in the larger phase 3 to create a strong, evidence-based clinical and pharmacoeconomic positioning
- Given what we believe to be an attractive opportunity that may be pursued with less spend and have faster time to market, cardiogenic shock has become the organization's priority and focus



Highly experienced management team and company leadership

# **Pipeline**

Lead Products	Indication	Phase	Development Status	Regulatory Status
Istaroxime	Early Cardiogenic Shock	Phase 2	<ul> <li>Positive Phase 2 study</li> <li>Planning the execution of the next study and plans to meet with regulatory agencies regarding development path</li> </ul>	Potential for Breakthrough Designation
Istaroxime	Acute Heart Failure	Phase 2b	<ul> <li>Plan a second Phase 2b clinical trial in ~300 patients targeted to start once clinical trial operations are fully funded</li> </ul>	FDA Fast Track Designation
Oral SERCA2a Activators	Chronic Heart Failure, including potentially HFpEF	Preclinical	<ul><li>Chronic and Acute Heart Failure</li><li>Target for collaboration/partnership</li></ul>	
Rostafuroxin	Genetically Associated Hypertension	Phase 2b	Out-licensing opportunity	
KL4 Surfactant and AEROSURF	KL4 surfactant Drug/Device Tx for RDS and potential other applications	Phase 2b	Global out-license to Lee's Pharmaceutical and Zhaoke Pharmaceutical	FDA Fast Track Designation, Orphan Drug





# Istaroxime

# **Early Cardiogenic Shock**

Potential indication in active clinical development



# **Cardiogenic Shock**

A severe presentation of heart failure characterized by very low blood pressure and hypoperfusion accompanied by high filling pressures of the heart and decreased urine output. It is a treatment emergency



- Caused by severe impairment of cardiac function that results in diminished cardiac output, end-organ hypoperfusion and hypoxemia
- Commonly requires pharmacological or mechanical intervention to increase SBP to >90mmHg and improve tissue perfusion
- High in-hospital mortality (~30-40%) and substantial morbidity in survivors<sup>1</sup>
- Represents an approximate \$1.25B total market potential<sup>2</sup>

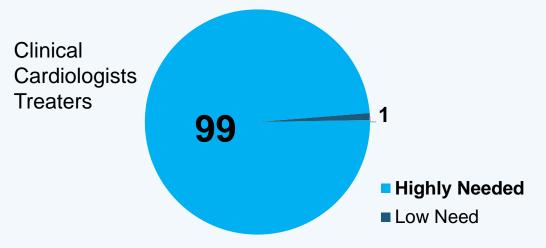


## **Early Cardiogenic Shock Treatment**

### Istaroxime Potential Opportunity to Address Significant Unmet Need

- No satisfactory pharmacological intervention to reverse the conditions
  - Available therapies have unwanted side effects such as risk for arrhythmias, decreasing blood pressure, renal dysfunction and even increases in mortality that limit their usefulness and position them as "rescue medicines" for severe cases
- A therapy that can be used earlier to rapidly improve blood pressure and cardiac function without unwanted side
  effects is needed

### 100 U.S. Cardiologists questioned on degree of unmet need for new innovative pharmacologic treatments for ECS



- ✓ 84% of the cardiologists responded they would be likely to extremely likely to use istaroxime for early cardiogenic shock patients
- ✓ Majority responded they would position utilization before use of other existing classes of therapies such as inotropes and vasopressors



# **Istaroxime – Novel First-in-Class Therapy**

Novel intravenous agent designed to improve systolic contraction <u>and</u> diastolic relaxation of the heart

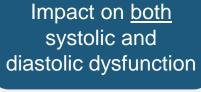
> **Dual Mechanism of** Action

Inhibition of the sodiumpotassium pump and effects on the sodium-calcium exchanger results in increased contraction

## **Istaroxime**

Impact on both systolic and

Stimulation of SERCA2a activity enhances calcium reuptake resulting in improvement of the diastolic relaxation and subsequent contraction cycle

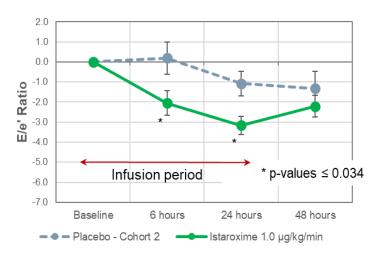




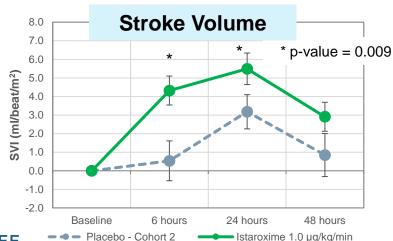
# Rationale for Istaroxime in Cardiogenic Shock Came from AHF Phase 2 Trials

### E/e' (cardiac filling pressure)

#### Istaroxime 1.0 μg/kg/min vs. placebo

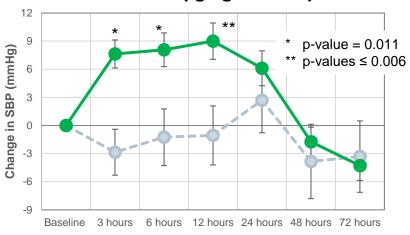


Improved cardiac function <u>and</u> SBP along with a favorable renal profile



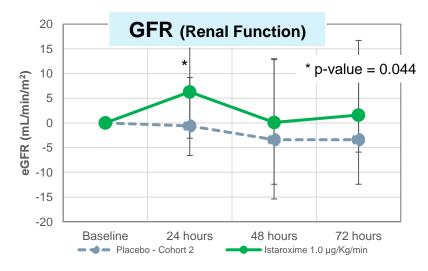
#### **Systolic Blood Pressure (SBP)**

#### Istaroxime 1.0 µg/kg/min vs. placebo









# Early Cardiogenic Shock Treatment Istaroxime Potential Opportunity for Accelerated Pathway

# Potential for a relatively fast and less expensive developmental and regulatory pathway

FDA Regulatory
Commentary with
Break-Through
Therapy Designation
Potential

Sponsors are potentially **not required to show benefit other than an** increase in blood pressure to support approval of drugs to treat hypotension in the setting of shock<sup>(1)</sup>

Precedent NDA: Giapreza® (IV Angiotensin II), approved in 2017 for increasing MAP in distributive shock – a different type of shock, not a competitor to istaroxime in early cardiogenic shock)<sup>(2)</sup> Precedent also indicates potential accelerated regulatory pathway and review opportunities

# **SEISMiC Early Cardiogenic Shock Study**

Clinical strategy: Start development with patients in early cardiogenic shock caused by severe heart failure



60 patients in early cardiogenic shock (SBP 75-90mmHg) with AHF



Study drug was infused for 24 hours in a 1:1 randomization to placebo or istaroxime. Two istaroxime target doses were evaluated,  $1.5\mu g/kg/min$  in the first group and  $1.0 \mu g/kg/min$  in the next group.

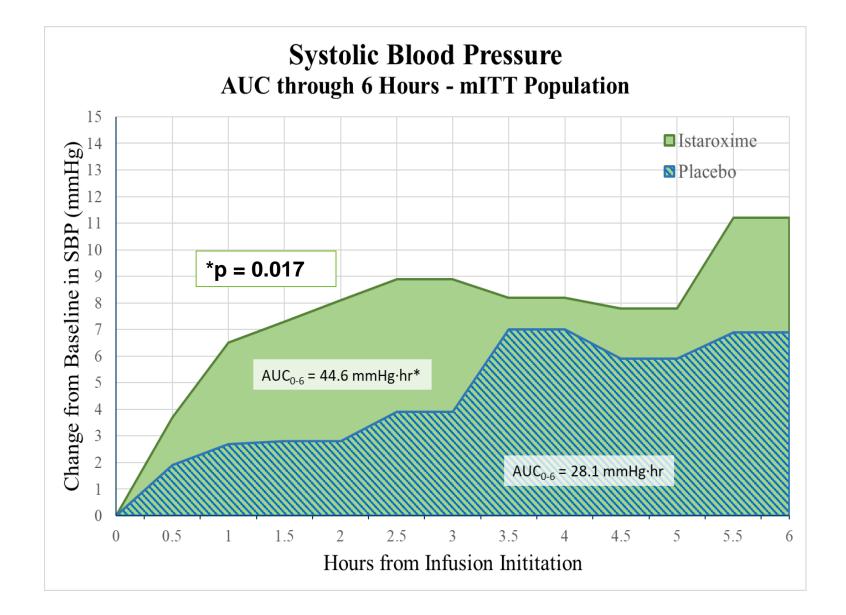


Primary endpoint was SBP AUC at 6 hours comparing istaroxime to placebo

Secondary measures included: SBP profile at 24 hours, echocardiology measures associated systolic and diastolic cardiac function, renal function, various safety and tolerability measures



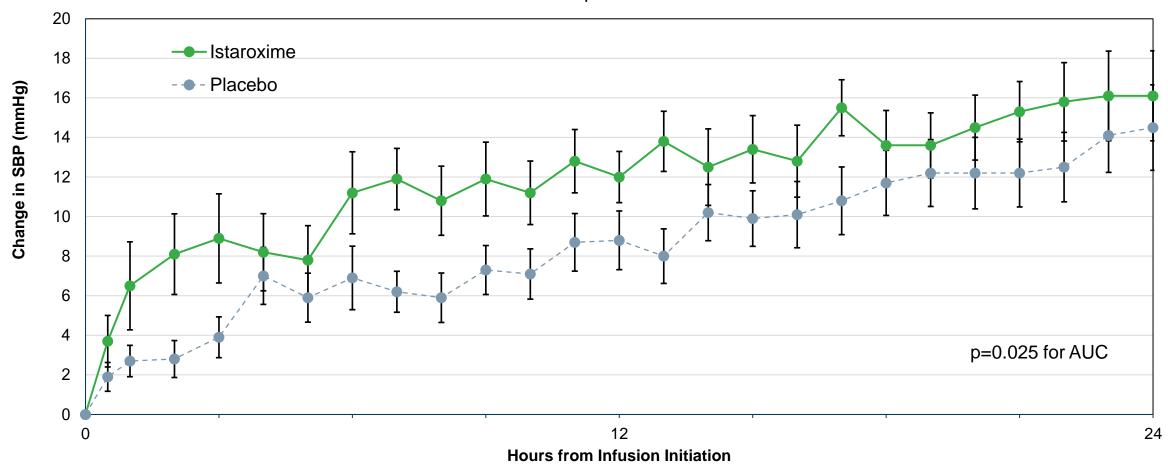
## **Difference in SBP Profile**





# **Systolic BP Improvements Persisted over 24 Hours**

Systolic Blood Pressure mITT Population





## **Cardiac Function Improvement**

Echocardiography demonstrated improvements in key systolic and diastolic cardiac function measures including:

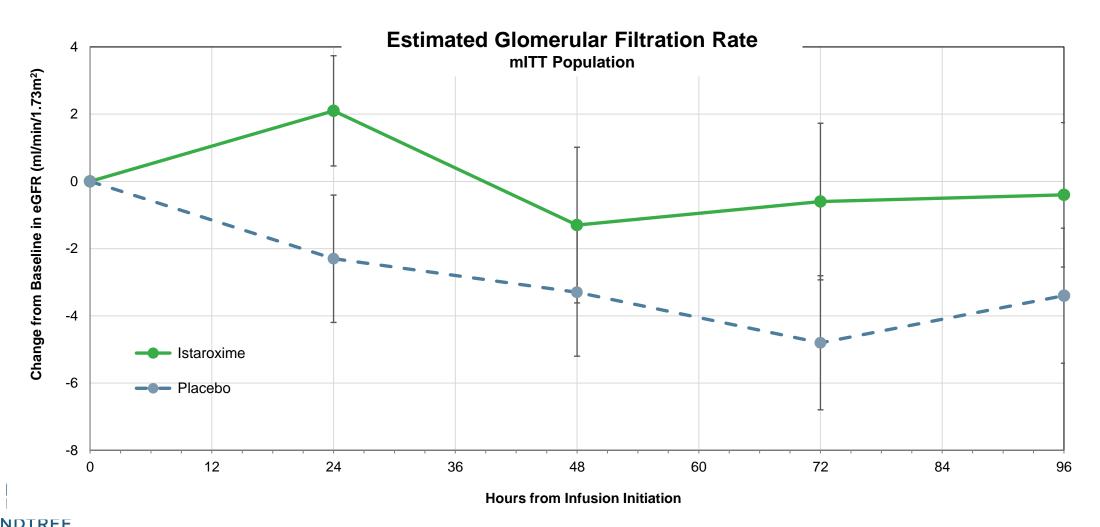
- Cardiac index significantly increased
- Stroke volume index substantially increased (4 mL/m²) approaching statistical significance
- Other echocardiographic measurements improved:
  - Left atrial area was reduced
  - Left ventricular end systolic volume was reduced
  - Left ventricular end diastolic volume was reduced





## Treatment was Associated with a Favorable Renal Profile

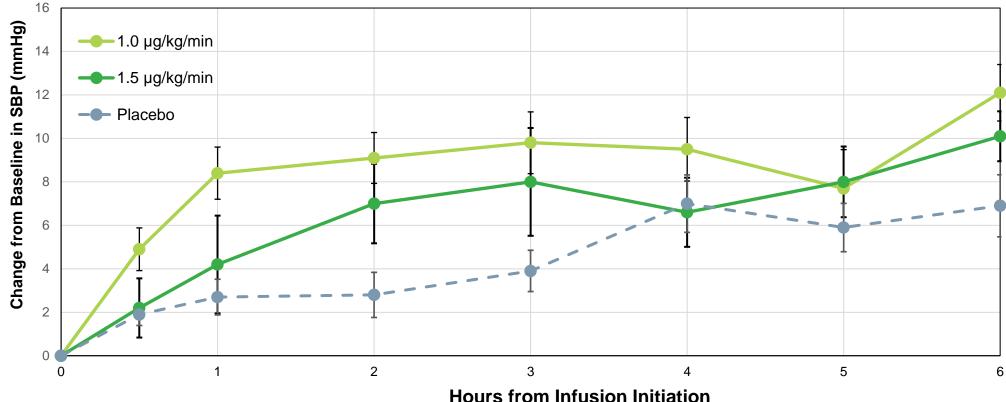
### Renal function was not decreased in istaroxime treated patients



## 1.0 µg/kg/min Produced a Favorable Effect on SBP

#### 1.0 µg/kg/min dosing was associated with:

- Early, rapid SBP increase and improvement in more echocardiographic assessments of cardiac function
- More favorable adverse event, serious adverse event and clinical event profile





# **SEISMiC Results Summary**

### SEISMiC was a positive study in early cardiogenic shock patients

- ✓ Systolic blood pressure significantly increased within the first 6 hours of initiating the infusion (p=0.017) and the increase was maintained throughout the 24-hour infusion (p=0.025)
  - SBP increases were rapid within the first hour and sustained through the 96-hour postinfusion measure
- √ Key secondary endpoints of systolic and diastolic cardiac function and performance were improved
- √ Renal function was maintained.
- ✓ SEISMiC provided valuable information for optimizing our dose moving forward
- ✓ These data substantiate and advance the rationale for istaroxime as a potential treatment for cardiogenic shock and support the existing data from the program in AHF



## **Cardiogenic Shock Opportunity**

#### **INTENDED TARGET THERAPEUTIC PROFILE**

"For patients in cardiogenic shock due to heart failure, Istaroxime will be a unique, first-in-class dual action agent and the only treatment for cardiogenic shock that rapidly and significantly improves blood pressure *and* cardiac output performance and does so while maintaining a favorable renal and overall safety profile - unlike other available agents. Istaroxime will be associated with an improved clinical course that has less resource utilization and cost reductions for positive Pharmacoeconomics for the hospital and health system".

#### **INTENDED POSITIONING:**

1. Expand the Market due to Profile: Used in SCAI Stage B / Early Cardiogenic Shock (where vasopressors are reserved) to help stabilize the patient and prevent deterioration



2. Become the Preferred Agent:
Preferred agent with first line use in SCAI Stage C / Classic Cardiogenic Shock due to differentiation

#### **OPPORTUNITY DRIVERS**



Currently available pharmacologic treatments have undesirable side effects and poor outcomes



Very high cost of cardiogenic shock treatment create opportunity for Istaroxime pharmacoeconomic benefits



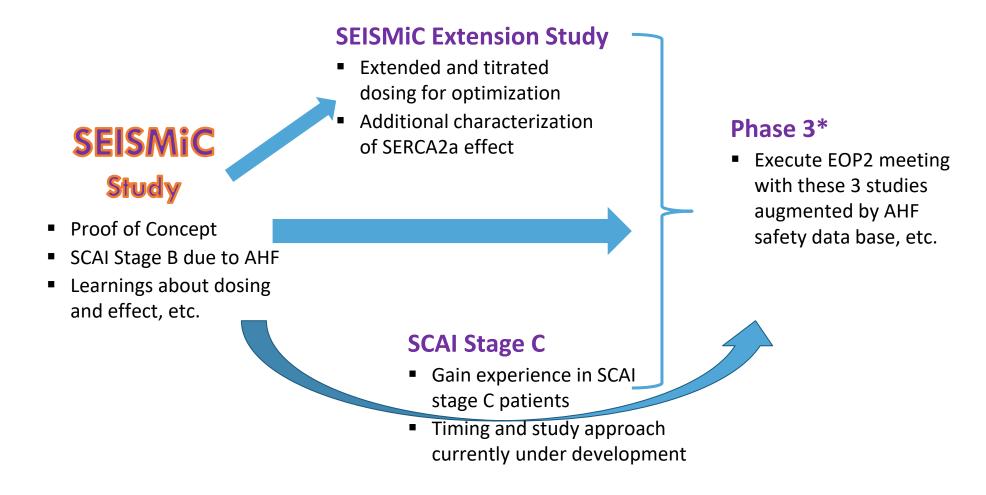
Lack of active competition in development or the market



Attractive commercial market potential (as well as time and cost of development)



# **Cardiogenic Shock Development Strategy**





<sup>\*</sup> Study plans and progression to Phase 3 dependent upon regulatory alignment and resourcing

# Plan for Dose Optimization – Extension Study

Following the positive results in the early cardiogenic shock study, an extension study is planned to support ongoing development in early cardiogenic shock and acute heart failure

### Study objectives:

- ✓ Advance the characterization of the physiology associated with longer istaroxime dosing as well as evaluate a dose titration
- ✓ More fully illuminate the effects and potential benefits associated with SERCA2a activation.
- ✓ Support our regulatory strategy for istaroxime

### Current study plan design:



Double-blind, placebo controlled in up to 30 patients (2:1 randomization) with SBP between 70-100mmHg conducted in sites in the US, EU and LATAM



Two treatment arms of 60-hour infusions, titrating down from 1.0 starting dose Placebo controlled arm



Multiple physiologic measures associated with cardiac function, blood pressure and safety

# **Istaroxime**

Dual Mechanism SERCA2a Activator

**Acute Heart Failure** 



# Heart Failure – Large, Growing Market But Underserved

The prevalence and mortality of heart failure is high and increasing

#1 cause of U.S. hospitalization in patients > 65 years old

**Annual Admissions** 

~1.3M u.s.

~1.5M E.U.



Patients
7M U.S.,
25M+ worldwide

~7%



In-patient mortality

30-day mortality can exceed 10%

>\$18B



annual U.S. hospital costs

**Most expensive of the Medicare diagnoses** 

0

New pharmacologic advancements in acute heart failure for decades

Lack of therapeutic advances led the FDA to issue new Heart Failure Guidance in July 2019 for greater development flexibility in acceptable endpoints, specifically acknowledging mortality is not required



# Acute Heart Failure – Significant Unmet Clinical Need

### Patient Management Goals

- Clinical objectives for AHF patient management include:
  - Relieve pulmonary congestion and general edema (e.g., "dry out") with IV diuretics
  - Improve cardiac function and peripheral/organ perfusion
  - Achieve stable, fully compensated clinical state
  - Transition to oral, outpatient medicines (for chronic management of heart failure)

### **Current Treatment Options**

- Current approaches to acutely improve cardiac function are associated with unwanted effects:
  - Heart rhythm disturbances
  - Increased heart rate and myocardial oxygen demand
  - Decreased blood pressure
  - Potential damage to the heart muscle
  - Worsening renal function
  - Mortality
- Patients with low blood pressure (SBP) and peripheral hypoperfusion are high risk, challenging patients who are also generally resistant to diuretic therapy and often discharged in a sub-optimal state



## Istaroxime AHF Phase 2a & 2b Studies

Phase **2**a



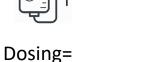
n=**120** 

**ADHF Patients** 



**0.5, 1, 1.5** μg/kg/min





**6** hour Infusion

- Primary: PCWP significantly improved
- Stroke Vol & SBP significant increase
- Heart Rate (HR) lowered

Phase **2**b

n=**120 ADHF Patients** (dyspnea plus need for IV furosemide ≥ 40mg) Dosing=

24 hour **0.5, 1.0** μg/kg/min

Infusion

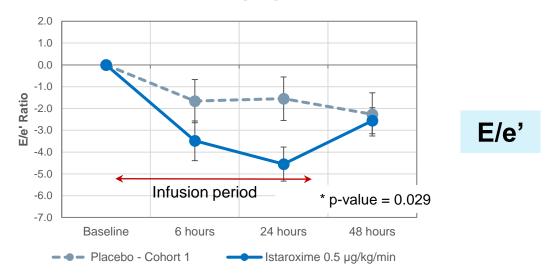
#### **Results**

Positive Phase 2 trial results demonstrated improved cardiac function without unwanted side effects of existing rescue therapies

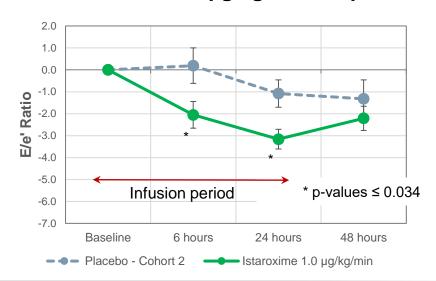


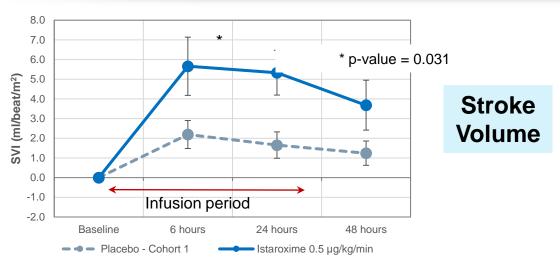
# Primary Endpoint Achieved Significant Changes in E/e' Ratio<sup>1</sup> and Stroke Volume

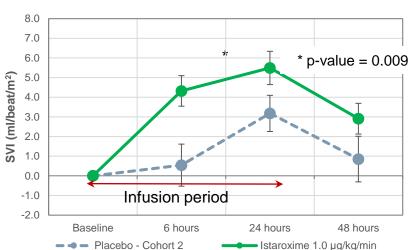
#### Istaroxime 0.5 µg/kg/min vs. placebo



#### Istaroxime 1.0 μg/kg/min vs. placebo



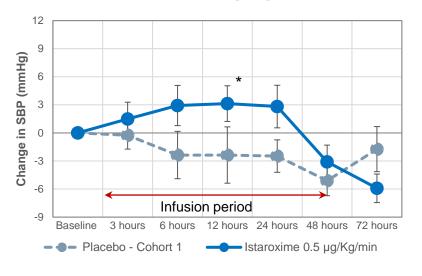






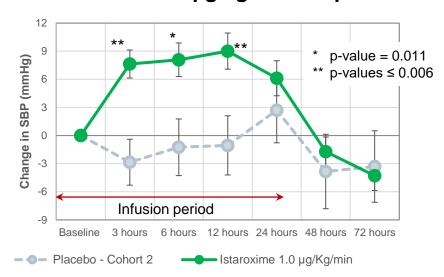
# Systolic Blood Pressure Increased During Treatment and Renal Function Tended to Improve

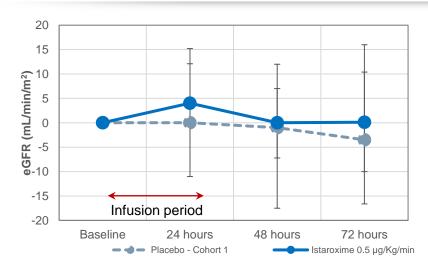
#### Istaroxime 0.5 µg/kg/min vs. placebo



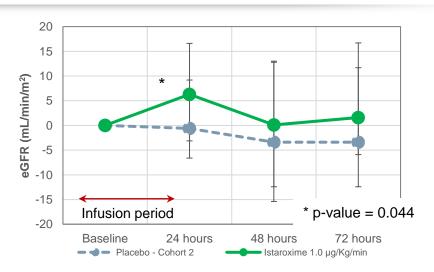
Systolic Blood Pressure (SBP)

#### Istaroxime 1.0 µg/kg/min vs. placebo





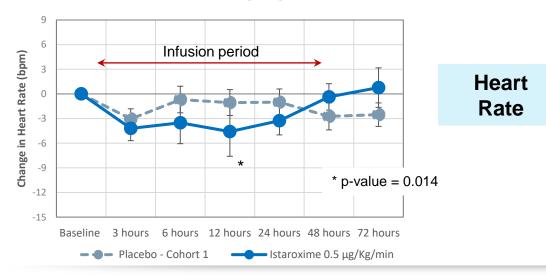
GFR (Renal Function)



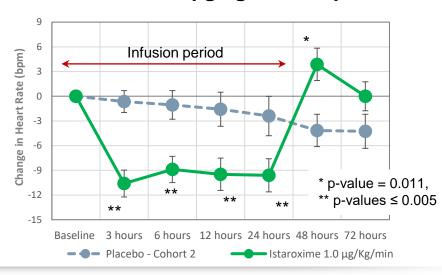


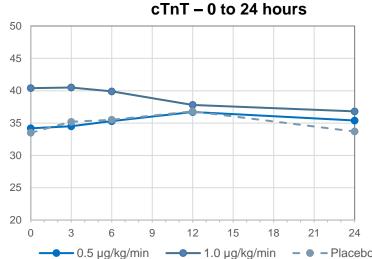
# Heart Rate Decreased and No Increases in Cardiac Troponins

#### Istaroxime 0.5 µg/kg/min vs. placebo

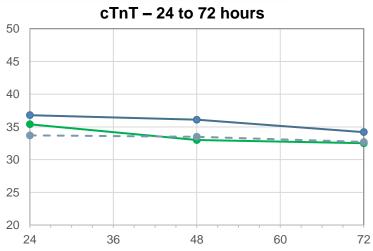


#### Istaroxime 1.0 µg/kg/min vs. placebo



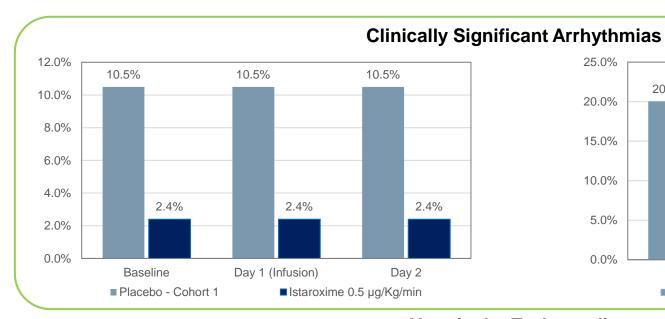


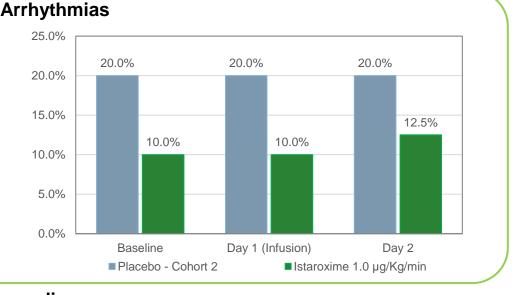
Cardiac TnT (Myocardial Damage)

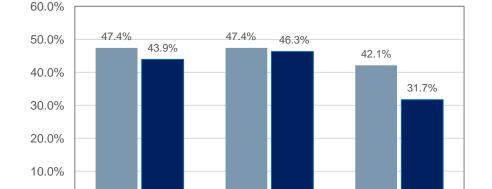




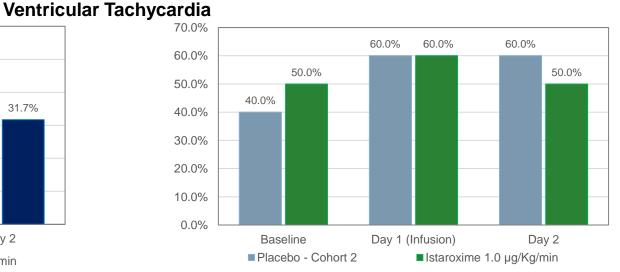
# **Favorable Profile Observed with 24-hour Holter Monitoring**







Day 1 (Infusion)





0.0%

Baseline

■ Placebo - Cohort 1

■ Istaroxime 0.5 µg/Kg/min

Day 2

### Istaroxime – Acute Heart Failure

Objective: Optimize therapy and employ study enrichment strategies to create strong Phase 3 and partnership position

Execute an additional study designed to complete Phase 2 and inform Phase 3 - 300 patients, 60 centers globally\*



Enrich therapeutic impact by leveraging characteristics in target population whose needs match the unique attributes of istaroxime: patients with low blood pressure and/or diuretic resistance



Increase infusion time to >24 hours in pursuit of dose optimization



Primary endpoint will again be E/e', but also obtain data on measures that will inform Phase 3 design and pivotal endpoint

Pending adequate funding; ~18 months to execute



# Next Generation, Oral SERCA2a Activators Acute and Chronic Heart Failure Platform

The Company also has pre-clinical programs on product candidates including:

# Selective SERCA2a Activators

- Oral & i.v. therapies for chronic heart failure (CHF) and AHF
- Attractive approach for heart failure with preserved ejection fraction (HFpEF)

Dual Mechanism, (SERCA2a & Na+/K+)
Compounds

"Next generation istaroxime" as oral/i.v. for in-patient acute and outpatient chronic use

These next generation agents help form complete chronic and acute heart failure treatment portfolio for both licensing/partnership and potential commercialization



# **Summary**



- Istaroxime has produced positive, differentiating data in three Phase 2 studies for two separate and complementary indications. These markets have significant unmet needs, and no known other late-stage programs in development to address the acute decompensated patient
  - The data is consistent, across all regions/populations and across many endpoints (including many in early cardiogenic shock despite small trial)



- Istaroxime has demonstrated a highly unique and desirable profile as compared to existing therapies:
  - Improved cardiac function and SBP while maintaining renal function and overall safety profile



 Recent positive Phase 2 study with istaroxime in early cardiogenic shock (ECS) paves the way for what we believe is a relatively fast and less expensive developmental and regulatory pathway



The AHF program will proceed with business development (which remains a pre-Phase 3 strategy for istaroxime) and/or additional resourcing while also advancing the next generation, oral SERCA2a activators for chronic and acute HF including HFpEF



## Funding Development-Actively Engaged to Address Resources and Create Opportunity

Windtree is actively engaged and assessing various options to fund development and operations including:

# Strategic Transaction

- Mergers & Acquisitions
- Management Buyout

# Business Development – Licensing

 Global or regional out-licensing

# Capital Markets

- Public or Private
- Possible role for debt



# **Financial Summary & Capitalization**

Cash & Equivalents of ~\$8.4 million as of September 30, 2022

	Common Equivalents as of November 14, 2022
Common Stock	38,610,119
Options (WAEP \$7.84)	3,883,169
Restricted Stock Units	558,100
Warrants (WAEP \$6.64)	16,546,336
Fully Diluted Equivalents	59,597,724



# **Strategy for Value Generation**

**Communicate Our Milestones** 



**Transactions** 



**Optimization** 



Prioritize development of istaroxime in cardiogenic shock – communicate milestones including extension study progress, regulatory news and registration pathway

 Secure focused BD transactions for deal revenue and non-dilutive financial support of clinical development

Progress heart failure
 platform to an attractive and
 valuable position for global
 partnership (while retaining
 US co-promotion rights)

Bring in new, wellsuited development opportunities and transactions

www.windtreetx.com





# **Appendix**



## Istaroxime Unique Opportunity With Attractive Risk / Return Profile

- Highly consistent results across 3 controlled Phase 2 studies (and 300 patients dosed thus far), in a spectrum of severity and executed in all regions of the world
- Attractive profile as the only acute heart failure or shock drug that has been shown to significantly improve cardiac function of a failing heart, while rapidly and significantly improving blood pressure, with what so far has been a differentiating safety profile (avoiding many of the use-limiting side effects of existing therapies such renal, arrhythmias, etc.)

3 Complementary acute CV programs with high unmet need and no active or developing competition

Istaroxime:
Attractive Risk,
Time, Cost and
Return Profile

Long, successful history of CMC

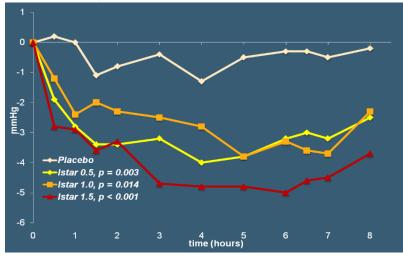
- 4 Faster and less expensive developmental and regulatory pathway possible
  - Attractive pivotal endpoint of blood pressure response is expected to be more straight-forward and better align with a smaller study than one requiring clinical outcome measures.
  - Additionally, istaroxime demonstrated significance in many other benefits that we expect will continue to help us build a strong evidence-based position with doseoptimization and the larger Phase 3 planned for 2023.



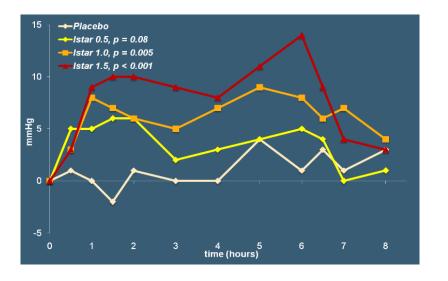
## Istaroxime Phase 2a (HORIZON-HF) Study

- Multicenter, double blind, placebo-controlled, doses 6-hour infusion of istaroxime 0.5, 1.0, 1.5 ug/kg/min, conducted in the EU
- Hospitalized with AHF, with criteria including:
  - LVEF ≤ 35%
  - SBP 90-150 mmHg
- N=120 (30/group)
- Significant improvement in PCWP, SBP, heart rate was lower. Istaroxime was generally well tolerated with no unexpected adverse events

# **Primary Endpoint:**PCWP Significant Improvements



#### **Dose-dependent Increase in SBP**





## **Istaroxime AHF Phase 2b Adverse Events**

Event	Pooled placebo (n=39)	Istaroxime 0.5 mg/Kg/min (n=41)	Istaroxime 1.0 mg/Kg/min (n=40)	
All adverse events	23 (59.0%)	31 (75.6%)	33 (82.5%)	
Adverse events leading to discontinuation	1 (2.6%)	-	4 (10.0%)	
Serious adverse events	2 (5.1%)	2 (4.9%)	6 (15.0%)	
Cardiac death	-	-	1 (2.5%)	
Cardiogenic shock	-	-	1 (2.5%)*	
Cardiac failure	1 (2.6%)	2 (4.9%)	3 (7.5%)	
Renal embolism	-	-	1 (2.5%)	
Transient ischemic attack	1 (2.6%)	-	-	
Hyperventilation	1 (2.6%)	-	-	
Hypotension	1 (2.6%)	-	-	
Adverse Drug Reactions†	10 (25.6%)	23 (56.1%)	25 (62.5%)	
Cardiovascular††	9 (23.1%)	4 (9.8%)	7 (17.5%)	
Gastrointestinal‡	2 (5.1%)	4 (9.8%)	14 (35.0%)	
Infusion site pain/inflammation	-	20 (48.8%)	13 (32.5%)	



Note: data shown as n° patients (%) - patients can have more than one event during the 30-day follow up period

<sup>\*</sup> Same patient who then died, and 1 additional death occurred at Day 31 (cardiac death) outside the 30 day window

<sup>†</sup> Adverse Drug Reactions are AEs related to study drug

<sup>††</sup>Most common - arrhythmia, atrial fibrillation, cardiac failure, ventricular tachycardia

<sup>‡</sup> Most common - abdominal pain, nausea, vomiting, diarrhoea

# **SEISMiC:** Serious Adverse Events and Adverse Drug Reactions

Event	Istaroxime (N=29)	Placebo (N=31)
All adverse events	27 (93%)	25 (81%)
Serious adverse events	6 (21%)	6 (19%)
Cardiac arrest	1 (3%)	0
Cardiac failure	2 (7%)	2 (6%)
Cardiac failure acute	0	1 (3%)
Cardiac ventricular thrombosis	0	1 (3%)
Cardiac artery stenosis	0	1 (3%)
Ventricular fibrillation	1 (3%)	0
Ventricular tachycardia	1 (3%)	0
Coronavirus infection	0	1 (3%)
Pneumonia	1 (3%)	0
Acute kidney injury	1 (3%)	0
Adverse drug reactions†	15 (52%)	3 (10%)
Gastrointestinal‡	9 (31%)	2 (6%)
Infusion site pain/inflammation	4 (14%)	1 (3%)



# SEISMiC: Safety and Efficacy Appeared More Favorable with the 1.0 vs 1.5 µg/kg/min and Placebo

### 1.0 μg/kg/min dosing was associated with:

- Early SBP increase and improvement in more echocardiographic parameters of cardiac function
- More favorable adverse event, serious adverse event and clinical event profile

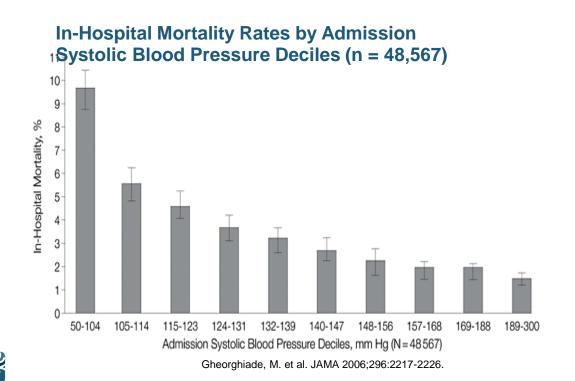
Clinical Events by Dose	Statistic	Placebo (N=31)	Istaroxime 1.0 μg/kg/min (N=16)	Istaroxime 1.5 μg/kg/min (N=13)
SBP AUC 0-24hrs	LS-Means (SE)*	209.9 (27.38)	282.7 (35.79)	304.1 (44.11)
Worsening HF through 96-hours	No. events	1 (3%)	0 (0%)	5 (38%)
Heart Failure Readmissions through 30-days	No. events	3 (12.9%)	0 (0%)	0 (0%)
Length in ICCU/CCU, days [c]	Mean (SD)	4.55 (2.23)	3.50 (1.41)	6.38 (4.46)
All-Cause Mortality through 30-Days	No. events (%)	1 ( 3%)	1 ( 6%)	3 (23%)
All-Cause mortality or HF readmission through 30-days	No. events (%)	4 (12%)	1 (6%)	3 (23%)



### **Acute Heart Failure**

### Significant Healthcare Issue with Significant Unmet Clinical Need

- Patients with low blood pressure (SBP) and peripheral hypoperfusion are high risk, challenging patients. These patients
  are also generally resistant to diuretic therapy and often discharged in a sub-optimal state.
  - Low SBP in-patient mortality approximately two-fold greater than normal/high SBP<sup>1</sup>
  - There is a direct relationship between early drop in SBP and worsening renal function in acute heart failure2



European Journal of Heart Failure; Voors, PRE-RELAX AHF Study; 2011; 13

ADHERE Registry, n=48,567; JAMA 2006

# Early drop in systolic blood pressure and worsening renal function in Acute Heart Failure: renal results of Pre-RELAX-AHF Study

