# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): October 1, 2024**

# Windtree Therapeutics, Inc.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-39290** | **94-3171943** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

| **2600 Kelly Road, Suite 100, Warrington, Pennsylvania** | **18976** |
|---|---|
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (215) 488-9300**

**Not Applicable**
**(Former name or former address, if changed since last report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, par value $0.001 per share | WINT | The Nasdaq Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01 Regulation FD Disclosure.**

On October 1, 2024, Windtree Therapeutics, Inc. (the "Company") updated information reflected in a slide presentation, which is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the updated presentation in various meetings with investors from time to time.

The information contained in this Item 7.01 (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

The following exhibits are being filed herewith:

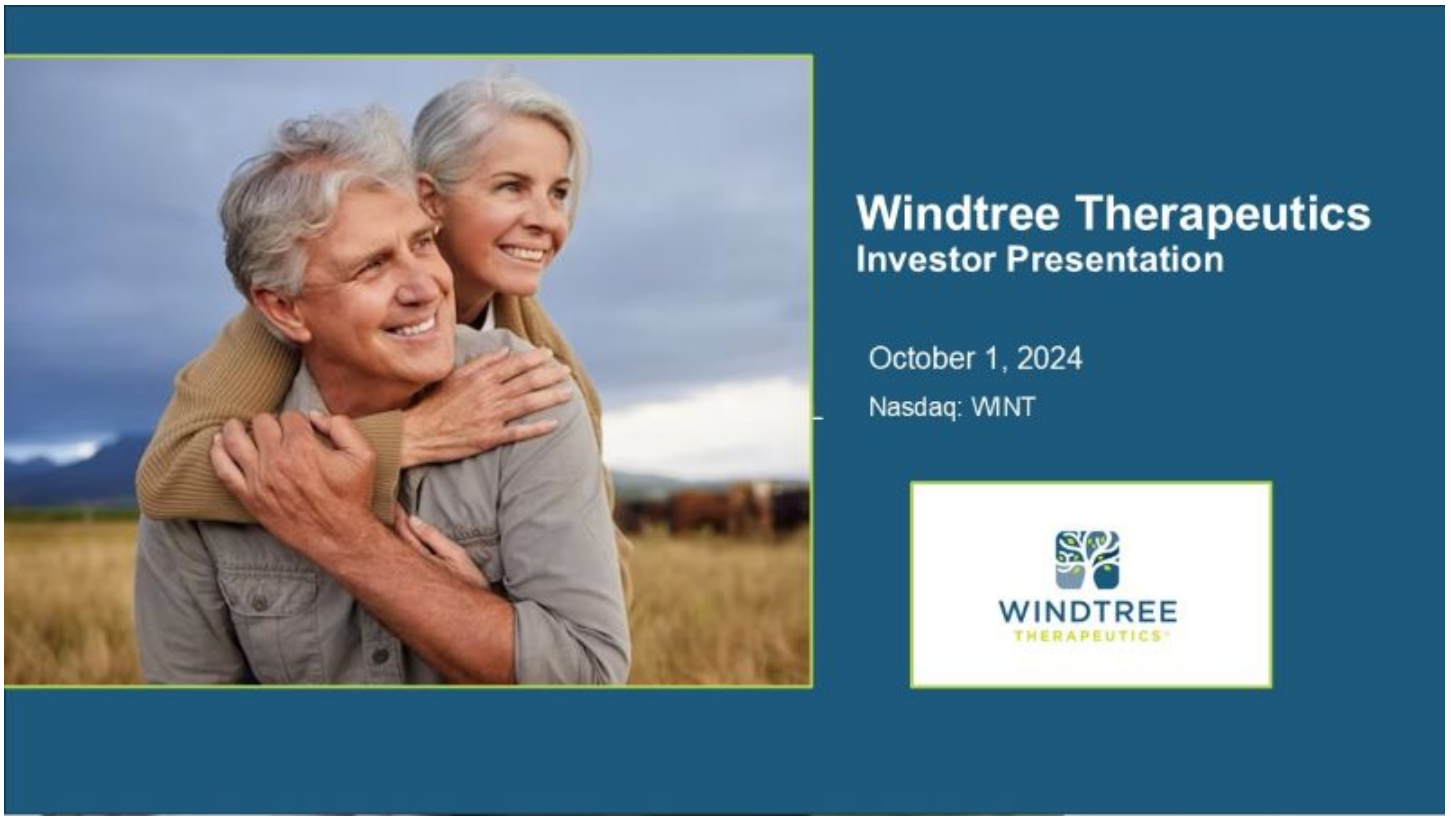
| Exhibit No. | Document |
|---|---|
| 99.1 | Investor Presentation of Windtree Therapeutics, Inc. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: October 1, 2024

Windtree Therapeutics, Inc.
By: /s/ Craig E. Fraser
Name: *Craig E. Fraser*
Title: *President and Chief Executive Officer*


Windtree Therapeutics
Investor Presentation
October 1, 2024
Nasdaq: WINT
WINDTREE
THERAPEUTICS

# Forward-Looking Statements

This presentation includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, among other things, include statements about the Company's clinical development programs, business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development activities, or otherwise as to future events. The forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will," "should," "could," "targets," "projects," "contemplates," "predicts," "potential" or "continues" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. These risks and uncertainties are further described in the Company's periodic filings with the Securities and Exchange Commission ("SEC"), including the Company's most recent reports on Form 10-K, and any subsequent quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments thereto ("Company Filings"). Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Under no circumstances shall this presentation be construed as an offer to sell or as a solicitation of an offer to buy any of the Company's securities. In addition, the information presented in this deck is qualified in its entirety by the Company Filings. The reader should refer to the Company Filings for a fuller discussion of the matters presented here.

# Windtree Investment Highlights

- Biopharmaceutical company focused on cardiovascular and oncology treatments intended to address markets with significant unmet need (NASDAQ: WINT)
- First in class, novel asset istaroxime has demonstrated positive efficacy and an attractive profile in four Phase 2 global studies, highlighted by improvements in cardiac function and increases in blood pressure with favorable renal and arrythmias profile
- Istaroxime is in Phase 2b clinical development for cardiogenic shock (CS) and acute heart failure; platform also includes next generation oral, SERCA2a activators in preclinical development
- Positive top line results from istaroxime Phase 2b SEISMiC Part B Study in CS reported September 2024 with next clinical milestone planned for late Q1 '25 – in the progress toward Phase 3 readiness
- Cardiogenic shock is an estimated $1.25B global market where patients have high mortality, morbidity and costs. It represents a significant opportunity for istaroxime because currently available drugs have undesirable side effects and can result in poor outcomes and there is a lack of competition in development or active competition in the market
- Global and regional license deals are in place with Windtree in active discussions on potential additional global license for cardiovascular assets
- Newly acquired first in class, novel, protein kinase C iota inhibitor oncology platform with both topical and oral formulations creates significant opportunity that we plan to advance this year
- Lean, capital efficient operation led by a highly experienced management team

# Multi-Asset / Indication Pipeline with Several Near-Term Milestones

| Product Candidates | Indication | Phase | Development Status / Plans |
|---|---|---|---|
| **Istaroxime** (SERCA2a activator/ Na/K ATPase inhibitor) | **Cardiogenic Shock** | **Phase 2b** | • **Positive Phase 2b studies**<br>• **Executing small follow-on studies intended to transition to Phase 3** |
| **Istaroxime** | Acute Heart Failure | Phase 2b | • Positive Phase 2a and 2b data<br>• Greater China regional license with **Lee's Pharma who is advancing and paying for Phase 3 AHF program in territory** |
| **SERCA2a Activators (oral)** | Chronic Heart Failure, including potentially HFpEF | Preclinical | • Chronic and Acute Heart Failure<br>• Target for collaboration/partnership |
| **aPKCi inhibitor (topical and oral)** | **Cutaneous and systemic treatment in broad and/or rare malignant diseases** | Preclinical | • **IND enabling studies** |
| **Rostafuroxin** | Treatment Resistant Hypertension – Genotypically identified patients | Phase 2b | • Phase 2 data in hypertension<br>• Company holding development to out-license and reposition for the attractive and large Resistant Hypertension market |
| **KL4 Surfactant and AEROSURF** | KL4 surfactant Drug/Device Tx for RDS and potential other applications | Phase 2b | • **Global out-license in place**<br>• Partner responsible for all costs of development |

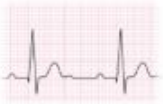
# Positive Istaroxime Phase 2 Studies Demonstrated:

**Cardiac Function Improved**

- Significant increases in cardiac output
- Significant increase in stroke volume (amount of blood pumped with each heartbeat)
- Lowered cardiac filling pressures

**Increase in Systolic Blood Pressure**

**Increase or Preserve Renal Function (eGFR)**



**Decrease in Heart Rate**

**Favorable Heart Rhythm Profile Observed**

- No increase in clinically significant arrythmias or ventricular tachycardia

**Fast Track Approval for Acute Heart Failure and Potential Favorable Pathway for Cardiogenic Shock**

WINDTREE THERAPEUTICS

# Istaroxime

## Cardiogenic Shock

*Potential to transform the standard of care for critical patients*

WINDTREE THERAPEUTICS

## Cardiogenic Shock - *A Critical Condition Caused by a Failing Heart*

**A severe presentation of heart failure** characterized by **low blood pressure and inadequate blood flow to vital organs (hypoperfusion)** accompanied by congestion and high filling pressures of the heart. It **requires very urgent treatment.**

- Most often requires pharmacological or mechanical intervention with key clinical objective to increase SBP to >90mmHg and improve tissue perfusion
- Cardiogenic shock patients typically require hospital intensive care and consume significant hospital resources
- High mortality (~20-30%) and substantial morbidity in survivors[1]
- US + EU markets represent an ~$1.0B market potential[2] with high unmet need
- Potential for relatively faster and less expensive developmental and regulatory pathway

1) Burgos, JSCAI (1) 2021Kolte D. American Heart Association; 2014 Jan 13; (rates associated with classic, stage C shock)
2) Estimates from claims data and epi data September 2021, multiplied by assumed various regional prices

## What Would the Ideal Treatment for Cardiogenic Shock due to Heart Failure Look Like?

- ✓Improves systolic and diastolic cardiac function--the root cause of cardiogenic shock
- ✓Improves blood pressure and organ perfusion--the main problem in cardiogenic shock
- ✓Avoids harming the kidneys
- ✓Does not increase heart rate or increase myocardial oxygen demand or energy requirements of the heart
- ✓Does not increase the risk for cardiac arrhythmias
- ✓Contributes to effective diuresis and resolving fluid overload in lungs and body
- ✓Rapid onset of action with a predictable effect that can be titrated to individual patient needs

WINDTREE THERAPEUTICS

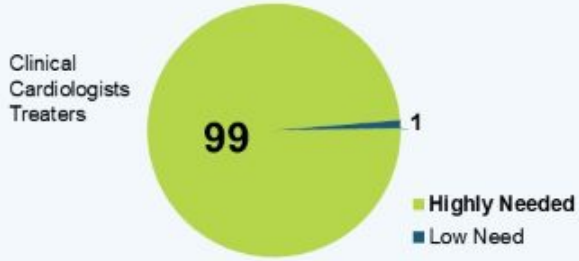
# Significant Unmet Need and Reported Desire for Istaroxime

## No current satisfactory pharmacological intervention to reverse the condition

- 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"

***Market research shows need and enthusiasm for istaroxime profile***

***100 U.S. Cardiologists*** *questioned on degree of* ***unmet need for new innovative pharmacologic treatments for ECS[1]***



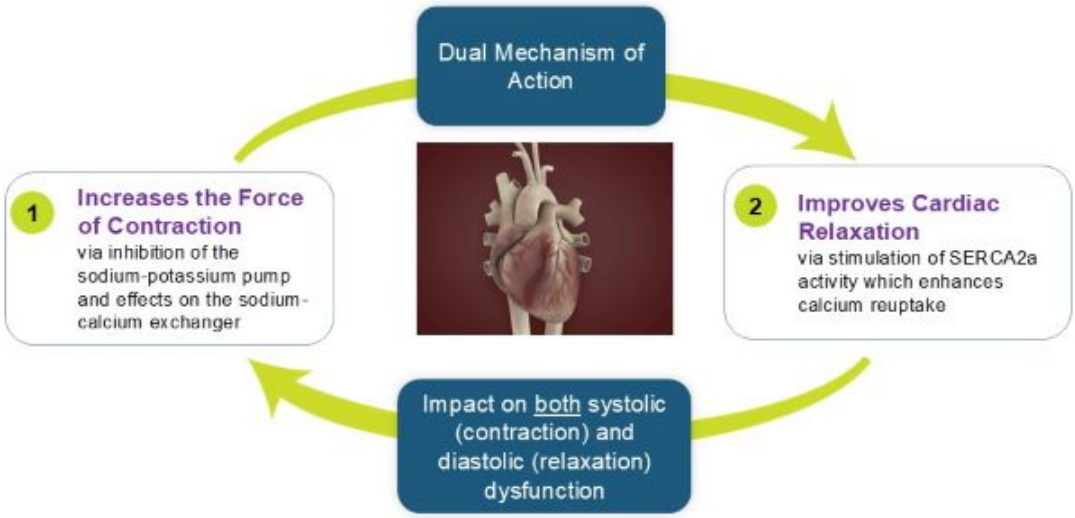

- ✓ **84%** of the cardiologists responded they would be **likely to extremely likely to use** istaroxime for early cardiogenic shock patients
- ✓ Majority responded they would position utilization before use of other existing classes of therapies such as inotropes and vasopressors

WINDTREE THERAPEUTICS

1) Market research conducted by Sermo, a leading provider of real time physician insights

# Istaroxime – Novel First-in-Class Therapy

**Novel intravenous agent** designed to **improve systolic contraction *and* diastolic relaxation of the heart**




WINDTREE THERAPEUTICS

# SEISMiC Early Cardiogenic Shock Studies

## SEISMiC Part A

60 patients in early cardiogenic shock (SBP 75-90 mmHg) 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 µg/kg/min and 1.0 µg/kg/min

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

Secondary measures included: echocardiology measures of cardiac function, renal function, various safety and tolerability measures

**Positive Results**

## SEISMiC Part B

30 patients in early cardiogenic shock (SBP 70-100 mmHg) with AHF

Study drug was infused for **up to 60 hours** in a 2:1 randomization:

- Ista 1.0/0.5/0.25 µg/kg/min for 6/42/12 hours
- Ista 0.5 µg/kg/min 48 hrs, then placebo for 12 hrs
- Placebo for 60 hours

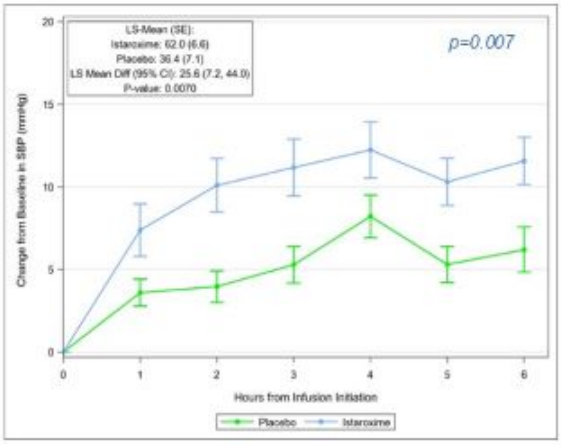
Primary endpoint was SBP AUC over 6 hours comparing istaroxime Part A and B to placebo

Secondary measures included SBP AUC in Part B alone, pulmonary capillary wedge pressure, echocardiography measures of cardiac function, renal function, safety and tolerability

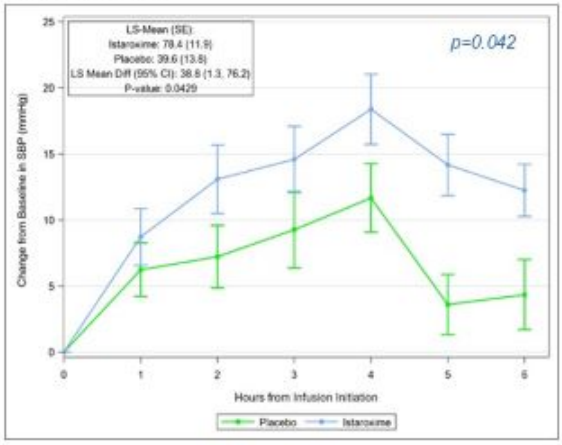
*Per Metra et al. JCF 2023

# Significant Improvement on the Primary Endpoint SBP AUC 6 hours in SEISMiC and Part B Alone

## SEISMiC A+B



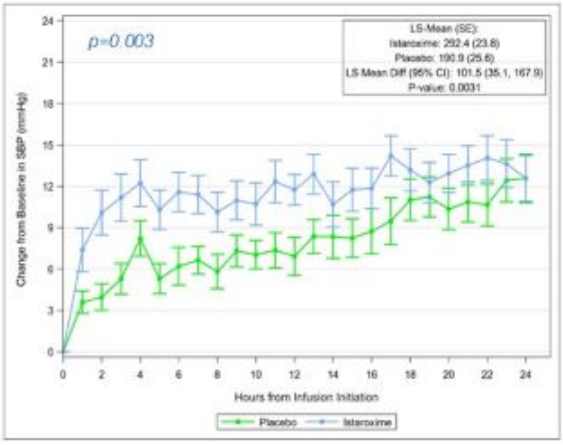

## SEISMiC B



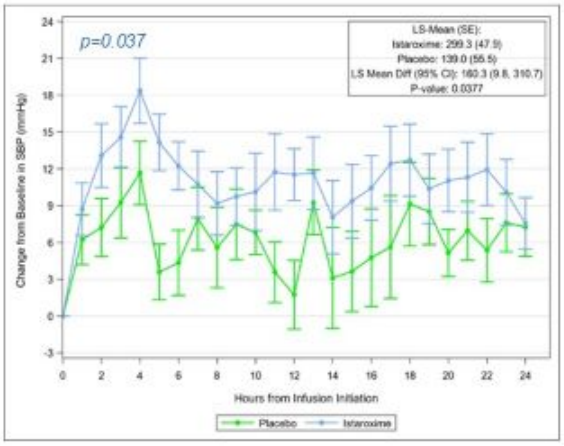

WINDTREE THERAPEUTICS

# Significant Improvement Persisted with SBP AUC 24 hours

## SEISMiC A+B



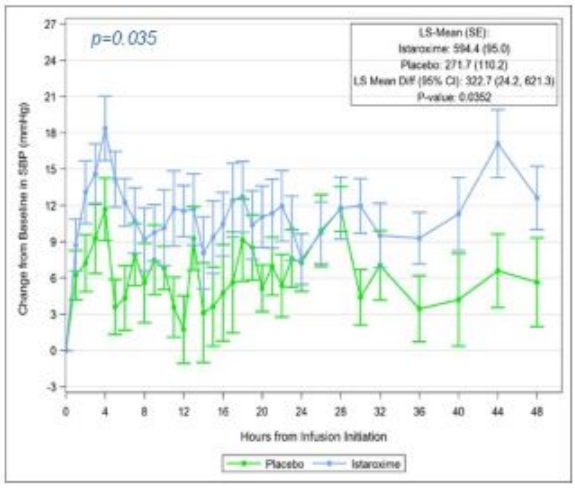

## SEISMiC B



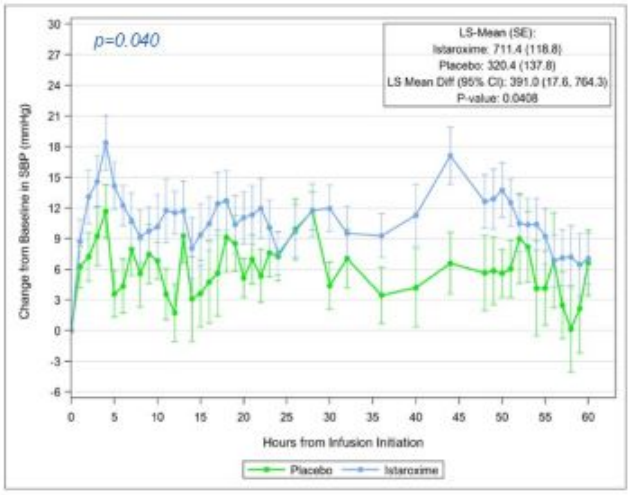

WINDTREE THERAPEUTICS

# Significant SBP Increase AUC 48 and 60 hours – SEISMIC B

## SBP AUC to 48 hours

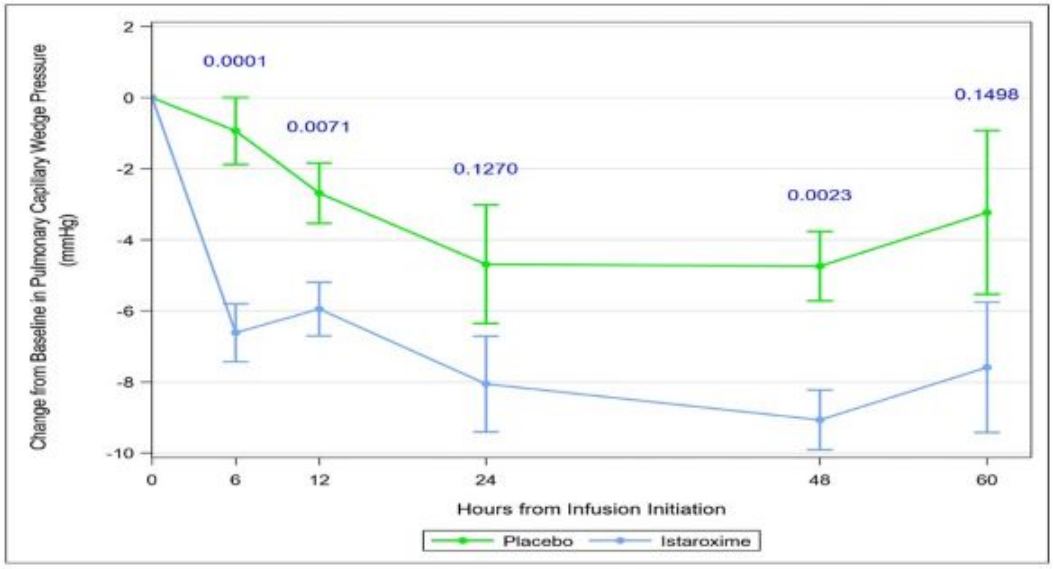



## SBP AUC to 60 Hours




WINDTREE THERAPEUTICS

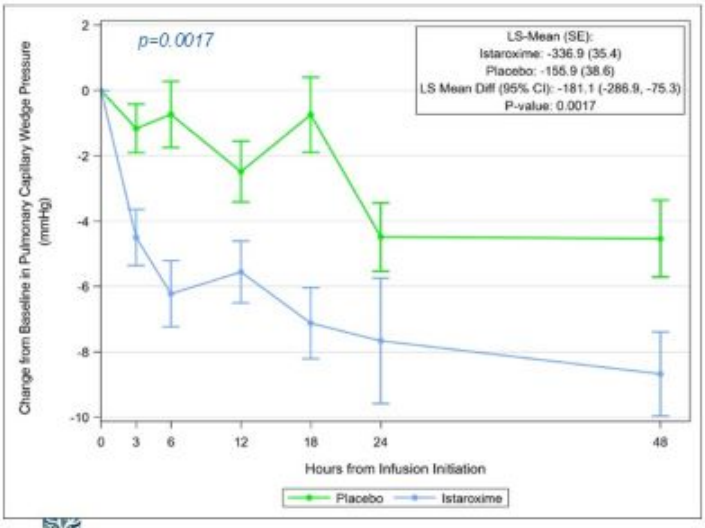
# Changes in PCWP (Wedge Pressure) in SEISMiC B



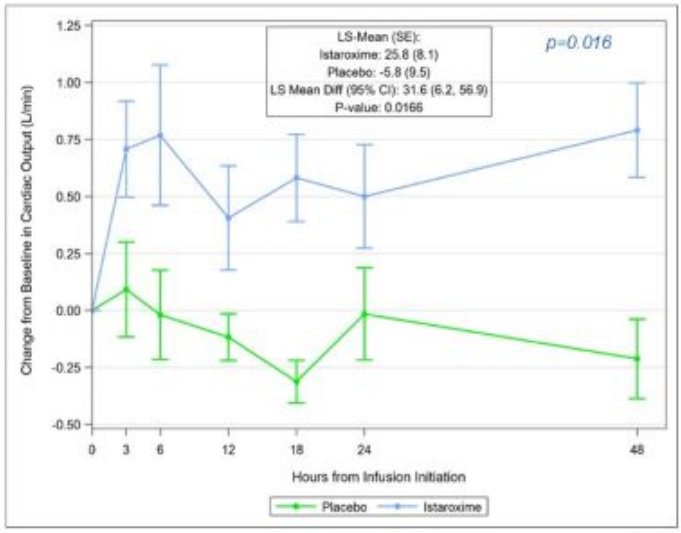

WINDTREE THERAPEUTICS

# Significant Improvements in Cardiac Function Measured by Wedge Pressure and Cardiac Output AUCs to 48 hours in SEISMiC B

## Wedge Pressure

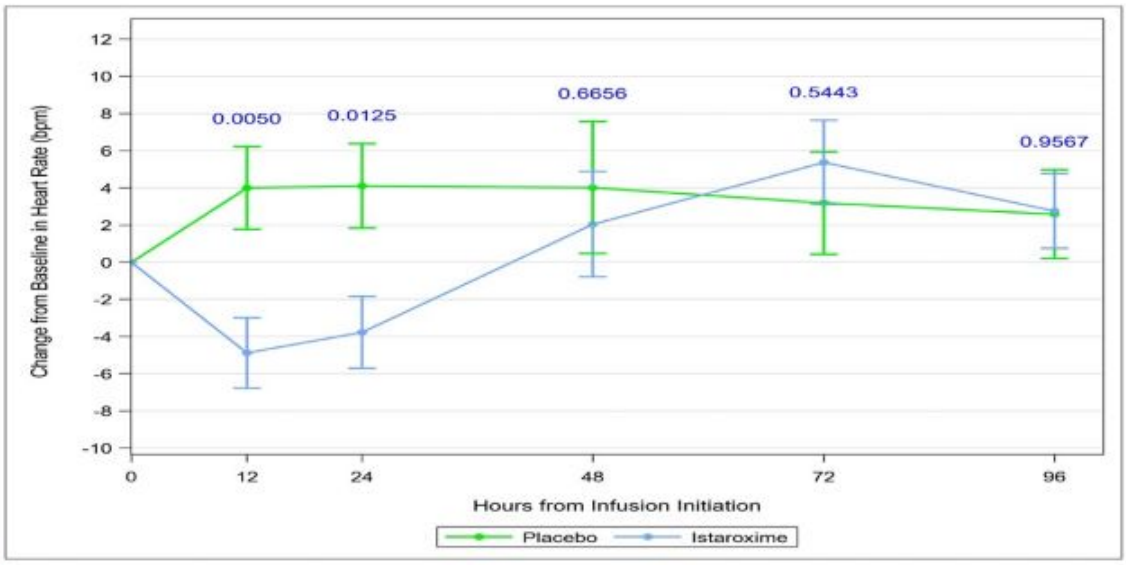



## Cardiac Output



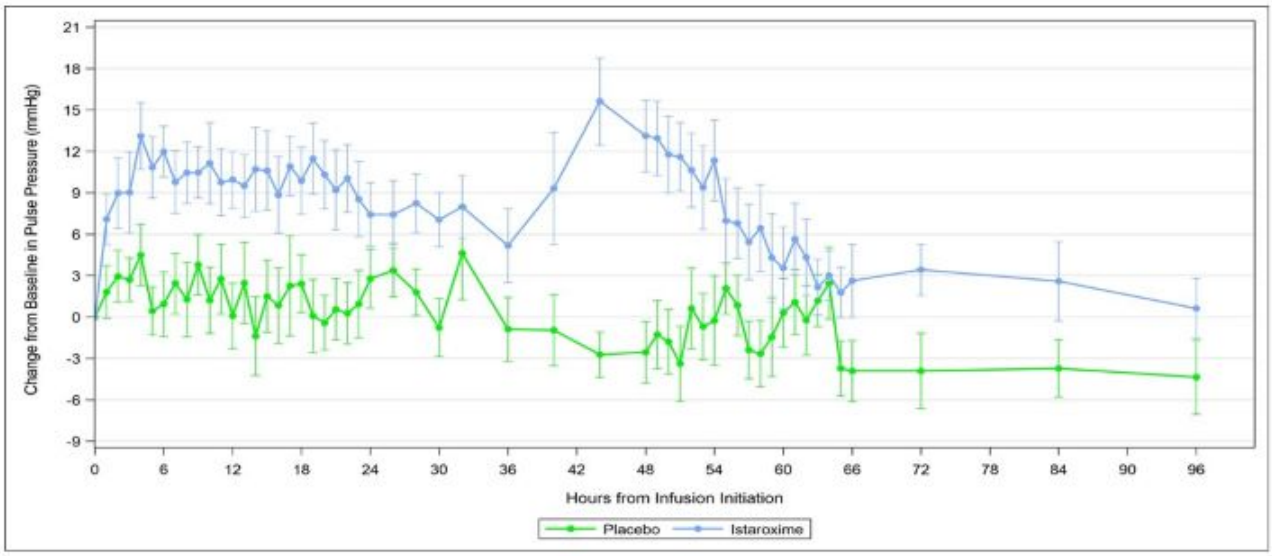

WINDTREE THERAPEUTICS

# Changes in Heart Rate to 96 hours in SEISMiC B



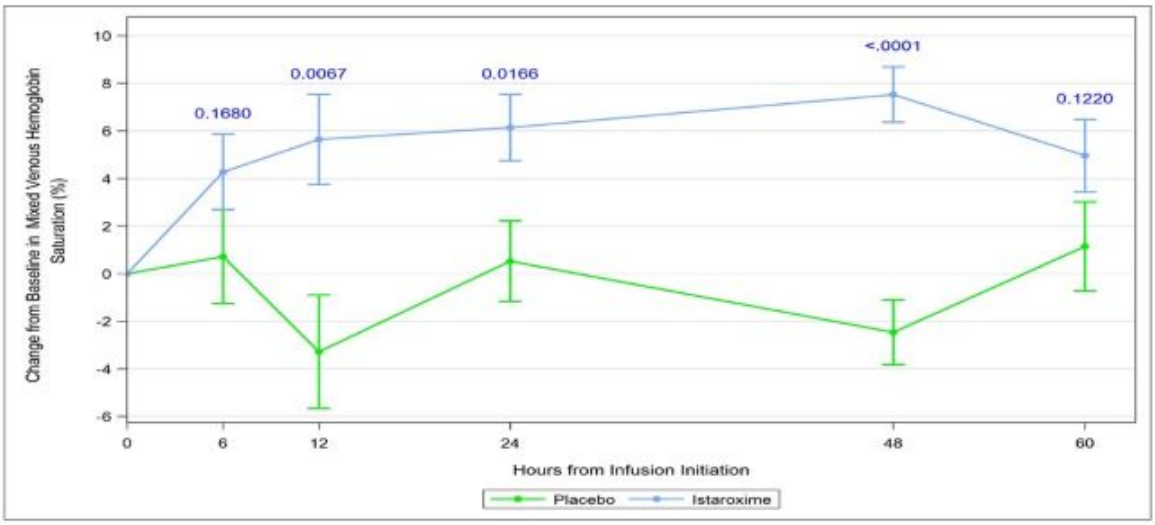

WINDTREE THERAPEUTICS

# Improvements in Pulse Pressure to 96 hours - SEISMiC B
## Post-hoc analysis




Pulse Pressure can be a surrogate for force of cardiac contraction. Diastolic blood pressure was relatively constant

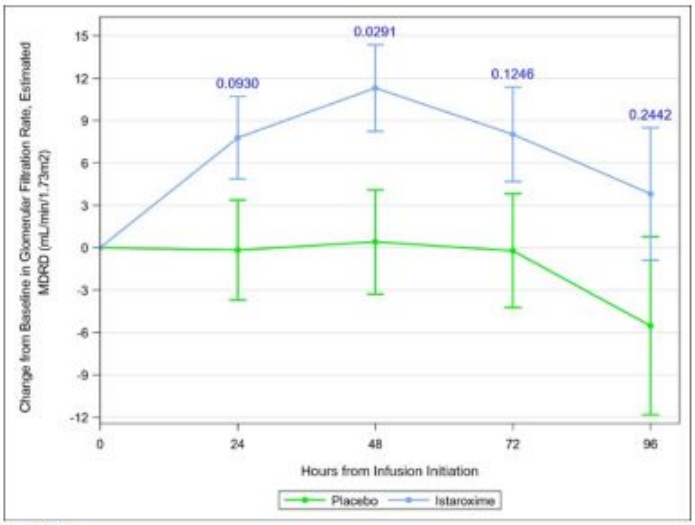
# Mixed Venous Oxygen Saturation (SVO2), an Assessment of Organ Perfusion, was Significantly Improved by 12 Hours and Persisted



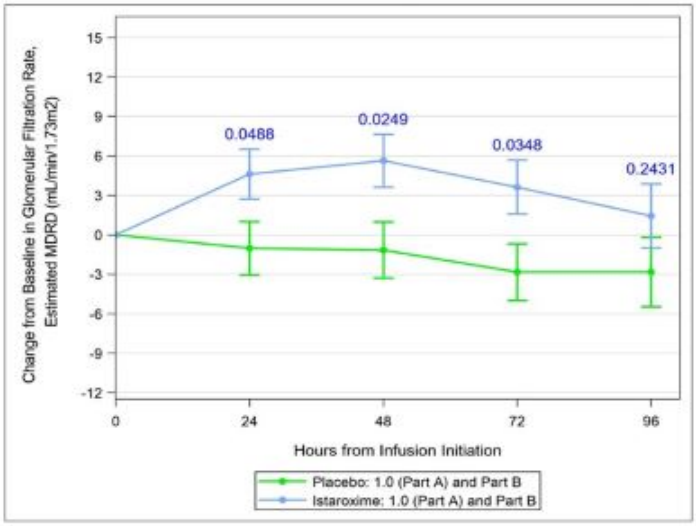

WINDTREE THERAPEUTICS

# Positive Profile in Renal Function Measured by eGFR

**SEISMiC B**

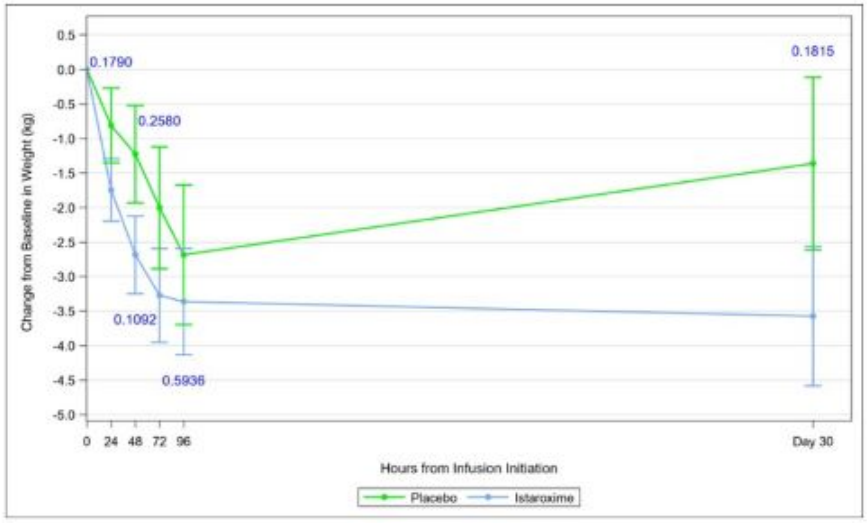



**SEISMiC A + SEISMiC B pts.**
Pts. treated with ≤1.0 mcg/kg/min **(61 Pts.)**



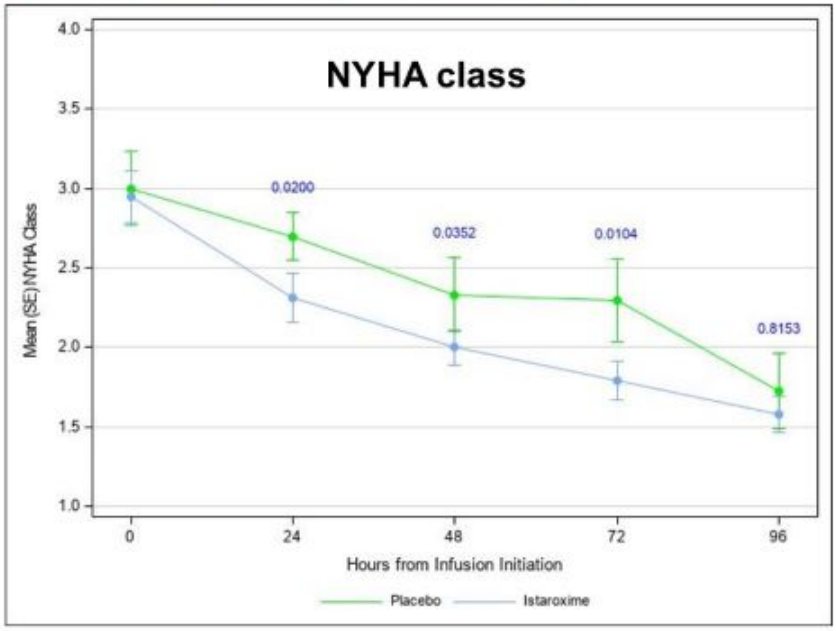

WINDTREE THERAPEUTICS

# Reductions in Weight in SEISMiC B



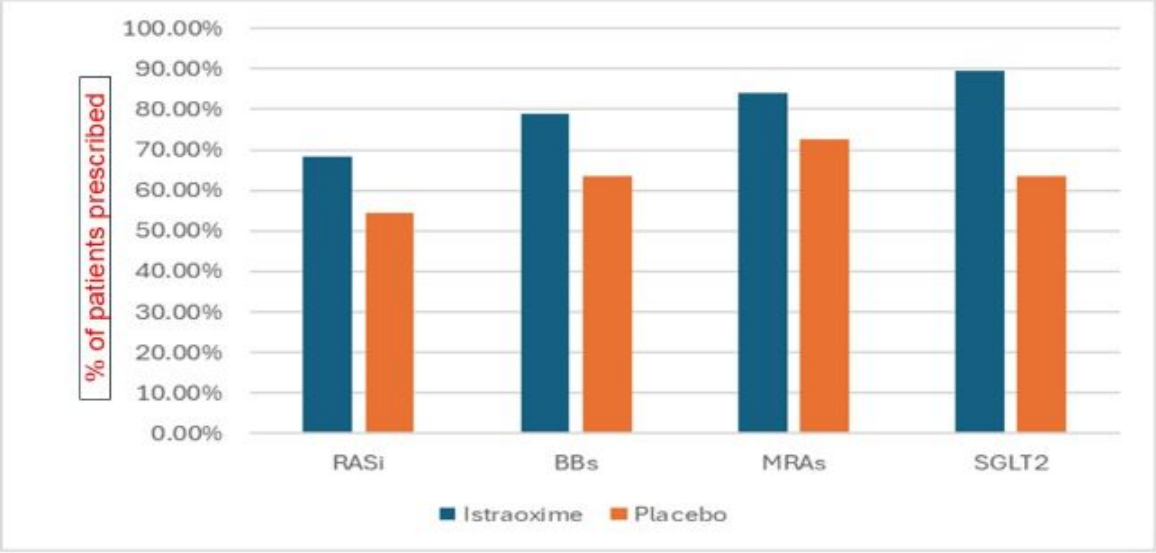

WINDTREE THERAPEUTICS

# Symptoms and Signs of Congestion Improved with both Placebo and Istaroxime. Heart Failure Severity by NYHA Class Improved Significantly with Istaroxime Treatments




P-values for win odds adjusted for baseline and stratified by pooled site

# More Istaroxime Patients Were Successfully Transitioned to Goal Directed Medical Therapy / Concomitant Meds at 96 hours – SEISMiC B




WINDTREE THERAPEUTICS

# Adverse Events in SEISMiC B

| Event | Istaroxime (N=19) | Placebo (N=11) |
|---|---|---|
| **All adverse events** | 15 (79%) | 5 (46%) |
| Thrombocytopenia | 0 | 2 (18%) |
| Cardiac failure | 2 (11%) | 3 (27%) |
| Atrial fibrillation | 1 (5%) | 0 |
| Myocardial ischemia | 1 (5%) | 0 |
| Ventricular extrasystoles | 0 | 1 (9%) |
| Ventricular tachycardia | 2 (11%) | 1 (9%) |
| Infection | 3 (16%) | 1 (9%) |
| Metabolism and Nutrition | 3 (16%) | 3(27%) |
| Headache | 2 (11%) | 0 |
| | | |
| **Adverse drug reactions** | | |
| Gastrointestinal (Nausea/Vomit) | 2 (11%) | 0 |
| Infusion site pain/inflammation | 9 (47%) | 0 |

WINDTREE THERAPEUTICS

# Serious Adverse Events in SEISMiC B

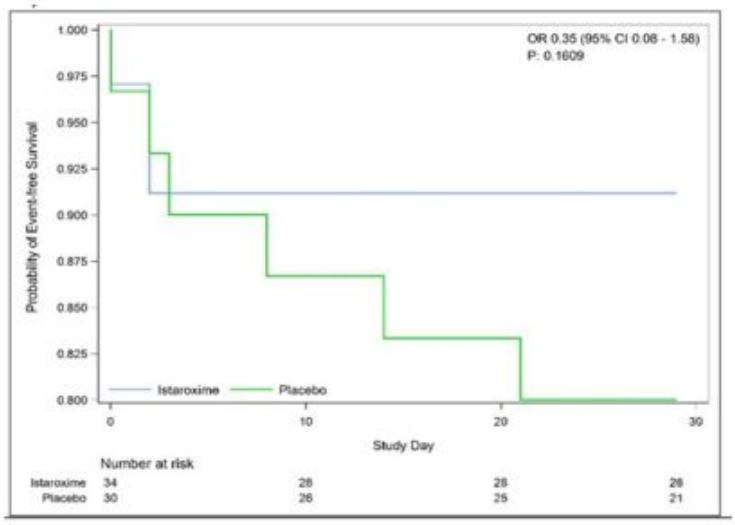
| Event | Istaroxime (N=19) | Placebo (N=11) |
|---|---|---|
| **All serious adverse events** | **2 (11%)** | **3 (27%)** |
| Cardiac Failure (Worsening HF) | **1 (5%)** | **2 (18%)** |
| Cholecystitis | 0 | 1 (9%) |
| Infection | 2 (11%) | 0 |
| Arterial hemorrhage | 0 | 1 (9%) |

WINDTREE THERAPEUTICS

## *Positive Trend in Composite Endpoint:*

## Time to Worsening Heart Failure AE, Heart Failure Readmission or Death through 30 days

**– SEISMiC A (1.0) + B**



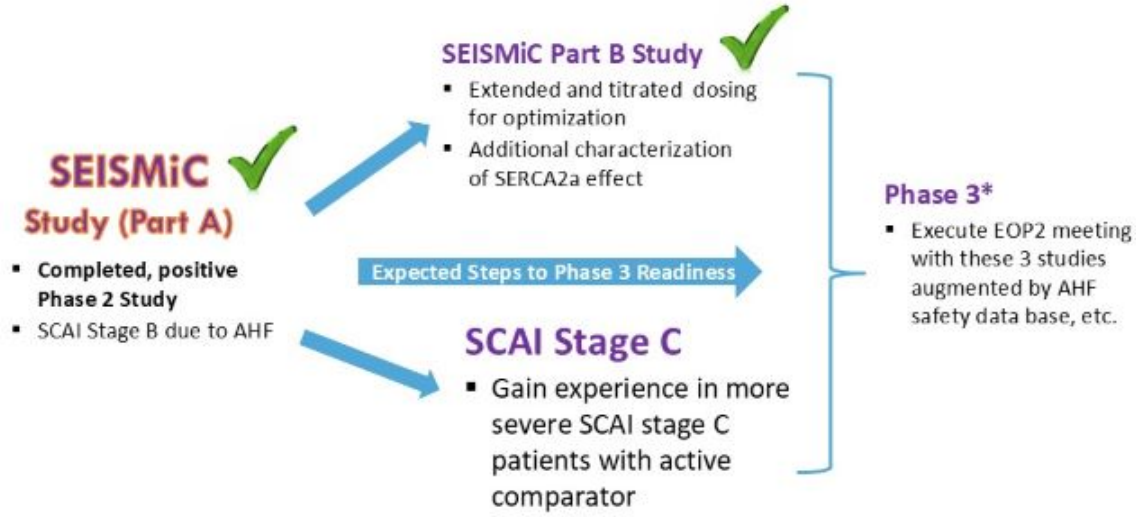

3 patients have not yet completed 30 days in SEISMiC B

## Study Results Summary

- ✓ Systolic blood pressure significantly increased with istaroxime. The increase was rapid and sustained through the infusion period
- ✓ Key secondary endpoints of systolic and diastolic cardiac function such as cardiac output and filling pressures (PCWP) were significantly improved
- ✓ Mixed venous oxygen saturation (SVO2), an assessment of organ perfusion, was significantly improved by 12 hours and remained significant through 48 hours
- ✓ Renal function was significantly improved and maintained over time compared to placebo
- ✓ The New York Heart Association (NYHA) classification of heart failure severity significantly decreased in the istaroxime group, and more patients subsequently transitioned to Goal Directed Medical Therapy.
- ✓ The istaroxime safety profile was favorable and generally consistent with what has been previously reported in other istaroxime clinical trials. Serious adverse events were infrequent in both the istaroxime and placebo groups (10.5% vs. 27.3%, respectively) and worsening heart failure reported as a serious adverse event occurred less frequently in the istaroxime group compared to placebo 5.3% versus 18.2%, respectively. Importantly, Istaroxime did not increase clinically significant arrythmias compared to the placebo group.

# Cardiogenic Shock Development Strategy

*Focus on thoroughness, speed and relatively low cost of trials*




WINDTREE THERAPEUTICS

** Study plans and progression to Phase 3 dependent upon regulatory alignment and resourcing*

# Professor Alexandre Mebazaa, MD, PhD, FESC

## Cardiogenic Shock

Specialty: Anesthesiology and Critical Care
Institute: Hôpital Lariboisière, Paris, France
Function: Chairman of the Department of Anesthesia and Critical Care

**University positions**

2000-now **Professor in Anesthesiology and Critical Care Medicine**, Paris Diderot School of Medicine,

2019– 2024 **Director of the "Biotherapy in the critically ill" team (U 942) funded by Inserm (french NIH)**, 42 Boulevard de la Chapelle, 75010, Paris, France

**Clinical activities**

2012- now Chairman of the Department of Anesthesia and Critical Care (57 ICU beds and 40 anesthesia rooms), Hôpitaux Universitaires Saint-Louis & Lariboisière Hospitals, 2 Rue A Paré, 75475 Paris Cedex 10, Paris, France

**Research activities (2018-2020)**

Our group perform pre-clinical models (mouse and rats) of heart failure, cardiogenic or septic shock. We perform biotherapies experiment, cardiovascular monitoring and biochemistry on plasma and tissues. This program is led by N Vodovar and JL Samuel, basic researchers.

Concerning clinical research on critically ill patients, the group carries large national (eg FROG-ICU) and international surveys (eg ADRENOSS program, the GREAT network), collecting demographic and biobank in 50 countries. We also perform multiple national and international large randomised trials on cardiovascular and sepsis areas (STOP-or-NOT; Adrenoss-2; STRONG-HG). Clinical research is performed by Prof A Mebazaa (cardiovascular), Prof M Legrand (renal), Prof E Gayat (biostatistics, novel technologies).

**Publications and fellowship:** *promoting young fellow toward excellence*

A Mebazaa published 300+ articles on PubMed that are referenced more than 12,000 times and the H-index is 50+. M Legrand and E Gayat have also outstanding publication records.

For 2018, the group already published 50+ papers including original papers or reviews in the highest impact factor journal in intensive care or cardiology (Intensive care Medicine, Eur Heart Journal, Journal of the American College of Cardiology).

The group has an international recognition in "novel biotherapies in critical conditions" and already include 2-4 fellows/year, intensivists or cardiologists from Europe and Asia. Fellows that stayed in the lab several months and up to 2 years, left with numerous publications and academic promotions when back home.

WINDTREE THERAPEUTICS

# Cardiogenic Shock Represents a Significant Opportunity for Istaroxime and Windtree

- Significant opportunity for Istaroxime to make a difference:
  - ~20-30% mortality in classic shock and high morbidity
  - Very long median length of hospital stay (~ 10 days[1]) means high cost of hospital care (estimated >$175k[2]) and creates opportunity for pharmacoeconomic benefits
- Currently available pharmacologic treatments have undesirable side effects and can result in poor outcomes
- Lack of competition in development or active competition in the market
- Attractive $1.25B valuation of market potential versus time and cost of development supports potential deals

[1] US Hospital Claims Data, 2022
[2] Healthcare.gov, Department of Health & Human Services , estimated from average cost of hospital stay
[3] Long et al, USC Cardiology Review, Describing and Classifying Shock: Recent Insights, Sept 2021

## What Would the Ideal Treatment for Cardiogenic Shock due to Heart Failure Look Like? (Our Objective)

- ✓ Improves systolic and diastolic cardiac function--the root cause of cardiogenic shock
- ✓ Improves blood pressure and organ perfusion--the main problem in cardiogenic shock
- ✓ Avoids harming the kidneys
- ✓ Does not increase heart rate or increase myocardial oxygen demand or energy requirements of the heart
- ✓ Does not increase or cause cardiac arrhythmias
- ✓ Contributes to effective diuresis and resolving fluid overload in lungs and body
- ✓ Rapid onset of action with a predictable effect that can be titrated to individual patients

**Istaroxime data to date demonstrate a unique and compelling profile and opportunity to be a better treatment for cardiogenic shock and low blood pressure acute heart failure patients**

WINDTREE THERAPEUTICS

# Istaroxime

Dual Mechanism
SERCA2a Activator

## Acute Heart Failure

WINDTREE THERAPEUTICS

# Heart Failure –
## *A Large and Growing Market with Significant Mortality and Unmet Need*

**#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

WINDTREE THERAPEUTICS

Sources: American Heart Association; DRG Data

# Istaroxime – Acute Heart Failure

## Development Strategy

**Regional Strategy: Licensing Partner in Asia / Pac Intends to Start Phase 3 AHF Study**

Global Phase 3 AHF Program Strategy

Augment our data from the positive phase 2a and phase 2b AHF studies with the efficacy, safety and dosing and characterization learnings from the extension and other studies in the severe AHF patients experiencing cardiogenic shock. If positive and adequate, move istaroxime into phase 3 for AHF.

Our strategy is to focus on treating heart failure patients with low blood pressure, who also tend to be diuretic resistant, as a patient population that we believe could particularly benefit from the unique profile and potential ability of istaroxime to increase cardiac function and increase blood pressure while maintaining or improving renal function.

*Currently seeking partnership to finance global program*

WINDTREE THERAPEUTICS

# Next Generation, Oral SERCA2a Activators Platform has Potential for *both Major* Types of HF in Acute *and* Chronic Therapy

***Today:***

**Istaroxime**

- **Dual Mechanism (SERCA2a & Na+/K+)**
- **IV only, Acute Heart Failure with Reduced Ejection Fraction (HFrEF) with normal / low blood pressure**

***Future:***

**Preclinical Dual Mechanism, (SERCA2a & Na+/K+) Activators**

- **Same mechanism as Istaroxime with potential for oral / chronic use**
- **Granted composition of matter IP (U.S. and EU)**
- **Strategy: Fast follow-on to Istaroxime in AHF; then add on hospital discharge / chronic use development**

&

**Preclinical Pure SERCA2a Activators**

- **Innovative pure SERCA2a activator** (without the Na+/K+ mechanism) with **newly granted composition of matter IP (EU)**
- **Develop for Heart Failure including Preserved Ejection Fraction (HFpEF)** for chronic and acute use

***Development Strategy:***

# Windtree Strategy for Value Creation – Deliver Data and Deals

## 2024 Accomplishments

- ✓ FPI global Phase 2b Extension Study of istaroxime in Cardiogenic Shock
- ✓ $138MM plus royalties' regional license secured for CV products
- ✓ Eliminated $15MM in liabilities with Deerfield, added to shareholder equity
- ✓ Delivered positive data with istaroxime and the pure SERCA2a in arrythmias
- ✓ Started concomitant therapy Stage C study in more severe shock patients
- ✓ Acquired a novel pre-clinical atypical Protein Kinase C iota platform

## 2H 2024 / 1H 2025
## Focus and Planned Deliverables[1]

- ➢ Positive istaroxime Phase 2b SEIMiC part B Study Results in Cardiogenic Shock (CS)
- ➢ Execute istaroxime study in Stage C CS with interim data planned for late Q1 2025
- ➢ Support our license partner start up of Phase 3 Acute Heart Failure study in Asia/PAC
- ➢ Secure additional licenses for istaroxime and SERCA2a activators
- ➢ aPKCi inhibitor IND-enabling studies
- ➢ Drive capital efficacy and partnerships

WINDTREE THERAPEUTICS

1) Assumes additional resourcing

# Financial and Deal Summary

### Cash*

| | |
|---|---|
| June 30, 2024 | $1.8M |

### Common Stock Outstanding

| | |
|---|---|
| September 13, 2024 | 1,610,734 |

* Pre-July PIPE financing

**Completed Deals- $217MM in Potential Milestones Plus Royalties**

- **Istaroxime, Dual-Mechanism SERCA2a Activators, Rostafuroxin**
  - Exclusive Greater China regional license to Lee's Pharm
  - Potential proceeds: Up to ***$138.1 million*** in potential milestone payments, low double-digit % royalties; Partner pays for development, regulatory and commercial costs
- **AEROSURF / KL4 Platform –**
  - Exclusive global license to Lee's Pharm and Zhaoke
  - Potential proceeds: Up to ***$78.9 million*** in potential milestone payments, low double-digit % royalties; Partner pays for all costs

**Potential Next Deal**

- **Global (ex-Greater China) license for Istaroxime, SERCA2a Activators**


WINDTREE
THERAPEUTICS