
Filed Pursuant to Rule 433 of the Securities Act of 1933
Issuer Free Writing Prospectus dated April 13, 2023
Registration Statement No. 333-269775
Windtree Therapeutics
Company Overview
April 13, 2023
WINDTREE
THERAPEUTICS™
(NASDAQ: WINT)

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.

Disclaimers

This presentation highlights basic information about the Company. Because it is a summary that has been prepared solely for informational purposes, it does not contain all of the information that you should consider before investing in our Company. Except as otherwise indicated, this presentation speaks only as of the date hereof.

This presentation does not constitute an offer to sell, nor a solicitation of an offer to buy, any securities by any person in any jurisdiction in which it is unlawful for such person to make such an offering or solicitation.

Neither the SEC nor any other regulatory body has approved or disapproved of our securities or passed upon the accuracy or adequacy of this presentation. Any representation to the contrary is a criminal offense.

This presentation includes industry and market data that we obtained from industry publications and journals, third-party studies and surveys, internal company studies and surveys, and other publicly available information. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Although we believe the industry and market data to be reliable as of the date of this presentation, this information could prove to be inaccurate. Industry and market data could be wrong because of the method by which sources obtained their data and because information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. In addition, we do not know all of the assumptions that were used in preparing the forecasts from the sources relied upon or cited herein.

We have filed a registration statement on Form S-1 (File No.333-269775) with the SEC, as amended including a preliminary prospectus dated April 13, 2023 (the "Preliminary Prospectus"), with respect to the offering of our securities to which this communication relates. Any offer of the Company's securities will be made only by means of a written prospectus. Before you invest, you should read the Preliminary Prospectus (including the risk factors described therein) in the registration statement and, when available, the final prospectus relating to the offering, and the other documents we have filed with the SEC, for more complete information about the Company and the offering. You may obtain these documents, including the Preliminary Prospectus, for free by visiting EDGAR on the SEC website at http://www.sec.gov. Alternatively, copies of the prospectus may be obtained, when available, from: Ladenburg Thalmann & Co. Inc. by written request addressed to Syndicate Department, 640 5th Avenue, 4th Floor, New York, NY 10019 (telephone number 1-800-573-2541) or by emailing prospectus@ladenburg.com.

Risk Factors

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, and those discussed under the section entitled "Risk Factors" contained in our Annual Report on Form 10-K for fiscal year ended December 31, 2022 and our subsequent Quarterly Reports, together with other information in the prospectus. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Risk factors include, but are not limited to:

- Our current cash position, losses, negative cash flows from operations, and accumulated deficit raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings.
- We have incurred significant operating losses since inception, we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, or other operations.
- We are substantially dependent on the success of our lead product candidate, istaroxime. To the extent that our clinical development of istaroxime is not successful, our business, financial condition, and results of operations may be materially adversely affected and the price of our common stock may decline.
- Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to continue development activities, including our ability to obtain trial results, regulatory approval and commence product sales or allow for competition to emerge.
- We have conducted, and may in the future conduct, clinical trials for our product candidates at clinical sites located in the U.S. and outside of the U.S. If the FDA and other foreign equivalents raise concerns about certain of the clinical sites based on location and regulatory environment, they may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.
- Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.
- A small group of our investors, including Panacea Venture Management Company Ltd., may be able to exercise significant influence over our business strategy and operations.
- We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

Investment Highlights

- **Advanced clinical focus in Cardiogenic Shock and Acute Heart Failure**

- **Lead asset Istaroxime has demonstrated positive results and a unique, highly attractive profile through three Phase 2 global studies**
  - Recent positive Phase 2 data provides for a potentially faster and less expensive development and regulatory pathway in cardiogenic shock

- **Increasing efficiency and cutting cash burn – 58% decrease Q1' 23 vs. Q1' 22**
  - 53% reduction in non-program monthly burn and 46% reduction in FTEs (Q1' 23 vs. Q1 '22)

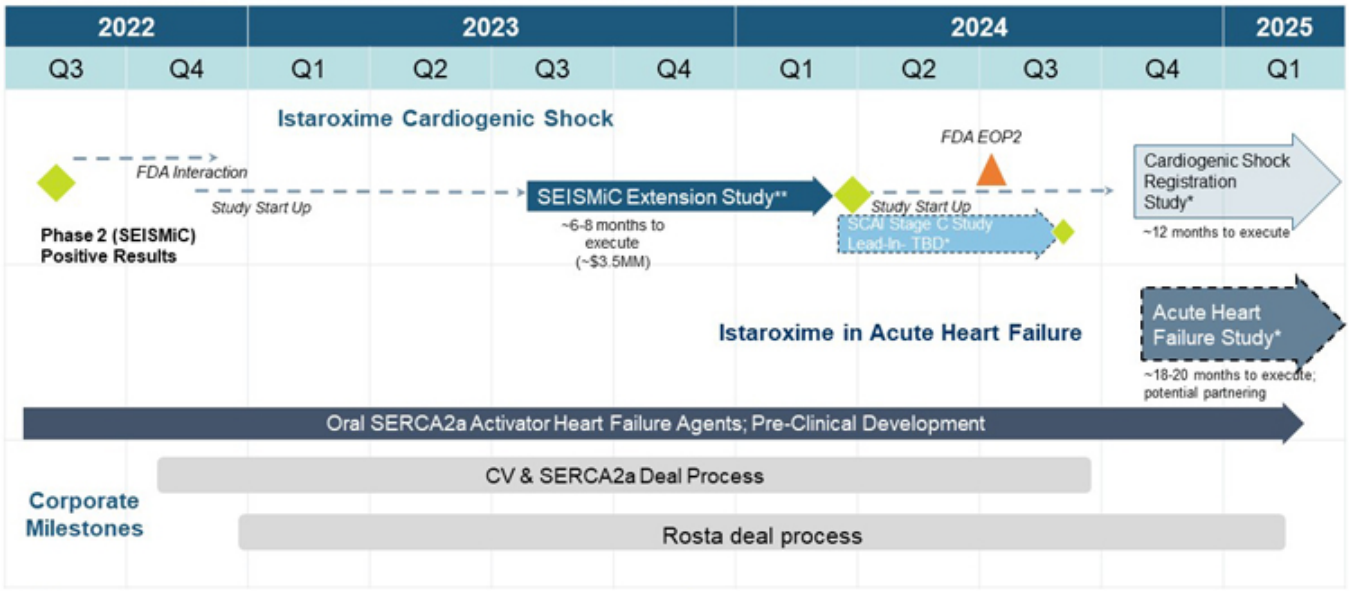
- **Actively engaged in business development opportunities (including strategic opportunities)**
  - Global out-license of KL4 surfactant and AEROSURF platform to Lee's Pharmaceuticals (SEHK:950) executed as of 8/09/2022.
    - Potential for milestone payments of up to $78.9 million
  - Potential opportunities:
    - Partnership with istaroxime and oral SERCA2a activators
    - Rostafuroxin out-licensing opportunity

FTE: defined as full time employee
Non-program monthly burn: defined as average monthly cash expended for all costs other than clinical trial and clinical development costs

Pipeline

Product	Indication	Phase	Development Status	Regulatory Status
Istaroxime	Cardiogenic Shock	Phase 2	• Positive Phase 2 study • Planning the execution of the next study and plans to meet with regulatory agencies regarding development path	*Executed Phase 2 in early cardiogenic shock, ongoing discussions*
	Acute Heart Failure	Phase 2b	• Augment AHF data with the efficacy, safety and dosing and 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 with partnership	*FDA Fast Track Designation*
Pursing Licensing Arrangement or Strategic Opportunities				
Oral SERCA2a Activators	Chronic Heart Failure, including potentially HFpEF	Preclinical	• Chronic and Acute Heart Failure • Target for collaboration/partnership	*IND-enabling studies*
Rostafuroxin	Genetically Associated Treatment Resistant Hypertension	Phase 2b	• Phase 2 data in hypertension and genetically associated hypertension • Company repositioned for the attractive and large Resistant Hypertension market • Out-licensing opportunity	*Ex-U.S. filings* *Open U.S. IND*
Out-Licensed				
KL4 Surfactant and AEROSURF	KL4 surfactant Drug/Device Tx for RDS and potential other applications	Phase 2b	• Global out-license to Lee's Pharmaceuticals (minus small European territory previously licensed to Esteve)	*FDA Fast Track Designation, Orphan Drug*

Strategy for Value Creation – expected timeline



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*study initiation pending positive data, regulatory input and adequate funding
**study pending adequate funding

Represents topline data available
Represents end of Phase 2 meeting

Istaroxime

Cardiogenic Shock

Potential indication in active clinical development

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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 intervention to increase SBP to >90mmHg and improve tissue perfusion
- High in-hospital mortality (~30-40%) and substantial morbidity in survivors[1]
- Represents an approximate $1.25B total market potential[2]

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1) Kolte D, American Heart Association; 2014 Jan 13
2) Estimates from claims data and epi data September 2021, multiplied by assumed various regional prices

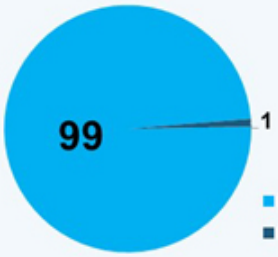
Early Cardiogenic Shock Treatment

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***

Clinical Cardiologists Treaters



- ✓ **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

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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**

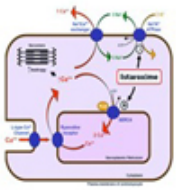
Dual Mechanism of Action

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

Istaroxime

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

Impact on both systolic and diastolic dysfunction



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

Phase 2a and 2b data in AHF demonstrated istaroxime uniquely and significantly improved:

- **Cardiac Function**
  - increased stroke volume
  - lowered cardiac filling pressures
- **Increased Systolic Blood Pressure**
- **Increased Renal Function (GFR)**

SEISMiC Study and Results Summary

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

Infused for 24 hours in a 1:1 randomization to placebo or istaroxime. Two istaroxime target doses were evaluated, 1.5µg/kg/min and 1.0 µg/kg/min

Primary endpoint: SBP AUC at 6 hours comparing istaroxime to placebo
Secondary measures included: SBP profile at 24 hours, echocardiology measures of systolic and diastolic cardiac function, renal function, various safety and tolerability measures

- ✓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 post-infusion 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

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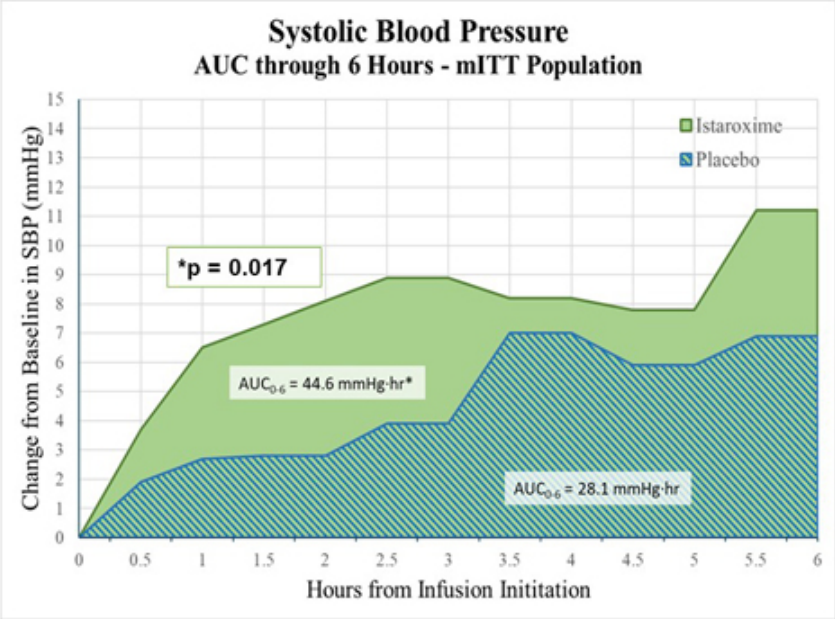
Difference in SBP Profile



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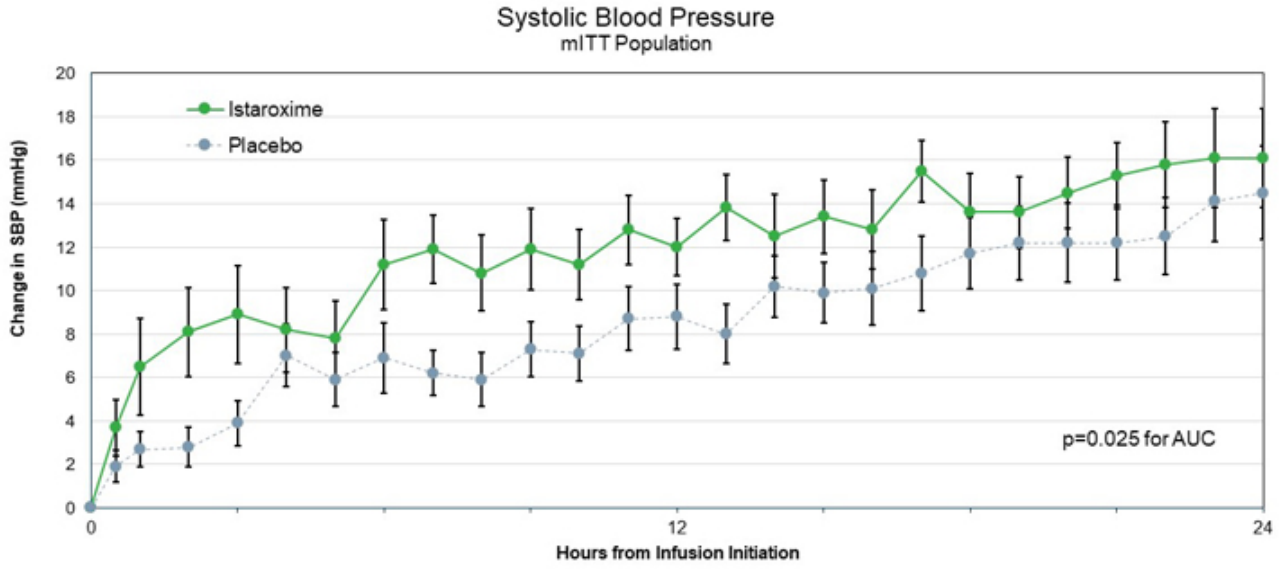
Systolic BP Improvements Persisted over 24 Hours



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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/m^2) 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**

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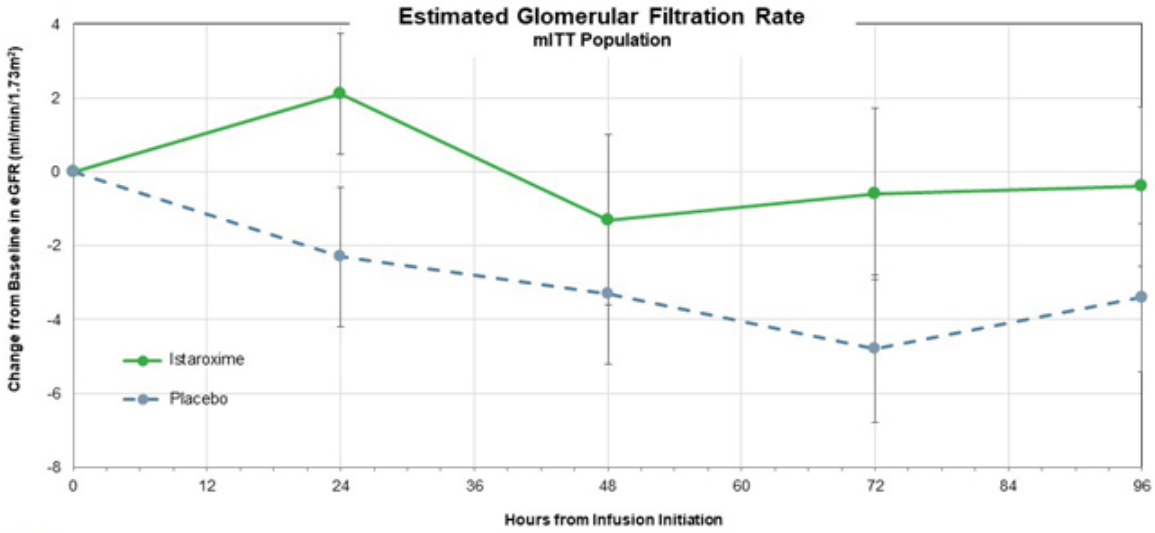
Treatment was Associated with a Favorable Renal Profile

Renal function was not decreased in istaroxime treated patients



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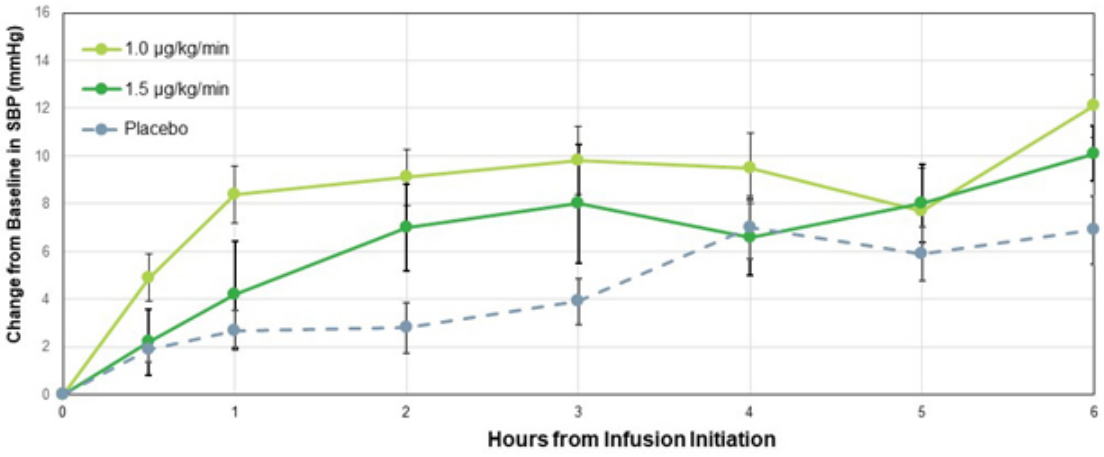
Data shown as means and standard errors

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



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All Subjects (n=60)

Cardiogenic Shock Development Strategy

An extension study is planned and ready to support ongoing development in cardiogenic shock and acute heart failure.

SEISMiC Extension Study

- Extended and titrated dosing for optimization
- Additional characterization of SERCA2a effect

~8 months to execute and ~$3.5MM in cost
Study plans and progression dependent upon resourcing

Topline data available

Execute EOP2 meeting (with these 3 studies augmented by AHF safety data base, etc.)

Cardiogenic Shock Registration Study*

SCAI Stage C (open label)

- Gain experience in SCAI stage C patients
- *Timing and study approach currently under development*

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

Cardiogenic Shock Treatment
Istaroxime Potential Opportunity for Regulatory Pathway

Potential for a relatively faster and less expensive developmental and regulatory pathway

FDA Regulatory Pathway Assumptions

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**[1]

End of Phase 2 meeting will confirm requirements for Phase 3:

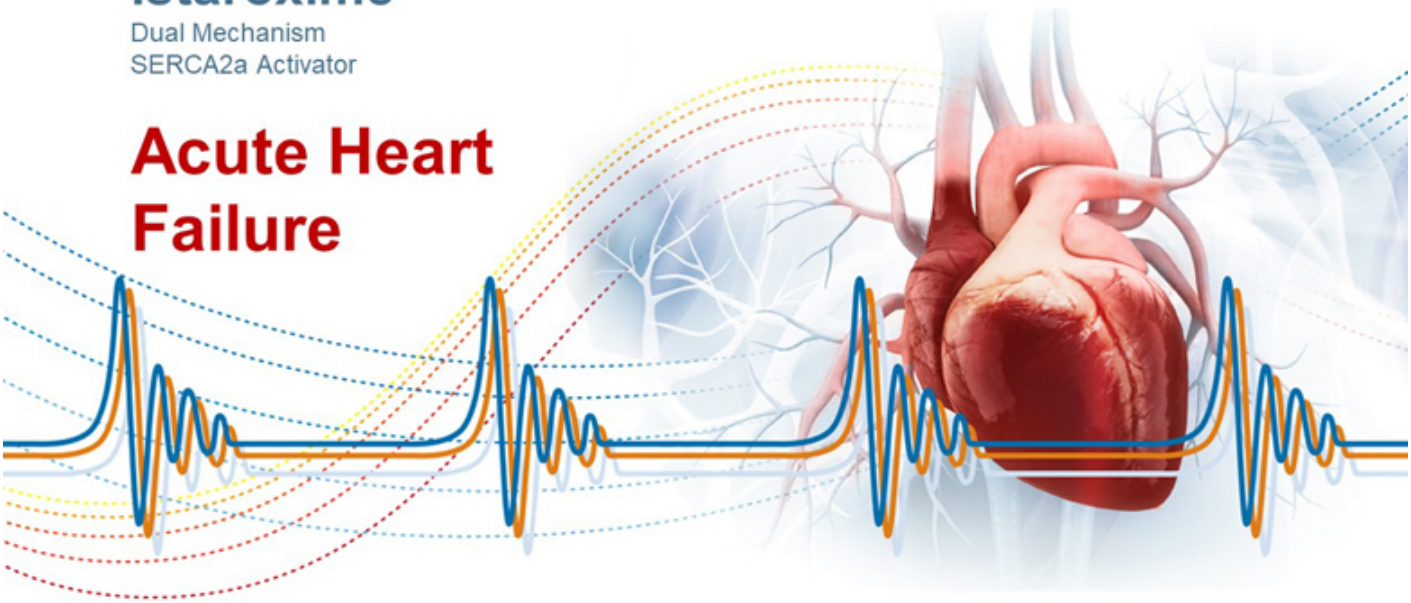
- Endpoint is blood pressure increase
- Superior mortality over control group endpoint is not required
- Smaller number of subjects required than typical cardiovascular clinical trials

1) Kosaraju A, Hai O. Cardiogenic Shock. [Updated 2019 Jan 25]. In: www.ncbi.nlm.nih.gov/books/NBK482255/ CSRC Think Tank - July 24, 2019

Istaroxime

Dual Mechanism
SERCA2a Activator

Acute Heart Failure



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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.

Patients
6M U.S.,
25M+ worldwide

~7%
In-patient mortality
30-day mortality can exceed 10%

High 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

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Sources: American Heart Association; DRG Data

Istaroxime AHF Phase 2a & 2b Studies

Phase 2a

n=**120**
ADHF Patients

Dosing=
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 2b

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

Dosing=
0.5, 1.0 µg/kg/min

24 hour
Infusion

Results

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

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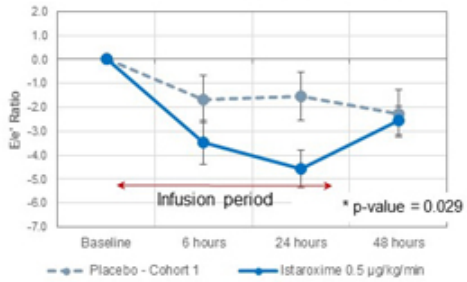
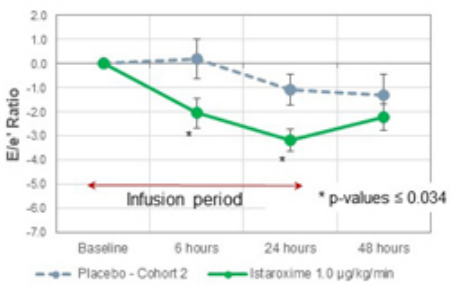
Primary Endpoint Achieved
Significant Changes in E/e' Ratio[1] and Stroke Volume

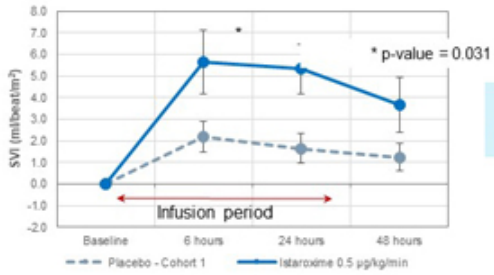
Istaroxime 0.5 µg/kg/min vs. placebo



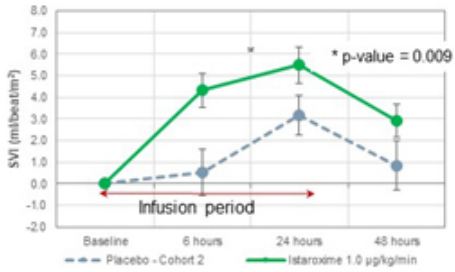
Istaroxime 1.0 µg/kg/min vs. placebo



E/e'



Stroke Volume



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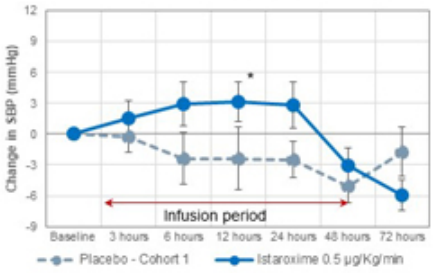
1) E/e' echocardiographic assessment of PCWP; Note: Data shown as means and standard errors

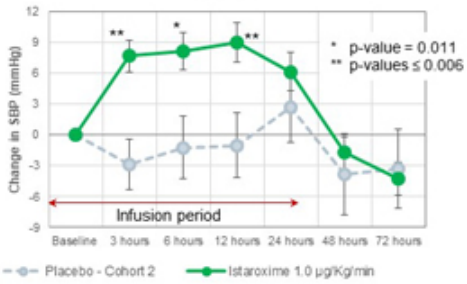
Systolic Blood Pressure Increased During Treatment and Renal Function Tended to Improve

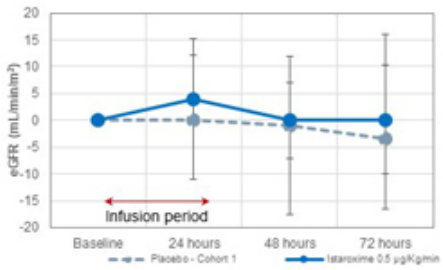
Istaroxime 0.5 µg/kg/min vs. placebo



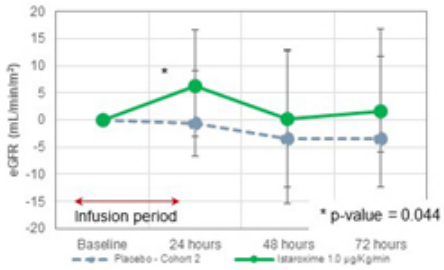
Systolic Blood Pressure (SBP)

Istaroxime 1.0 µg/kg/min vs. placebo





GFR (Renal Function)



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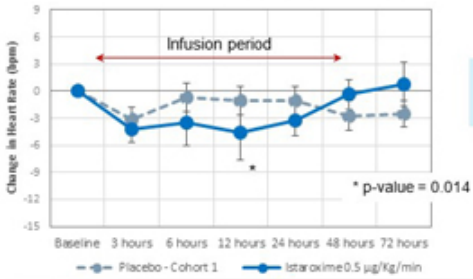
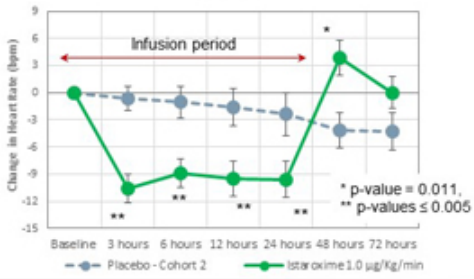
Data shown as means and standard errors

Heart Rate Decreased and No Increases in Cardiac Troponins

Istaroxime 0.5 µg/kg/min vs. placebo

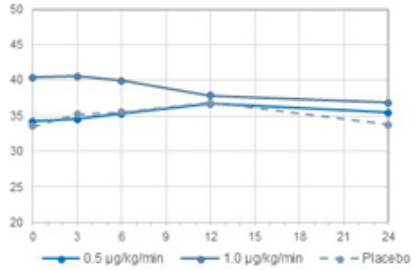


Istaroxime 1.0 µg/kg/min vs. placebo

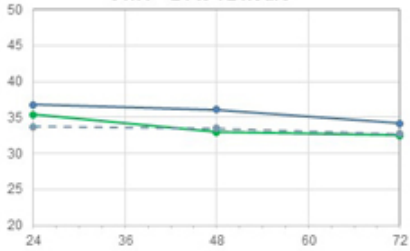


Heart Rate

cTnT – 0 to 24 hours



cTnT – 24 to 72 hours



Cardiac TnT (Myocardial Damage)

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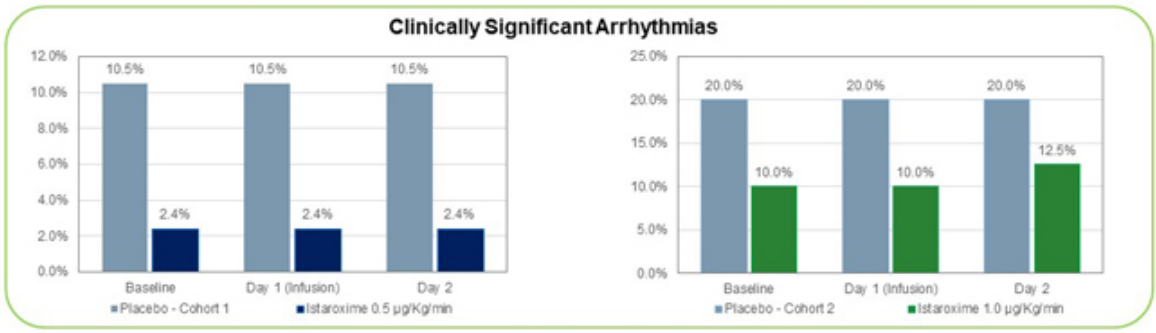
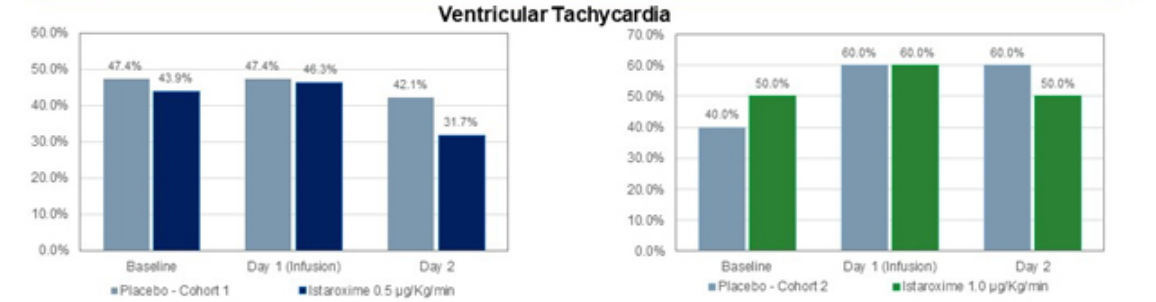
Favorable Profile Observed with 24-hour Holter Monitoring





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PVCs (n°/24 hours) shown as median, ventricular tachycardia and clinically significant arrhythmias shown as percentage of patients

Istaroxime – Acute Heart Failure

Objective: Evaluate potential Phase 3 AHF program based on data from our cardiogenic shock program

Potential Phase 3 AHF Program*

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 early 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.

We currently seek partnership to execute this clinical trial

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*study pending positive EOP2 regulatory and adequate funding (i.e. partnership)

Out-License / Partnership Opportunities

Out-Licensed

AEROSURF / KL4 Platform

Exclusive global license to Lee's Pharm (SEHK:950) and Zhaoke.

Potential proceeds:

- Up to $78.9 million in milestone payments
- Low double-digit % royalties
- WINT no longer carries any costs for KL4 platform

Licensing / Partnership Opportunities

Istaroxime – AHF and Cardiogenic Shock

SERCA2a Activators – Chronic and Acute Heart Failure

Rostafuroxin – Treatment Resistant Hypertension

Actively engaged in business development activities and discussion

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 out-patient chronic use**

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

Financial Summary & Capitalization

Cash:	$4.2M (3/31/23)

Securities	Common Equivalents as of March 31, 2023
Common Stock	909,013
Options (WAEP $389.91)	70,972
RSUs	6,524
Warrants (WAEP $179.56)	449,345
Fully Diluted	1,435,854

Driving Capital Efficiency to Program Investment

Significantly reduced company expenses and cash burn via out-licensing KL4 platform, focused resources on lead priority program

- 58% • Total Company Burn / Month Reduction Q1'23 vs. Q1'22
- 53% • Non-Program Burn / Month Reduction Q1'23 vs. Q1'22
- 46% • FTE Reduction Q1'23 vs. Q1'22

While the Company has plans to start new studies, it plans to also continue to lower non-program cash burn moving forward

WINDTREE THERAPEUTICS


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Appendix

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

~8 months to execute and ~$3.5MM in cost
Study plans and progression dependent upon regulatory alignment and resourcing

Cardiogenic Shock Opportunity

INTENDED TARGET THERAPEUTIC PROFILE

For patients in cardiogenic shock due to heart failure, istaroxime is expected to be a unique, first-in-class dual action agent and a treatment for cardiogenic shock that rapidly and significantly improves blood pressure *and* cardiac output performance while maintaining a favorable renal and overall safety profile - unlike other available agents.

OPPORTUNITY DRIVERS

- ✓ Currently available pharmacologic treatments have undesirable side effects and poor outcomes
- ✓ Very high cost of cardiogenic shock treatment creates 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)

INTENDED POSITIONING:

1. ***Expand the Market due to Profile:*** 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

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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**

WINDTREE THERAPEUTICS

1) ADHERE Registry, n=48,567; JAMA 2006
2) European Journal of Heart Failure; Voors, PRE-RELAX AHF Study; 2011; 13

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
- Few opportunities have the unmet need of serious diseases, favorable regulatory environment and market size of the istaroxime opportunity

WINDTREE THERAPEUTICS

Rostafuroxin Next Steps

Windtree acquired rostafuroxin in a merger and acquisition and proceeded to improve the formulation and design a repositioning strategy and program from essential to resistant hypertension with an objective to leverage non-dilutive funding to achieve the goal of partnering the asset. Next steps include -

- Study Start-Up:
  - Prepare and file US investigational new drug application (IND) and manufacture drug for the planned Phase 2 study in RHTN
  - Use of regulatory consultant to assist creating and filing IND
  - Begin manufacturing with our outside contract manufacturing organization
- Study:
  - Phase 2 RHTN proof of concept study
- Transact:
  - A successful Phase 2 RHTN study could result in a business development deal with a pharmaceutical company

We currently seek grants or partnership to execute this clinical trial