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LEVEL Clinical Trial Topline Results

August 10, 2026

Today's Agenda

1. Opening Remarks	Chris Giordano	President and CEO
2. LEVEL Topline Results	Stuart Rich, MD	CMO
3. KOL Thoughts	Sanjiv Shah, MD	Northwestern University
4. Path Forward	Chris Giordano	CEO
5. Q&A	Chris Giordano	President and CEO
	Stuart Rich, MD	CMO
	Doug Randall	CBO
	Tom Staab	CFO
	Sanjiv Shah, MD	Northwestern University

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Forward-Looking Statements

Disclaimers

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Introduction

Chris Giordano
President and CEO, Tenax Therapeutics

What LEVEL Told Us

WHERE THE TRIAL LANDED

LEVEL did not meet its primary endpoint, but a strong treatment effect was seen across patients with higher disease burden

What we confirmed

- Oral levosimendan is safe and well-tolerated
- Biologically active, as measured by NT-proBNP and RVSP
- Treatment effect seen in HELP study validated
- Successful trial execution by sites and clinical development team

What we learned

- Drug effect is evident in patients with higher disease burden
- Study entry criteria allowed patients with moderate disease
- In patients with baseline 6MWD* < 333 m, treatment effect was **+26.3 m vs placebo** (95% CI: 6.0, 46.7; nominal p = 0.0112)
- In the overall population, NT-proBNP was reduced by 49% vs placebo (nominal p < 0.0001)

*Prespecified analysis; nominal p-values are not adjusted for multiplicity.
NT-proBNP: N-terminal pro B-type natriuretic peptide; RVSP: right ventricular systolic pressure; HELP: Hemodynamic Evaluation of Levosimendan in Patients with PH-HFpEF; 6MWD: 6-minute walk distance; CI: confidence interval.

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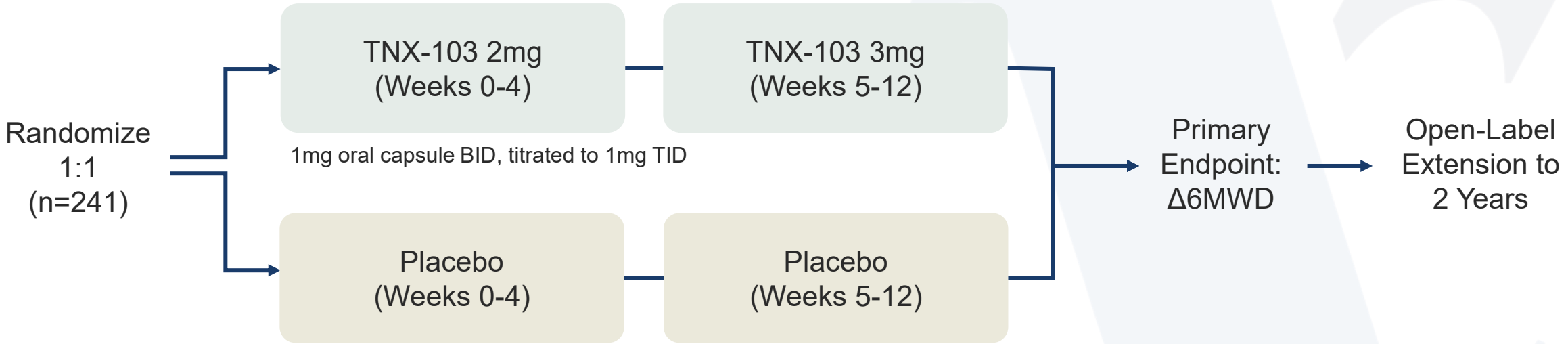
Phase 3 LEVEL Clinical Trial Topline Results

Stuart Rich, MD
CMO, Tenax Therapeutics

LEVEL Study

PHASE 3 REGISTRATIONAL TRIAL IN US AND CANADA



Hemodynamic Inclusion Criteria

RHC with qualifying hemodynamics at rest:

- PCWP > 18 mmHg, and
- mPAP > 30 mmHg, and
- RAP > 8 mmHg

OR

Hemodynamics with passive leg raise

- PCWP > 20 mmHg, and
- mPAP > 32 mmHg, and
- RAP > 8 mmHg

OR

Hemodynamics with bicycle exercise

- PCWP > 25 mmHg, and
- mPAP > 35 mmHg, and
- RAP > 10 mmHg

BID: twice a day; TID: three times a day; 6MWD: 6-minute walk distance; RHC: right heart catheterization; PCWP: pulmonary capillary wedge pressure; mPAP: mean pulmonary artery pressure; RAP: right arterial pressure.

Patient Demographics

BASELINE CHARACTERISTICS WERE BROADLY BALANCED ACROSS TREATMENT ARMS

Characteristic	TNX-103 (N=120)	Placebo (N=121)	Overall (N=241)
Age, years, mean (SD)	69.8 (9.7)	68.5 (10.1)	69.1 (9.9)
Female, n (%)	86 (71.7)	86 (71.1)	172 (71.4)
BMI, kg/m², mean (SD)	33.2 (5.8)	32.9 (6.6)	33.1 (6.2)
eGFR <60 mL/min/1.73 m², n (%)	33 (27.5)	44 (36.4)	77 (32.0)
SGLT2 inhibitor use, n (%)	80 (66.7)	93 (76.9)	173 (71.8)
GLP-1 receptor agonist use, n (%)	36 (30.0)	32 (26.4)	68 (28.2)
MRA use, n (%)	68 (56.7)	76 (62.8)	144 (59.8)
Diuretic use, n (%)	103 (85.8)	106 (87.6)	209 (86.7)
Baseline 6MWD, m, mean (SD)	316.5 (87.3)	322.5 (83.5)	319.5 (85.3)

Characteristic	TNX-103 (N=120)	Placebo (N=121)	Overall (N=241)
NYHA Functional Class II, n (%)	53 (44.2)	55 (45.5)	108 (44.8)
NYHA Functional Class III, n (%)	67 (55.8)	64 (52.9)	131 (54.4)
NYHA Functional Class IV, n (%)	0	2 (1.7)	2 (0.8)
Qualified at rest, n (%)	46 (38.3)	51 (42.1)	97 (40.2)
Qualified on provocation, n (%)	74 (61.7)	70 (57.9)	144 (59.8)
Slow acetylator, n (%)	66 (55.0)	54 (44.6)	120 (49.8)
Intermediate acetylator, n (%)	33 (27.5)	48 (39.7)	81 (33.6)
Rapid acetylator, n (%)	14 (11.7)	7 (5.8)	21 (8.7)
Acetylator status unknown, n (%)	7 (5.8)	12 (9.9)	19 (7.9)

BMI: body mass index; 6MWD: 6-minute walk distance; eGFR: estimated glomerular filtration rate; NYHA: New York Heart Association.

Primary and Key Secondary Endpoints

Primary Endpoint (Week 12)		TNX-103 (N=116)	Placebo (N=120)	Treatment difference
6MWD	LS mean	14.0 m (SE: 7.7 m)	10.4 m (SE: 7.6 m)	3.5 m (SE: 7.3; p = 0.63)
	Mean	17.7 m (SD: 40.2 m)	9.8 m (SD: 54.7 m)	8.0 m

Secondary Endpoints (Week 12)	TNX-103 (N=116)	Placebo (N=120)	Treatment difference
KCCQ-TSS, LS mean change	6.6 (SE: 2.4)	6.5 (SE: 2.3)	0.1 (SE: 2.2); NS
NYHA functional class improvement, n (%)	28 (24.1)	27 (22.5)	NS
Adjudicated clinical worsening, n (%)	3 (2.5)*	3 (2.5)*	NS

*N=120 and N=121 for TNX-103 and placebo arms, respectively.
6MWD: 6-minute walk distance; LS: least squares; SE: standard error; SD: standard deviation; KCCQ-TSS: Kansas City Cardiomyopathy Questionnaire-Total Symptom Score; NYHA: New York Heart Association; NS: not significant p-value.

Safety

TOLERABILITY DIFFERENCE BETWEEN ARMS; SERIOUS EVENTS AND CLINICAL WORSENING BALANCED

Adverse event summary	TNX-103 (N=120)	Placebo (N=121)
Any adverse event, n (%)	104 (86.7)	87 (71.9)
Treatment-related adverse event, n (%)	46 (38.3)	21 (17.4)
Leading to treatment discontinuation, n (%)	10 (8.3)	2 (1.7)
Leading to dose reduction, n (%)	18 (15.0)	5 (4.1)
Serious adverse event, n (%)	13 (10.8)	13 (10.7)
Adverse event of special interest, n (%)	11 (9.2)	7 (5.8)
Associated with adjudicated CWE, n (%)	3 (2.5)	3 (2.5)
Unplanned 24-hr CV hospitalization	0 (0)	3 (2.5)
Outpatient visit for IV diuretics	1 (0.8)	0 (0)
Death	2 (1.7)	0 (0)

- Higher rates of treatment-related AEs, dose reductions and discontinuations on drug, driven by headache, palpitations and hypotension
- Serious AEs and adjudicated clinical worsening events were balanced across arms
- No new-onset atrial fibrillation or ventricular tachycardia in patients without pre-existing evidence

CWE: clinical worsening event; AE: adverse event; CV: cardiovascular; IV: intravenous.

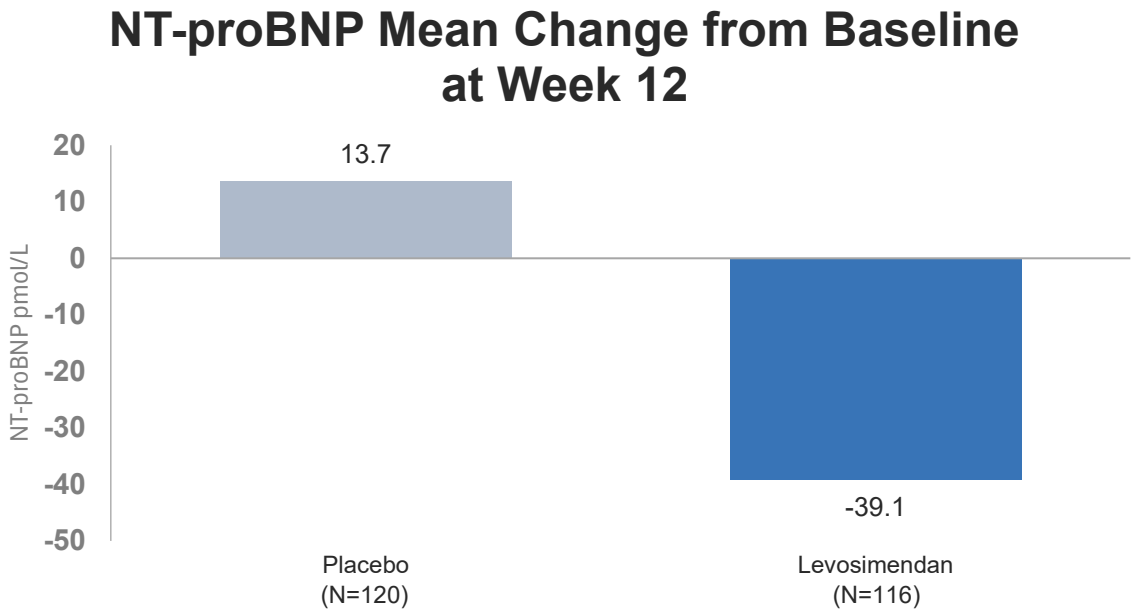
Confirming Biological Activity Using NT-proBNP

NT-proBNP FELL IN OVERALL POPULATION

All Patients

– 49%

NT-proBNP vs. placebo at Week 12
Geometrics LS mean ratio 0.51
(95% CI: 0.43, 0.60; p < 0.0001*)



*nominal p-value.
NT-proBNP: N-terminal pro B-type natriuretic peptide; LS: least squares; CI: confidence interval..

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Impressive Reductions in Exploratory Endpoints

BIOMARKER AND HEMODYNAMIC REDUCTIONS EVEN MORE PRONOUNCED IN PATIENTS WITH HIGHER DISEASE BURDEN

All Patients Enrolled in LEVEL

Exploratory endpoint	TNX-103	Placebo	Treatment Difference
NT-proBNP, mean change	− 39.1 pmol/L	+ 13.7 pmol/L	49% (p < 0.0001*)
RVSP (PASP), median	− 3.6 mmHg	+ 0.5 mmHg	− 3.5 mmHg#H (p = 0.0045*)

Patients in LEVEL with High Disease Burden

Below Median (Baseline < 333 m)

– 4.9 mmHg

RVSP Δ vs. placebo at Week 12
Echocardiography (p = 0.009*)

*nominal p-value; #95% confidence interval is -6.010, -1.100; HHodges-Lehmann shift estimate.
NT-proBNP: N-terminal pro B-type natriuretic peptide; RVSP: right ventricular systolic pressure; PASP: pulmonary artery systolic pressure; 6MWD: 6-minute walk distance..

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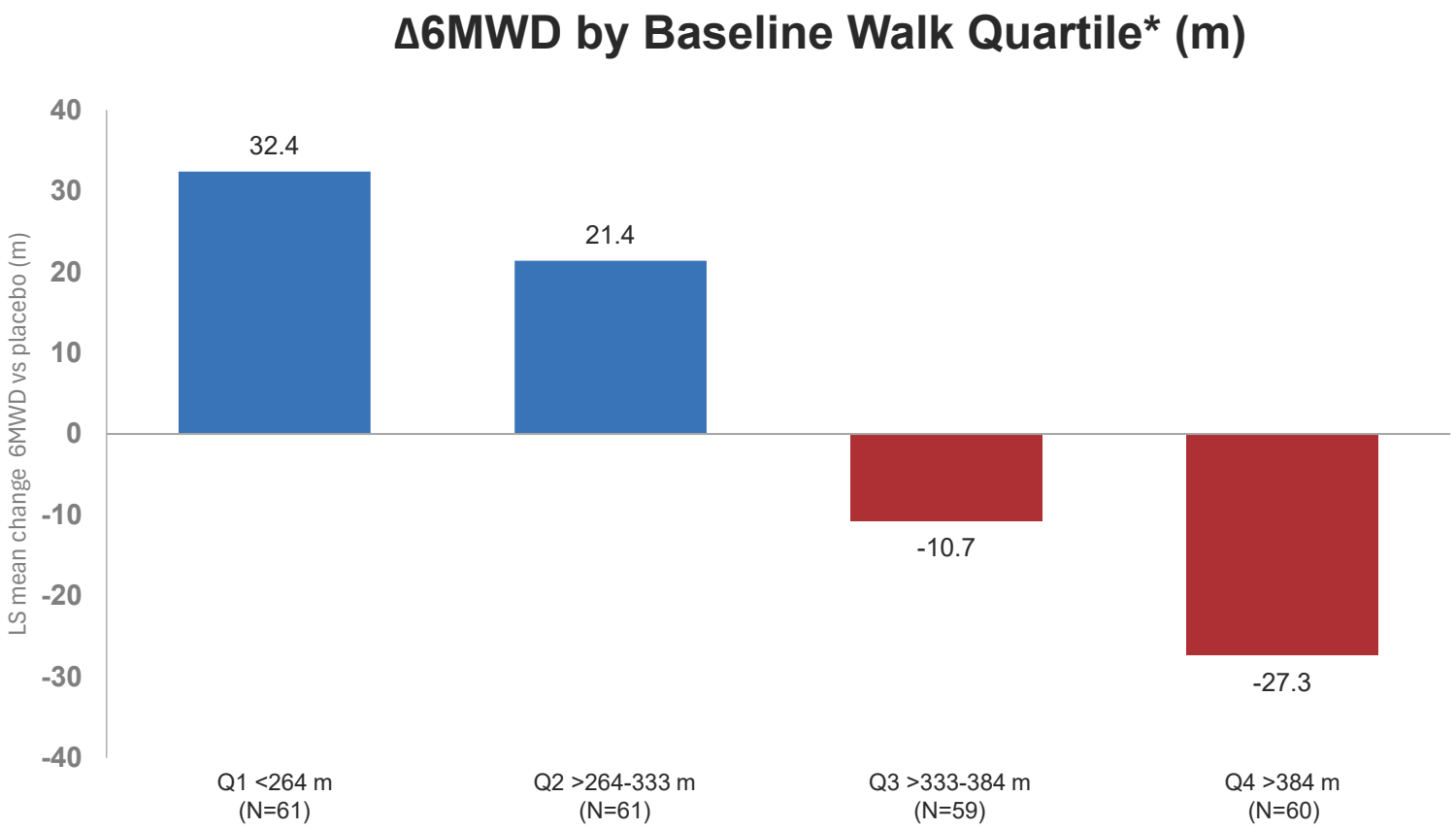
Treatment Effect Correlates with Disease Severity



Below Median (Baseline < 333 m)

+ 26.3 meters

Δ vs. placebo, LS mean
95% CI: 6.0, 46.7; nominal p = 0.0112

Above Median (Baseline ≥ 333 m)

− 17.6 meters

Δ vs. placebo, LS mean
95% CI: -36.7, 1.7; nominal p = 0.0744

*Post-hoc analysis
6MWD: 6-minute walk distance; LS: least squares; CI: confidence interval.

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Three Disease Burden Markers Correlate with Treatment Effect

KEY BASELINE CHARACTERISTICS PREDICT RESPONSE

By age	Δ 6MWD vs placebo	95% CI	Nominal p-value
Top tertile (> 74 years), N=77	+ 37.6 m	14.7, 60.5	0.0013
Above median (≥ 71 years), N=124	+ 27.1 m	9.9, 44.4	0.0021
Below median (< 71 years), N=117	- 19.2 m	- 42.0, 3.5	0.0972

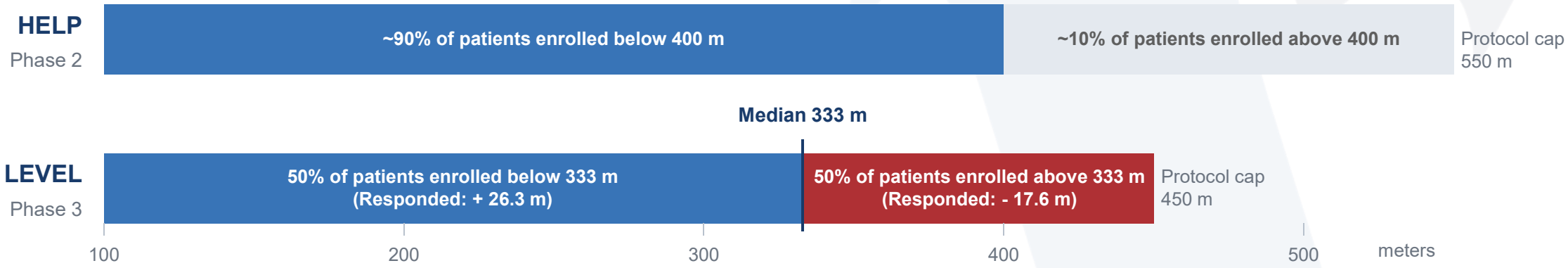
By baseline NT-proBNP#	Δ 6MWD vs placebo*	95% CI	Nominal p-value
Above median (≥ 225 pg/mL), N=122	+ 16.7 m	- 2.3, 35.8	0.0850
Below median (< 225 pg/mL), N=119	- 9.0 m	- 30.2, 12.3	0.4074

By baseline 6MWD	Δ 6MWD vs placebo*	95% CI	Nominal p-value
Below median (< 333 m), N=119	+ 26.3 m	6.0, 46.7	0.0112
Above median (≥ 333 m), N=122	- 17.6 m	- 36.9, 1.7	0.0744

*Least squares mean difference; #post-hoc analysis.
6MWD: 6-minute walk distance; NT-proBNP: N-terminal pro B-type natriuretic peptide; CI: confidence interval.

What We Learned

6MWD IS BOTH OUR PRIMARY ENDPOINT AND OUR BEST ENRICHMENT CRITERION



TNX-103 is safe and well-tolerated

TNX-103 is effective in patients with a higher disease burden

In patients with lower baseline walks, NT-proBNP decreased dramatically

Clear benefit seen in LEVEL will inform regulatory strategy moving forward

6MWD: 6-minute walk distance; HELP: Hemodynamic Evaluation of Levosimendan in Patients with PH-HFpEF.

Additional Thoughts On LEVEL Results

Sanjiv Shah, MD
Director of HFpEF Program
Northwestern University Feinberg School of Medicine
Principal Investigator on LEVEL Clinical Trial

Next Steps for Tenax

Chris Giordano
President and CEO, Tenax Therapeutics

Where We Go From Here

WHAT WE KNOW, WHAT WE WILL DO, AND WHAT IS STILL OPEN

WHAT LEVEL ESTABLISHED

- TNX-103 lowers NT-proBNP and RVSP, reflecting its biologic activity
- Therapeutic dose is confirmed
- Drug is safe and well-tolerated
- More effective in patients with higher disease burden

WHAT WE WILL DO NEXT

- Request a Type C meeting with the FDA
- Seek parallel EMA scientific consultation
- Present additional data at ESC and publish
- Baseline 6MWD in LEVEL-2 will be capped moving forward

WHAT REMAINS OPEN

- Modify overall Phase 3 development plan, following regulatory interactions

PK: pharmacokinetics; NT-proBNP: N-terminal pro B-type natriuretic peptide; RVSP: right ventricular systolic pressure; FDA: Food and Drug Administration; EMA: European Medicines Agency; NDA: New Drug Application; ESC: European Society of Cardiology; 6MWD: 6-minute walk distance.

Q&A

Chris Giordano
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