



Thiogenesis Therapeutics Announces Investigator-Initiated Study in Nephropathic Cystinosis and Provides Program Update

San Diego, California, February 2, 2026 - *Thiogenesis Therapeutics, Corp. (TSXV: TTI) (OTCQX: TTIPF)* ("Thiogenesis" or the "Company"), a clinical-stage biotechnology company developing next-generation sulfur-based prodrugs for rare pediatric diseases, today provided an update on its nephropathic cystinosis program and announced a new investigator-initiated study (IIS) collaboration with *Dr. Larry Greenbaum, a recognized global leader in cystinosis research, at Emory University and Children's Healthcare of Atlanta*.

The IIS will evaluate Thiogenesis' lead product candidate, TTI-0102, a next-generation cysteamine-based prodrug, in patients with nephropathic cystinosis to further characterize once-daily dosing, tolerability, and white blood cell (WBC) cystine control across a representative patient population. Data generated from the study are expected to support dose optimization and inform the Company's planned Phase 3 pivotal program.

Dr. Greenbaum serves as Chief of Pediatric Nephrology at Children's Healthcare of Atlanta and Professor of Pediatrics at Emory University School of Medicine. He has served as a principal investigator in multiple cystinosis clinical programs and sits on the scientific and medical advisory boards of leading cystinosis patient organizations. His clinical site previously participated in the development of delayed-release cysteamine therapy, providing direct continuity with current standards of care.

TTI-0102: Designed to Address Limitations of Current Cysteamine Therapies

Cystinosis requires lifelong cystine-depleting therapy; however, currently approved cysteamine products, Cystagon® and Procysbi®, are associated with frequent dosing, gastrointestinal intolerance, and adherence challenges that can limit long-term disease control.

TTI-0102 is a novel cysteamine-based disulfide prodrug designed to deliver sustained cysteamine exposure with lower peak plasma concentrations, enabling the potential for once-daily oral dosing.

Across clinical development programs, TTI-0102 has demonstrated:

- Sustained 24-hour cysteamine exposure with weight-based dosing
- Lower peak-related gastrointestinal adverse events compared to fixed dosing approaches
- Target cysteamine exposure achieved at approximately half the daily cysteamine base dose used with existing therapies
- A dual biological profile supporting cystine depletion and intracellular antioxidant pathways, including glutathione and taurine, consistent with cysteamine biology

Importantly, dosing and tolerability insights from Thiogenesis' Phase 2 MELAS program have directly informed cystinosis development strategy, supporting refined, weight-based dosing designed to optimize exposure while minimizing adverse events.

Phase 3 Development and Regulatory Pathway

Thiogenesis is preparing to initiate scale-up of the manufacturing process for a newly patented salt formulation of TTI-0102, which is required to produce sufficient clinical material to support formal stability testing. *Stability testing of the new salt formulation is expected to be conducted in parallel with finalization of the Company's Investigational New Drug (IND) application for cystinosis.*

Upon completion of these activities, the Company plans to initiate a Phase 3 pivotal, non-inferiority study comparing TTI-0102 to an approved cysteamine therapy under FDA's 505(b)(2) regulatory pathway.

The planned Phase 3 study is expected to leverage:

- WBC cystine concentration as a well-validated surrogate endpoint
- A non-inferiority design versus standard-of-care cysteamine therapy
- Simplified dosing and improved tolerability as key secondary and patient-reported outcomes

Given the well-established regulatory precedent in cystinosis and the sensitivity of WBC cystine as a biomarker, Thiogenesis believes this approach represents an efficient and well-defined path toward registration.

"This investigator-initiated study allows us to evaluate TTI-0102 in a real-world cystinosis population under the leadership of one of the most experienced investigators in the field," said Dr. Patrice Rioux, *Chief Executive Officer of Thiogenesis Therapeutics*. "We have spent years working alongside the cystinosis community and deeply understand the burden current therapies place on patients and families. TTI-0102 was engineered to simplify daily treatment while maintaining the biochemical efficacy patients depend on, and we are excited about its potential to offer a better-tolerated option that could meaningfully improve adherence and quality of life."

About Nephropathic Cystinosis

Nephropathic cystinosis is a rare, autosomal recessive lysosomal storage disorder caused by mutations in the *CTNS* gene, leading to toxic intracellular cystine accumulation and progressive multi-organ damage. Without disease-modifying therapy, patients develop renal Fanconi syndrome, growth failure, and progression to end-stage renal disease.

Cystinosis affects an estimated **2,000–2,500 patients worldwide**, representing a global market opportunity of **over \$300 million**. While cysteamine therapy slows disease progression, tolerability and adherence challenges remain a significant unmet medical need.

About TTI-0102

TTI-0102 is a sulfur-based disulfide prodrug consisting of two cysteamine molecules and one molecule of pantothenic acid (Vitamin B5). Following oral administration, metabolic activation delivers sustained cysteamine exposure with reduced peak-related toxicity, enabling once-daily dosing. TTI-0102 is currently in clinical development for MELAS, Leigh syndrome, pediatric MASH, and nephropathic cystinosis.

About Thiogenesis Therapeutics

Thiogenesis Therapeutics, Corp. (TSXV: TTI) (OTCQX: TTIPF) is a clinical-stage biopharmaceutical company with operations based in San Diego, CA. The Company is publicly traded on the TSX Venture Exchange and in the U.S. on the OTCQX. Thiogenesis is developing sulfur-containing prodrugs that act as precursors to previously approved thiol-active compounds, with the potential to treat serious pediatric diseases with unmet medical needs. Thiogenesis' lead product candidate, TTI-0102 has an active Phase 2

clinical trial in Mitochondrial Encephalopathy Lactic Acidosis and Stroke (“MELAS”), an IND-cleared Phase 2a clinical trial planned in Leigh syndrome spectrum, a Phase 2 clinical trial planned in pediatric Metabolic Dysfunction-Associated Steatohepatitis (“MASH”) and a Phase 3 clinical trial planned in nephropathic cystinosis.

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Forward Looking Statements

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