Thiogenesis Therapeutics Expands on Plans for Phase 3 Pivotal Trial of TTI-0102 in Nephropathic Cystinosis

IND expected in early 2026; TTI-0102 designed to improve tolerability & simplify dosing

San Diego, California--(Newsfile Corp. - November 24, 2025) - *Thiogenesis Therapeutics, Corp.* (TSXV: TTI) (OTCQX: TTIPF) *("Thiogenesis" or the "Company")*, a clinical-stage biotechnology company developing next-generation sulfur-based prodrugs for rare mitochondrial and metabolic diseases, today announced plans to initiate a Phase 3 pivotal clinical trial of its lead compound TTI-0102 for the treatment of nephropathic cystinosis, an inherited lysosomal storage disorder requiring lifelong cystine-depleting therapy. The Company plans to submit an Investigational New Drug (IND) application in early 2026.

About Nephropathic Cystinosis

Nephropathic cystinosis is a rare, autosomal recessive lysosomal storage disorder caused by mutations in CTNS, 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. Lifelong cysteamine treatment slows, but does not eliminate disease progression, and tolerability challenges frequently lead to suboptimal adherence. There are two currently approved drugs for cystinosis; immediate release cysteamine (Cystagon®) and delayed-release cysteamine (Procysbi®). Both require multiple daily dosings, and have significant side effects. The global cystinosis population exceeds 2,000 patients worldwide, representing a market opportunity of over $300 million.

A Next-Generation Approach to Cystine Depletion

TTI-0102 is a next-generation cysteamine-based prodrug engineered to address longstanding limitations of current standard-of-care therapies including their, short half-life, side effects and dosing frequency.

TTI-0102 is designed to potentially offer:

- Once-daily oral dosing, enabled by controlled prodrug metabolism and extended exposure
- Reduced peak-related GI intolerance, a major limitation of current cysteamine products
- Improved tolerability across weight ranges, supported by results from the Company's MELAS Phase 2 program
- Dual mechanistic activity: cystine depletion and enhancement of intracellular antioxidant pathways (glutathione and taurine), consistent with cysteamine biology

Phase 3 Cystinosis Trial Utilizing Well-Established Endpoints and Trial Design, Informed by Biomarker and Tolerability Data from the MELAS Clinical Study

Despite being a New Chemical Entity (NCE), TTI-0102 is reduced and metabolized in the GI tract releasing cysteamine, the active ingredient in (Cystagon®) and (Procysbi®) and therefore the Phase 3 trial will be conducted under the FDA's 505(b)(2) regulatory pathway.

A key design advantage of the planned pivotal study is the incorporation of dosing insights from Thiogenesis' ongoing Phase 2 MELAS trial, which demonstrated:

- Clear biomarker responses supporting thiol-mediated mitochondrial antioxidant activity
- Dose-dependent tolerability patterns, particularly in lighter-weight patients
- A fully characterized exposure-response profile, now informing cystinosis trial dosing strategies

These data enable Thiogenesis to initiate a cystinosis Phase 3 program with refined dosing regimens and enhanced biological rationale, reducing typical development risk.

Further, the endpoints and trial design are well understood, members of the Thiogenesis leadership and clinical team previously played pivotal roles in successfully advancing delayed-release cysteamine through clinical development and commercialization, giving the Company unique insight into optimal trial design and cysteamine pharmacology.

Delayed-release cysteamine remains the current standard-of-care but is associated with:

- Twice-a-day dosing requirements
- Nausea, vomiting, diarrhea, abdominal pain, halitosis, and dysgeusia (common adverse events)
- Fibrosing colonopathy, a rare but serious adverse event identified in multiple post-marketing case reports, prompting FDA labeling changes in 2022

"We understand the underlying mechanism of cystinosis at a deep biochemical level, cystine accumulation, oxidative stress, and the burden of lifelong thiol therapy," said Dr. Patrice Rioux, Chief Executive Officer, Thiogenesis Therapeutics. "TTI-0102 was engineered specifically to overcome the limitations of existing cysteamine formulations. By enabling the potential for once-daily or reduced dosing with a far better tolerability profile, we believe TTI-0102 represents the next-generation therapy that patients and families that would significantly increase their quality of life."

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

This news release contains certain forward-looking statements and forward-looking information (collectively referred to herein as forward-looking statements) within the meaning of Canadian securities laws including, without limitation, statements with respect to the future investments by the Company. All

statements other than statements of historical fact are forward-looking statements. Undue reliance should not be placed on forward-looking statements, which are inherently uncertain, are based on estimates and assumptions, and are subject to known and unknown risks and uncertainties (both general and specific) that contribute to the possibility that the future events or circumstances contemplated by the forward-looking statements will not occur. Although the Company believes that the expectations reflected in the forward-looking statements contained in this press release, and the assumptions on which such forward-looking statements are made, are reasonable, there can be no assurance that such expectations will prove to be correct. Readers are cautioned not to place undue reliance on forward-looking statements included in this document, as there can be no assurance that the plans, intentions, or expectations upon which the forward-looking statements are based will occur. By their nature, forward-looking statements involve numerous assumptions, known and unknown risks and uncertainties that contribute to the possibility that the predictions, forecasts, projections and other forward-looking statements will not occur, which may cause the Company's actual performance and results in future periods to differ materially from any estimates or projections of future performance or results expressed or implied by such forward-looking statements. The forward-looking statements contained in this news release are made as of the date hereof and the Company does not undertake any obligation to update publicly or to revise any of the included forward-looking statements, except as required by applicable law. The forward-looking statements contained herein are expressly qualified by this cautionary statement.