

Thiogenesis Announces Collaboration and Updates on Pediatric NASH Clinical Program

San Diego, California--(Newsfile Corp. - August 20, 2024) - **Thiogenesis Therapeutics, Corp. (TSXV: TTI) ("Thiogenesis" or the "Company")** a clinical-stage biotechnology company developing disulfides that are precursors to thiol-active compounds and potent antioxidants targeting unmet pediatric diseases, today announced that it has signed a Collaborative Agreement with the University of California San Diego ("UCSD"). Thiogenesis will work with Jeffrey Schwimmer, M.D., as the Principal Investigator at UCSD, in a proposed Phase 2 clinical trial titled: *"An Open Label, Controlled Clinical Trial to Evaluate the Efficacy and Safety of TTI-0102 in Pediatric Nonalcoholic Steatosis ("NASH")."*

Pediatric NASH and TTI-0102

Pediatric NASH is a more severe form of pediatric Nonalcoholic Fatty Liver Disease ("NAFLD"). There are estimated to be well-over 1,000,000 children in the U.S. with pediatric NASH, for which there are no approved drugs or treatments. Pediatric NASH is often linked to obesity and occurs when there is inflammation and fat in the liver, additionally there may be complications from liver damage and scarring ("fibrosis").

Thiogenesis' lead compound, TTI-0102, is a prodrug that becomes active after oral administration, leading to a well-tolerated and sustained release of a previously approved active pharmaceutical ingredient cysteamine. Cysteamine was approved by other pharmaceutical companies to treat pediatric patients with nephropathic cystinosis for decades. As a result, TTI-0102 is eligible for the accelerated 505 (b)(2) regulatory pathway in the U.S. that allows for the inclusion of third-party safety data from the previously approved drug for the safety component of its Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA"). Thiogenesis in collaboration with UCSD, is in the process of filing an IND with the FDA. The two critical mechanisms of action of TTI-0102 in potentially treating pediatric NASH are i) it increases intracellular glutathione and moderates oxidative stress which may reduce or prevent steatosis, and ii) it assists in fatty acid synthesis which has the potential to reduce fibrosis.

The proposed Phase 2 clinical trial is designed to treat 10 NAFLD patients with TTI-0102, ages 10-17 in a single center, open label trial, for a duration of 12 weeks. The primary objective will be to monitor for improvements in serum of alanine aminotransferase ("ALT") levels that is typically elevated in fatty liver patients.

The secondary objectives in the clinical trial include to:

- Evaluate safety and tolerability of TTI-0102
- Measure several biomarkers associated with NAFLD
- Assess changes in steatosis; and
- Evaluate changes in liver fibrosis

"I am extremely happy to be working with Dr. Schwimmer again in the field of pediatric NASH," said Patrice Rioux, M.D., Ph.D., Chief Executive Officer of Thiogenesis. "For several years now, we have believed in the potential and safety of cysteamine in treating pediatric NASH and look forward to potentially offering these pediatric patients some relief from this terrible condition."

About Dr. Schwimmer

Dr. Jeffrey Schwimmer, clinical professor of pediatrics at UC San Diego School of Medicine, is a pediatric gastroenterologist who has specialized in nonalcoholic fatty liver disease research for over two decades. His lab is focused on clinical and translational research on nonalcoholic fatty liver disease in children, young adults and families. Its goal is to improve the diagnosis and treatment of pediatric

NAFLD to promote the health and quality of life of children, adolescents and young adults. Dr. Schwimmer founded and directs the Fatty Liver Clinic at Rady Children's Hospital San Diego. He has over 160 peer reviewed publications focused on NAFLD, obesity, and metabolic health.

About TTI-0102

Thiogenesis' lead compound, TTI-0102, is a new chemical entity that is an asymmetric disulfide and a prodrug that acts as a precursor to the thiol-active compound cysteamine. Thiols, which have a functional SH group (containing sulfur and hydrogen) are versatile bio-active molecules that are known to be involved in key biochemical reactions and metabolic processes, making them promising candidates for several therapeutic applications. Thiols are known to be precursors to important antioxidants such as glutathione, and to further reduce inflammation, as a result they have the potential to significantly reduce oxidative stress in the mitochondria. The oral prodrug TTI-0102 was developed to address the challenges of first-generation thiol-active drugs, including their short half life, adverse side effects and dosing limitations.

About Thiogenesis

Thiogenesis Therapeutics, Corp. (TSXV: TTI) is a clinical-stage biopharmaceutical company operating through its wholly owned subsidiary based in San Diego, CA. The Company is publicly traded on the TSX Venture Exchange. 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. Prodrugs are drugs that contain previously approved active pharmaceutical ingredients and are modified so that they only become active when metabolized. For regulatory purposes prodrugs can use existing third-party safety data in regulatory submissions in the streamlined 505 (b)(2) regulatory pathway in the U.S., and its equivalent hybrid system in Europe, to proceed into human efficacy trials with regulatory approval. Prodrugs may enhance the profile of the active pharmaceutical ingredient to increase its bioavailability and reduce side effects. The Company's initial target indications include mitochondrial encephalopathy lactic acidosis and stroke-like episodes ("MELAS"), Leigh syndrome, Rett syndrome and pediatric NASH.

For further information, please contact:

Brook Riggins, Director, and CFO

Email: info@thiogenesis.com

Tel.: (888) 223-9165

Forward Looking Statements

This press 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 press release, 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 press 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.

Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this press release.

To view the source version of this press release, please visit
<https://www.newsfilecorp.com/release/220405>