UPDATE – Kalaris Therapeutics Now Enrolling Phase 1b/2 Multiple Ascending Dose Study of TH103 in Neovascular Age-Related Macular Degeneration

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Recently initiated Phase 1b/2 multiple ascending dose study intended to assess safety and efficacy in nAMD patients receiving four initial monthly doses of TH103

Phase 1b/2 study to inform dose selection for potential Phase 3 development program, with initial data expected in 2H 2026

TH103's ongoing Phase 1a single ascending dose study remains on track for data to be reported in Q4 2025

PALO ALTO, Calif., Sept. 15, 2025 (GLOBE NEWSWIRE) -- Kalaris Therapeutics, Inc. (Nasdaq: KLRS) ("Kalaris"), a clinical-stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases, today announced that it is now enrolling a Phase 1b/2 multiple ascending dose (MAD) study of TH103 in patients with neovascular age-related macular degeneration (nAMD). The study is intended to build upon the company's ongoing Phase 1a single ascending dose (SAD) study and represents a key advance in the clinical development program for TH103 towards potential Phase 3 clinical development. The new Phase 1b/2 dose-finding study is designed to evaluate multiple dose levels of TH103 in up to 80 nAMD patients. Patients will receive 4 initial monthly intravitreal injections of TH103. Study assessments are expected to include safety and preliminary efficacy with a primary time point for analysis at one-month following the last injection. Patients will then be followed in an extension phase of the study.

The Phase 1b/2 study replaces a smaller Part 2 design originally planned to follow the ongoing Phase 1a study. Data from the Phase 1a study, including safety, preliminary efficacy (e.g., visual acuity and lesion morphology), and pharmacokinetics remains on track to be reported in the fourth quarter of 2025. Further details on the Phase 1b/2 design will be shared at that time.

"The Phase 1b/2 study represents an important milestone in advancing TH103 toward a potential future Phase 3 program," said Andrew Oxtoby, Chief Executive Officer of Kalaris Therapeutics. "We remain committed to developing this innovative therapy with the goal of potentially addressing major unmet needs in the treatment of retinal diseases such as nAMD."

TH103 represents a novel approach to treating exudative and neovascular retinal diseases, building on decades of research in anti-VEGF therapy. The investigational drug was developed by company co-founder and current board member Napoleone Ferrara, MD, whose pioneering work led to the creation of the anti-VEGF class of drugs that transformed the treatment of cancer and retinal diseases and for which he received the prestigious Lasker Award.

"Having dedicated my career to understanding the role of VEGF in human disease, I am encouraged by the potential of TH103 and its novel molecular approach to potentially provide both increased VEGF inhibition and longer retinal retention," said Dr. Ferrara. "This dose-finding study is a critical step in our efforts to potentially advance this novel investigational therapy toward pivotal trials that could benefit patients with exudative and neovascular retinal diseases."

About Neovascular Age-related Macular Degeneration

Neovascular AMD affects millions of people worldwide and is a leading cause of vision loss in individuals over 50. While current anti-VEGF therapies have transformed treatment outcomes, many patients continue to experience progressive vision loss despite treatment, highlighting the need for continued therapeutic innovation.

About TH103

TH103 is a dual-action investigational therapy engineered to potentially provide increased and longer-lasting anti-VEGF activity to treat exudative and neovascular retinal diseases, including neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME), and retinal vein occlusion (RVO). The drug represents a novel molecular approach, building on extensive research in anti-VEGF mechanisms. TH103 is currently being evaluated in an ongoing **Phase 1a single ascending dose study** to determine safety, preliminary efficacy, and pharmacokinetics in nAMD patients, with data on track to be reported in the fourth quarter of 2025, and a recently initiated **Phase 1b/2 multiple ascending dose study** in nAMD patients, with preliminary data expected in the second half of 2026. TH103 is an investigational therapy, and its safety and efficacy have not been established by regulatory authorities.

About Kalaris

Kalaris Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases with major unmet medical needs. Founded by renowned scientist Dr. Napoleone Ferrara,

whose pioneering research led to the development of anti-VEGF therapy, the company is committed to advancing novel therapeutic approaches for patients with sight-threatening retinal conditions such as neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME), and retinal vein occlusion (RVO).

For more information, visit www.kalaristx.com.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 that involve substantial risk and uncertainties. All statements, other than statements of historical fact, contained in this press release, including statements regarding the strategy, future operations, prospects, plans and objectives of management of Kalaris, including the therapeutic potential of TH103 for nAMD and other exudative and neovascular retinal diseases, the anticipated timelines for reporting clinical data from the Phase 1a and Phase 1b/2 clinical trials of TH103, plans to advance TH103 into Phase 3 clinical trials and to develop TH103 for additional indications and the sufficiency of Kalaris' cash resources for the period anticipated, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are based on current expectations and beliefs of the management of Kalaris as well as assumptions made by, and information currently available to, the management of Kalaris and are subject to risks and uncertainties. There can be no assurance that future developments affecting Kalaris will be those that it has anticipated. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: risks associated with the clinical development and regulatory approval of TH103, including potential delays in the completion of clinical trials; expectations regarding the therapeutic benefits, clinical potential and clinical development of TH103; risks related to the inability of Kalaris to obtain sufficient additional capital to continue to advance its product candidate; uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; risks related to the failure to realize any value from any product candidates being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; the ability to obtain, maintain, and protect intellectual property rights related to product candidates; changes in regulatory requirements and government incentives; Kalaris' competitive position and expectations regarding developments and projections relating to its competitors and any competing therapies that are or become available; potential adverse reactions or changes to business relationships resulting from the completion of the merger with AlloVir, Inc.; risks associated with the possible failure to realize, or that it may take longer to realize than expected, certain anticipated benefits of the merger, including with respect to future financial and operating results; the risk of involvement in current and future litigation, including securities class action litigation, that could divert the attention of the management of Kalaris, harm Kalaris' business and for which Kalaris may not have sufficient insurance coverage to cover all costs and damages; and such other factors as are set forth in Kalaris' public filings with the SEC, including, but not limited to, those described under the heading "Risk Factors". Kalaris may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on its forward-looking statements. The forward-looking statements contained in this press release are made as of the date of this press release, and Kalaris does not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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