Kalaris Therapeutics Reports Positive TH103 Phase 1a SAD Results from Expanded Neovascular AMD Cohorts

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Data from the expanded cohorts reinforce the positive BCVA, OCT, pharmacokinetic and time-to-retreatment findings observed in the original cohorts

Enrollment in the Phase 1b/2 multiple-ascending dose trial of TH103 continues, with preliminary data on track for 1H 2027

BERKELEY HEIGHTS, N.J., July 17, 2026 (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 positive additional data from its Phase 1a single ascending dose (SAD) trial of TH103 in neovascular age-related macular degeneration (AMD). Data from the expanded cohorts build on previously reported positive findings from the trial, with additional patients showing improvements in vision and retinal anatomy and further supporting the potential for extended treatment durability after a standard four-dose loading regimen. The updated SAD results will be presented today at 8:00 am EDT by Dr. Joel Pearlman, MD, PhD, at the American Society of Retina Specialists (ASRS) Annual Meeting.

The expanded Phase 1a SAD dataset now includes a total of 17 treatment-naive patients, as well as an additional 3 treatment-experienced patients which were included in the safety cohort. All 20 patients completed six months of follow-up. Consistent with Kalaris' previously reported findings, the expanded efficacy analysis, which includes the 17 treatment-naïve patients, continued to demonstrate robust structural and functional improvements.

TH103 plasma pharmacokinetic findings continued to suggest greater intraocular retention, with 27- to 53-fold lower Cmax compared to current leading anti-VEGF agents on a molar equivalence basis. Additionally, the time to retreatment results further supported the hypothesis that increased intraocular retention may contribute to prolonged biological activity: following only a single TH103 injection, 41% of treatment-naïve patients (N=17) received a first retreatment at 4 months or later, 35% at 5 months or later, and 29% received no additional anti-VEGF treatment during the entire six-month follow-up period. Separately, after a single TH103 injection, time to retreatment in treatment-experienced patients (N=3) was extended by an average of 2 months compared with prior anti-VEGF treatment intervals.

No cases of intraocular inflammation (IOI) were observed among the six patients treated at the 2.5 mg dose using product manufactured following process adjustments to reduce impurities. As previously reported, one patient treated at the 5 mg dose experienced transient IOI that resolved without sequelae.

"The expanded Phase 1a SAD dataset continues to strengthen our confidence in potential TH103 differentiation," said Andrew Oxtoby, CEO of Kalaris Therapeutics. "The consistency of the structural, functional and pharmacokinetic findings reinforces our belief that TH103 has the potential to offer a best-in-class treatment option for patients with neovascular AMD."

Building on these findings, Kalaris is actively enrolling and dosing patients in its ongoing Phase 1b/2 study aimed at evaluating a standard four-dose loading regimen of TH103 in treatment-naïve patients using an ascending-dose design. The study is designed to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of repeated TH103 intravitreal injections as well as time to retreatment following a complete loading course. Study results will inform dose selection for potential future Phase 3 trials of TH103, and Kalaris remains on track to share initial data from the Phase 1b/2 study in the first half of 2027.

About TH103

TH103 is a potential best-in-class, investigational dual-targeting biologic engineered by VEGF scientific discoverer Dr. Napoleone Ferrara to achieve extended intraocular retention with enhanced VEGF inhibition through optimized binding to VEGF receptor 1 ligands and concurrent heparan sulfate proteoglycan (HSPG) anchoring. It is a fully humanized, recombinant fusion protein designed for intravitreal delivery, with potential applications as a treatment for exudative and/or neovascular retinal diseases, such as neovascular AMD, diabetic eye disease and retinal vein occlusion. TH103 is currently being investigated in a Phase 1b/2 clinical trial in patients with neovascular Age-related Macular Degeneration (nAMD).

About Kalaris

Kalaris Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases. 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 with major unmet medical needs.

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 and Section 21E of the Securities Exchange Act of 1934, as amended, 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; the therapeutic potential of TH103 for neovascular Age-related Macular Degeneration and other exudative and neovascular retinal diseases; the anticipated timeline for reporting data from the ongoing Phase 1b/2 clinical trial of TH103; plans to advance TH103 into Phase 3 clinical trials and to develop TH103 for additional indications, plans to improve the manufacturing process for TH103 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; the timing of and Kalaris’ ability to enroll patients in clinical trials; whether results from preclinical studies and initial data from early clinical trials will be predictive of the final results of the clinical trials or future trials; dependence on third parties for the development and manufacture 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; 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; the risk of involvement in current and future litigation; 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.

Kalaris Therapeutics Investor Contact:
Corey Davis, Ph.D.
LifeSci Advisors, LLC
+1 212 915 2577
cdavis@lifesciadvisors.com
ir@kalaristx.com