Marea Therapeutics, a Subsidiary of Lisata Therapeutics, Announces MAR001 Reduces Triglycerides Without Worsening Glycemic Control in Phase 2b TYDAL-TIMI 78 Trial; Results Presented as AHA 2026 Late-Breaker and Published in The New England Journal of Medicine

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Part A of TYDAL-TIMI 78 Trial met all objectives, with statistically significant placebo-adjusted triglyceride reductions of 39.1%–45.5% across all three doses at Week 12 and up to 57.2% in participants with baseline triglycerides ≥300 mg/dL

Reductions from baseline of up to 72.2% in participants with triglycerides ≥500 mg/dL strongly support MAR001's potential in severe hypertriglyceridemia (sHTG); Part B of TYDAL-TIMI 78 trial now enrolling sHTG participants

Favorable and differentiated safety profile, with adverse event rates similar to placebo and no worsening of HbA1c

SOUTH SAN FRANCISCO, Calif. and LIBERTY CORNER, N.J., Nov. 09, 2026 (GLOBE NEWSWIRE) -- Marea Therapeutics, Inc. ("Marea"), a subsidiary of Lisata Therapeutics, Inc. (Nasdaq: LSTA) ("Lisata"), today announced that MAR001, its potential first-in-class monoclonal antibody product candidate targeting angiopoietin-like protein 4 (ANGPTL4), met all objectives in Part A of the Phase 2b TYDAL-TIMI 78 trial, reducing triglycerides by up to 72.2% from baseline in participants with triglycerides ≥500 mg/dL, along with a generally favorable and potentially differentiating safety profile including no worsening of HbA1c. The data are being presented today as a late-breaking clinical trial at the American Heart Association (AHA) Scientific Sessions 2026 and were simultaneously published in *The New England Journal of Medicine* (NEJM).

MAR001 met the primary endpoint at every dose, with statistically significant placebo-adjusted reductions in fasting triglycerides of 39.1% to 45.5% at Week 12 ($p<0.001$ for all doses), sustained through Week 24. Triglyceride lowering deepened as baseline levels rose: placebo-adjusted reductions reached up to 57.2% in participants with baseline triglycerides ≥300 mg/dL, and reductions from baseline reached up to 72.2% in participants with triglycerides ≥500 mg/dL. At the 900 mg dose, 51.7% of participants reached normal triglyceride levels (<150 mg/dL), versus 3.4% on placebo. MAR001 also significantly reduced remnant cholesterol and was generally well tolerated through 24 weeks, with no cases of pancreatitis and no glycemic signal versus placebo, as measured by HbA1c, a key consideration for the up to 70% of patients with sHTG who also have type 2 diabetes. Marea has initiated enrollment in Part B of TYDAL-TIMI 78 in participants with sHTG.

sHTG substantially increases the risk of acute pancreatitis, a painful, often recurrent and potentially life-threatening condition. Because many people with sHTG also live with type 2 diabetes, obesity or cardiovascular disease, new treatments need to lower triglycerides enough to help prevent pancreatitis without worsening glycemic control or cardiovascular risk.

"MAR001 delivered on every objective in Part A, and we believe these data provide compelling clinical validation of ANGPTL4 inhibition," said Josh Lehrer, M.D., president and chief operating officer of Lisata Therapeutics and chief executive officer of Marea Therapeutics. "Triglyceride lowering was greatest in those with the highest baseline levels, with no glycemic signal versus placebo. People with sHTG need a therapy that can help prevent pancreatitis without worsening the diabetes and cardiovascular risk so many of them already carry, and we believe MAR001/MAR005 has the potential to be that therapy. We are now advancing into Part B in sHTG with strong momentum."

"The TYDAL-TIMI 78 Part A results provide important clinical evidence supporting ANGPTL4 inhibition as a promising new approach to treating hypertriglyceridemia," said Michelle L. O'Donoghue, M.D., MPH, McGillycuddy-Logue Endowed Chair in Cardiology at Brigham and Women's Hospital, Associate Professor of Medicine at Harvard Medical School and Senior Investigator, TIMI Study Group. "We observed significant reductions in triglycerides and remnant cholesterol across all three doses of MAR001, with even greater triglyceride lowering in participants with higher baseline levels. These findings are particularly encouraging given the need for additional treatment options for sHTG, where many remain at risk for serious complications including acute pancreatitis despite currently available therapies."

Key Results from Part A of the Phase 2b TYDAL-TIMI 78 Trial

Part A of the randomized, double-blind, placebo-controlled TYDAL-TIMI 78 trial dosed 235 adults with elevated triglycerides and remnant cholesterol. Participants were randomized to subcutaneous MAR001 300 mg, 450 mg or 900 mg, or placebo, every four weeks for 24 weeks.

Data highlights:

- **Primary endpoint met at every dose.** At Week 12, MAR001 achieved placebo-adjusted reductions in fasting triglycerides of 39.1%, 40.9% and 45.5% at 300 mg, 450 mg and 900 mg, respectively ($p<0.001$ for all doses). Reductions were sustained through Week 24.
- **Deeper lowering at higher baseline triglycerides, supporting development in sHTG.** Among participants with baseline triglycerides ≥300 mg/dL, placebo-adjusted reductions were 52.8%, 53.7% and 57.2% at 300 mg, 450 mg and 900 mg, respectively, at Week 12 ($p<0.001$ for all doses). Among participants with baseline triglycerides ≥500 mg/dL, reductions from baseline reached up to 72.2%.
- **More than half of participants at 900 mg reached normal triglyceride levels.** At Week 12, 31.0%, 35.1% and 51.7% of participants receiving MAR001 at 300 mg, 450 mg and 900 mg, respectively, reached fasting triglycerides below 150 mg/dL, compared with 3.4% on placebo ($p<0.001$ vs. placebo for all doses).

- **Significant reductions in remnant cholesterol.** MAR001 achieved placebo-adjusted reductions in fasting remnant cholesterol of 37.3% to 40.8% across the three doses at Week 12 ($p<0.001$ for all doses). Remnant cholesterol, carried in triglyceride-rich lipoprotein remnants, is increasingly recognized as a contributor to cardiovascular risk.
- **Favorable safety and tolerability, with no worsening of HbA1c.** Through 24 weeks, treatment-emergent adverse events occurred in 69.5% of MAR001-treated participants vs. 77.6% on placebo; serious adverse events in 2.8% vs. 6.9%; and injection-site reactions in 14.1% vs. 19.0%. There were no cases of pancreatitis and no deaths, and no worsening of HbA1c or other markers of glucose homeostasis was observed.

Marea has initiated enrollment in Part B of TYDAL-TIMI 78, which is designed to enroll approximately 100 participants with sHTG (fasting triglycerides of 450 to 2,000 mg/dL) randomized 1:1 to MAR001 or placebo, administered subcutaneously every four weeks. Marea is also developing MAR005, a half-life-extended version of MAR001 with an improved pharmacokinetic profile, as its planned Phase 3 candidate.

About MAR001/MAR005
MAR001 is a potential first-in-class monoclonal antibody in clinical development that targets ANGPTL4, a protein that is highly expressed in adipose tissue. By inhibiting ANGPTL4 and thereby augmenting lipoprotein lipase (LPL) activity, MAR001 is designed to lower triglycerides and improve adipose tissue function. Human genetic data have identified ANGPTL4 as a highly promising therapeutic target because loss-of-function alleles lead to lower triglyceride levels, improved adipose distribution, better insulin sensitivity, and protection from cardiovascular disease and type 2 diabetes.

MAR005, a half-life-extended version of MAR001 with an improved pharmacokinetic profile, is Marea's planned Phase 3 candidate and is in clinical development for the treatment of severe hypertriglyceridemia (sHTG), a condition characterized by very high triglyceride levels. Preclinical models with MAR001 demonstrated reduction in triglycerides, remnant cholesterol and ectopic fat, and improved insulin sensitivity. MAR001 has demonstrated strong Phase 1 and 2a results and is in Phase 2b clinical development.

About Marea Therapeutics
Marea Therapeutics is a clinical-stage biotechnology company harnessing the latest advances in human genetics to develop first-in-class, next-generation medicines for cardioendocrine diseases. The company’s lead product candidate, MAR001, is in Phase 2b clinical development for the treatment of severe hypertriglyceridemia (sHTG), a condition characterized by very high triglyceride levels. The company is also advancing MAR002 for the treatment of acromegaly.

About Lisata Therapeutics
Lisata Therapeutics is a clinical-stage pharmaceutical company. Following its acquisition of Marea, Lisata’s lead product candidate is MAR001, which is in Phase 2b clinical development for the treatment of severe hypertriglyceridemia (sHTG), a condition characterized by very high triglyceride levels. The company is also advancing MAR002 for the treatment of acromegaly.

Cautionary Note Regarding Forward-Looking Statements
Certain statements in this press release, other than purely historical information, may constitute “forward-looking statements” within the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995, concerning Lisata and Marea, including the acquisition of Marea by Lisata (the “Transaction”) and other matters. These forward-looking statements include, but are not limited to, express or implied statements relating to the company’s expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding expectations regarding or plans for the company’s pipeline, including its ongoing and planned clinical trials, research and development programs and the expected timing for key milestones; the design, results and presentation of data from the Phase 2b TYDAL-TIMI 78 study of MAR001; plans for the Phase 3 development of MAR005, including as a successor to MAR001; the potential for MAR001/MAR005 to be a first-in-class therapy; and the potential benefits of MAR001/MAR005 and MAR002. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “opportunity,” “potential,” “milestones,” “pipeline,” “can,” “goal,” “aim,” “strategy,” “target,” “seek,” “anticipate,” “achieve,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “predict,” “project,” “should,” “will,” “would” and similar expressions (including the negatives of these terms or variations of them) may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting the company or the Transaction will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond the company’s control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the risk that data presented at the American Heart Association Scientific Sessions 2026 or in subsequent analyses may differ from, or be interpreted differently than, previously reported or topline data; the risk that results of earlier clinical trials, including the TYDAL-TIMI 78 study, may not be predictive of results of later-stage clinical trials; the risk that MAR005 may not replicate, or reflect any improvements over, the pharmacokinetic, safety or efficacy profile of MAR001; the timing and outcome of interactions with, and approvals from, regulatory authorities; the company’s need for substantial additional capital to fund its operations and product development; and those uncertainties and factors described under the heading “Risk Factors” in Lisata’s Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission (the “SEC”) on March 12, 2026 or its subsequent Quarterly Reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors included in other filings by the company from time to time, together with risk factors associated with companies, such as Marea, that operate in the biotechnology industry. Should one or more of these risks or uncertainties materialize, or should any of the company’s assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Except as required by applicable law, the company does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements. This press release does not purport to summarize all of the conditions, risks and other attributes of an investment in the company.

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