Maze Therapeutics Doses First Patient in Phase 2 HORIZON Clinical Trial Evaluating MZE829 as a Potential Treatment for APOL1 Kidney Disease

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SOUTH SAN FRANCISCO, Calif., Feb. 07, 2025 (GLOBE NEWSWIRE) -- Maze Therapeutics, Inc. (Nasdaq: MAZE), a clinical-stage biopharmaceutical company harnessing the power of human genetics to develop novel, small molecule precision medicines for patients living with renal, cardiovascular, and metabolic diseases, today announced the first patient has been dosed in the company's Phase 2 clinical trial, the HORIZON Study, of MZE829 in patients with APOL1 kidney disease (AKD). MZE829 is an oral, small molecule APOL1 inhibitor that Maze is advancing as a potential treatment for people living with AKD, a subset of chronic kidney disease estimated to affect over one million patients in the United States alone.

"We are excited to announce the initiation of our HORIZON Study for MZE829, a Phase 2 clinical trial with a novel, potential new medicine that could disrupt current treatment for AKD," said Harold Bernstein, M.D., Ph.D., president, R&D, and chief medical officer of Maze. "We have designed HORIZON to include a broad spectrum of patients, reflecting the diverse characteristics of AKD, beyond the narrow criteria of existing studies. By evaluating MZE829 across a wider population and organized by cohorts, we aim to demonstrate proof of concept and refine patient selection for future pivotal trials. With its potential to be a truly disease-modifying therapy, MZE829 represents hope for the many patients living with AKD, addressing a critical unmet need in kidney disease treatment."

The HORIZON Study is a Phase 2, open-label basket design trial that will enroll AKD patients carrying the two high-risk APOL1 alleles (G1, G2), stratified by clinical phenotype and level of proteinuria, as well as patients who have type 2 diabetes. The trial will enroll patients with a wide array of characteristics of AKD, including patients with more severe disease who have nephrotic range proteinuria, such as those with focal segmental glomerulosclerosis (FSGS), patients with lower levels of proteinuria and hypertensive nephropathy, and patients with proteinuria and diabetic kidney disease. The HORIZON study is the first clinical trial with a small molecule APOL1 inhibitor to study diabetic AKD patients. Maze initiated a multicenter, clinical observational study in August 2024 to identify black and African American individuals who carry the *APOL1* G1 and G2 mutations, and to explore kidney disease biomarkers in patients with proteinuric kidney disease.

The primary endpoint of the HORIZON Study is reduction of proteinuria, or elevated protein in the urine, as measured by the percentage of subjects with a 30% or greater reduction from baseline in urinary albumin-to-creatinine ratio (uACR) at week 12, a reduction threshold that is expected to offer clinically meaningful benefit, according to external, published literature.[1] uACR is a sensitive measure of proteinuria across stages of glomerular kidney disease, particularly in hypertension and diabetes, and has been used to assess risk of cardiovascular disease. Maze expects to have a potential proof of concept interim data readout in the first quarter of 2026.

About Maze Therapeutics
Maze Therapeutics is a clinical-stage biopharmaceutical company harnessing the power of human genetics to develop novel, small molecule precision medicines for patients living with renal, cardiovascular and related metabolic diseases, including obesity. The company is advancing a pipeline using its Compass platform, which provides insights into the genetic variants in disease and links them with the biological pathways that drive disease in specific patient groups. The company's pipeline is led by two wholly owned lead programs, MZE829 and MZE782, each of which represents a novel precision medicine-based approach for patients. For more information, please visit mazetx.com, or follow us on LinkedIn and X (formerly Twitter).

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect the current beliefs and expectations of management. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including, without limitation, statements concerning the company's future plans and prospects, any expectations regarding the safety or efficacy of MZE829 and other candidates under development, the ability of MZE829 to treat APOL1 kidney disease or other indications, and the planned timing of the company's clinical trials, data results and further development of MZE829 and other therapeutic candidates. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to the company may identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Although the company believes the expectations reflected in such forward-looking statements are reasonable, the company can give no assurance that such expectations will prove to be correct. Readers are cautioned that actual results, levels of activity, safety, performance or events and circumstances could differ materially from those expressed or implied in the company's forward-looking statements due to a variety of factors, including risks and uncertainties related to the company's ability to advance

MZE829, MZE782 and its other therapeutic candidates, obtain regulatory approval of and ultimately commercialize the company's therapeutic candidates, the timing and results of preclinical studies and clinical trials, the company's ability to fund development activities and achieve development goals, its ability to protect its intellectual property, general business and economic conditions, and risks related to the impact on its business of macroeconomic conditions, including inflation, volatile interest rates, instability in the global banking sector, and public health crises. Further information on potential risk factors that could affect the company's business and its financial results are detailed under the heading "Risk factors" included in the company's prospectus dated January 30, 2025, filed with the U.S. Securities and Exchange Commission (SEC) on January 31, 2025, and the company's annual and quarterly reports and other filings filed from time to time with the SEC. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. These forward-looking statements speak only as of the date of this press release and Maze undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

Contacts:
Jillian Connell, Maze Therapeutics
jconnell@mazetx.com
(650) 850-5080

Media:
Dan Budwick, 1AB
dan@1abmedia.com

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[1] https://pubmed.ncbi.nlm.nih.gov/30635226/