



Applied Therapeutics to Present Results from Phase 3 ARISE-HF Study in Diabetic Cardiomyopathy at ACC 2024

April 4, 2024

NEW YORK, April 04, 2024 (GLOBE NEWSWIRE) -- Applied Therapeutics, Inc. (Nasdaq: APLT), a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates against validated molecular targets in indications of high unmet medical need, today announced that it will present full results from the Phase 3 ARISE-HF study evaluating AT-001 (caficrestat) in Diabetic Cardiomyopathy (DbCM) in an oral presentation at the 2024 American College of Cardiology (ACC) Annual Scientific Session to take place April 6-8, 2024 in Atlanta, Georgia.

The Company announced topline results from ARISE-HF in January 2024, demonstrating a strong trend in stabilizing cardiac functional capacity with AT-001 treatment, and a statistically significant difference in cardiac functional capacity in a prespecified subgroup of patients not receiving concomitant treatment with an SGLT2 or GLP-1 while preventing clinically significant worsening. The presentation at ACC will also include important data on progression to overt heart failure and other secondary outcome measures. AT-001 treatment prevented progression to overt heart failure in patients with DbCM as compared to placebo ($p=0.0285$). Detailed safety data will also be presented, demonstrating that AT-001 was safe and well tolerated in a large cohort of patients, providing proof of concept that the technology has overcome the selectivity and safety issues of "old" aldose reductase inhibitors. The oral presentation at ACC will be followed by simultaneous publication of the study results in the Journal of the American College of Cardiology Journal (JACC).

ACC Presentation:

A Selective Aldose Reductase Inhibitor (AT-001) For the Treatment of Diabetic Cardiomyopathy: Primary Results of the Phase 3 Randomized Controlled ARISE-HF Study

James L. Januzzi Jr, Javed Butler, Stefano Del Prato, Justin A. Ezekowitz, Nasrien E. Ibrahim, Carolyn S.P. Lam, Gregory D. Lewis, Thomas H. Marwick, Riccardo Perfetti, Julio Rosenstock, Scott D. Solomon, W.H. Wilson Tang, Faiez Zannad on behalf of the ARISE-HF Investigators

Monday, April 8, 2024, 8:30 – 9:45 am ET, Main Tent (Hall B1)

JACC Publication:

Randomized Trial of a Selective Aldose Reductase Inhibitor in Patients with Diabetic Cardiomyopathy

James L. Januzzi Jr, Javed Butler, Stefano Del Prato, Justin A. Ezekowitz, Nasrien E. Ibrahim, Carolyn S.P. Lam, Gregory D. Lewis, Thomas H. Marwick, Riccardo Perfetti, Julio Rosenstock, Scott D. Solomon, W.H. Wilson Tang, Faiez Zannad on behalf of the ARISE-HF Investigators

Journal of the American College of Cardiology

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About AT-001 (Caficrestat)

AT-001 (caficrestat) is an investigational oral, novel, potent Aldose Reductase inhibitor in Phase 3 clinical development for the treatment of Diabetic Cardiomyopathy. The global ARISE-HF Phase 3 study evaluated the ability of AT-001 to improve or prevent worsening of disease, as measured by changes in cardiac functional capacity, in 675 patients with DbCM at high risk of progression to overt heart failure. The study demonstrated a positive impact of AT-001 treatment, which was statistically significant in a prespecified subgroup of patients not on concomitant treatment with an SGLT2 or GLP-1 inhibitor. AT-001 has been previously studied in a Phase 1/2 study in approximately 120 patients with type 2 diabetes, a subset of which had DbCM.

About Applied Therapeutics

Applied Therapeutics is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates against validated molecular targets in indications of high unmet medical need. The Company's lead drug candidate, govorestat, is a novel central nervous system penetrant Aldose Reductase Inhibitor (ARI) for the treatment of CNS rare metabolic diseases, including Galactosemia, SORD Deficiency, and PMM2-CDG. The Company is also developing AT-001, a novel potent ARI, for the treatment of Diabetic Cardiomyopathy, or DbCM, a fatal fibrosis of the heart. The preclinical pipeline also includes AT-003, an ARI designed to cross through the back of the eye when dosed orally, for the treatment of Diabetic retinopathy.

To learn more, please visit www.appliedtherapeutics.com and follow the company on Twitter @Applied_Tx.

Forward-Looking Statements

This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, included in this press release regarding the strategy, future operations, prospects, plans and objectives of management, including words such as "may," "will," "expect," "anticipate," "plan," "intend," "predicts" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are forward-looking statements. Forward-looking statements in this release involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and we, therefore cannot assure you that our plans, intentions,

expectations or strategies will be attained or achieved.

Such risks and uncertainties include, without limitation, (i) our plans to develop, market and commercialize our product candidates, (ii) the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs, (iii) our ability to take advantage of expedited regulatory pathways for any of our product candidates, (iv) our estimates regarding expenses, future revenue, capital requirements and needs for additional financing, (v) our ability to successfully acquire or license additional product candidates on reasonable terms and advance product candidates into, and successfully complete, clinical studies, (vi) our ability to maintain and establish collaborations or obtain additional funding, (vii) our ability to obtain and timing of regulatory approval of our current and future product candidates, (viii) the anticipated indications for our product candidates, if approved, (ix) our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates, (x) our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources, (xi) the implementation of our business model and strategic plans for our business and product candidates, (xii) our intellectual property position and the duration of our patent rights, (xiii) developments or disputes concerning our intellectual property or other proprietary rights, (xiv) our expectations regarding government and third-party payor coverage and reimbursement, (xv) our ability to compete in the markets we serve, (xvi) the impact of government laws and regulations and liabilities thereunder, (xvii) developments relating to our competitors and our industry, (xviii) our ability to achieve the anticipated benefits from the agreements entered into in connection with our partnership with Advanz Pharma and (xix) other factors that may impact our financial results. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. Factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in our filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" contained therein. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

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