



## Applied Therapeutics to Present Baseline Data on the Phase 3 ARISE-HF Study in Diabetic Cardiomyopathy at the 2023 Annual Meeting of the American Diabetes Association

June 22, 2023

- *The ongoing ARISE-HF Phase 3 global clinical trial is evaluating the safety and efficacy of AT-001 (caficrestat) in improving or preventing worsening of cardiac functional capacity in Diabetic Cardiomyopathy (DbCM); topline data from the study is expected in the fourth quarter of this year*
- *Baseline data from ARISE-HF shows a strong statistical correlation between elevations in the cardiac stress biomarker, NT-proBNP, reduced cardiac functional capacity and physical activity, underscoring the importance of early diagnosis via NT-proBNP and impact of DbCM on physical function and quality of life*

NEW YORK, June 22, 2023 (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 multiple presentations on AT-001 (caficrestat) and the ARISE-HF Phase 3 study in Diabetic Cardiomyopathy at the 2023 Annual Meeting of the American Diabetes Association to take place June 23 - 26 in San Diego, California.

### **Oral Symposium: Early Diagnosis of Diabetes Cardiomyopathy (DbCM)—What Can Be Done?**

#### **Cross-Sectional Analysis of a Large Cohort of Patients with DbCM Enrolled in a Longitudinal Study – Baseline Results of the ARISE-HF Trial**

Justin Ezekowitz, MB, BCh, MSc, FACC, FESC, FAHA  
University of Alberta

Monday, June 26, 2023; 3:15pm – 3:30pm (Pacific), Room 24

#### **The Face of Diabetic Cardiomyopathy: Baseline Characteristics from the ARISE-HF Trial**

Javed Butler, Stefano Del Prato, Justin Ezekowitz, Nasrien E. Ibrahim, Carolyn S. Lam, Riccardo Perfetti, Julio Rosenstock, W.H. Wilson Tang, Alessia Urbinati, Faiez Zannad, James L. Januzzi, Jr.

Saturday, June 24, 2023, 11:30 AM – 12:30 PM (Pacific), Poster 1238

#### **N-Terminal Pro-B Type Natriuretic Peptide Concentrations in Diabetic Cardiomyopathy: Baseline Data from the ARISE-HF Trial**

Javed Butler, Stefano Del Prato, Justin Ezekowitz, Nasrien E. Ibrahim, Carolyn S. Lam, Riccardo Perfetti, Julio Rosenstock, W.H. Wilson Tang, Alessia Urbinati, Faiez Zannad, James L. Januzzi, Jr.

Monday, June 26, 2023, 11:30 AM – 12:30 PM (Pacific), Poster 450

### **About AT-001**

AT-001 (also called 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 study is currently ongoing, and is designed to evaluate the ability of AT-001 to improve or prevent worsening of disease, as measured by changes in cardiac functional capacity, in approximately 675 patients with DbCM at high risk of progression to overt heart failure. 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](http://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 strategy, future operations, prospects, plans and objectives of management, including words such as "may," "will," "expect," "anticipate," "plan," "intend," 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, including those about the timing of our topline data, 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, 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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