

# Applied Therapeutics to Present Baseline Data from Phase 3 ARISE-HF Study Evaluating AT-001 at the 2023 EASD Annual Meeting

September 28, 2023

- The ongoing ARISE-HF Phase 3 global clinical trial is evaluating the efficacy of AT-001 (caficrestat) on cardiac functional capacity in patients with diabetic cardiomyopathy (DbCM)
  - Baseline data from ARISE-HF shows patients with DbCM exhibit reduced cardiac functional capacity resulting in decreased physical activity

NEW YORK, Sept. 28, 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 it will participate in a Symposium presentation, entitled *Diabetic Cardiomyopathy (DbCM): a severe complication of diabetes*, at the 59th European Association for the Study of Diabetes (EASD) Annual Meeting to take place October 2-6, 2023 in Hamburg, Germany and online.

"Patients with diabetes are at a high risk of developing overt heart failure even when optimal glucose control is achieved," said Riccardo Perfetti, MD, PhD, Chief Medical Officer at Applied Therapeutics. "Diabetic Cardiomyopathy (DbCM) is a severe disease affecting approximately 20% of patients with diabetes. The Phase 3 ARISE-HF study is investigating the potential benefit of AT-001 in treating DbCM, and we look forward to the data readout later this year."

#### Symposium presentation agenda

#### Diabetic Cardiomyopathy (DbCM): A Severe Complication of Diabetes

Thursday, October 5

5:30PM - 5:35PM

#### Introduction

Stefano Del Prato, MD, Chief of the Section of Diabetes, University Hospital of Pisa, Italy

5:35PM - 5:55PM

## Diabetic Cardiomyopathy: Molecular Mechanism

Gary Lopaschuk, PhD, Professor, Department of Pediatrics, University of Alberta, Edmonton, Canada

Scientific Director, Mazankowski Alberta Heart Institute

5:55PM - 6:15PM

# Diagnosis of Diabetic Cardiomyopathy Based on Circulating Markers of Disease: Lessons from the Baseline Analysis of the ARISE-HF Study

Riccardo Perfetti, MD, PhD, Chief Medical Officer, Applied Therapeutics, New York City, USA

6:15PM - 6:30PM

#### **Questions and Answers**

### 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 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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