Applied Therapeutics Announces Presentation of Data on the Prevalence of Diabetic Cardiomyopathy at the 81st Scientific Sessions of the 2021 Annual Meeting of the American Diabetes Association

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~1 in 5 people with diabetes or pre-diabetes have Diabetic Cardiomyopathy, a serious and progressive disease that limits the heart's ability to function

People with diabetes or pre-diabetes who have Diabetic Cardiomyopathy are at high risk for developing overt heart failure

NEW YORK, June 25, 2021 (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 data presentations confirming the high prevalence of Diabetic Cardiomyopathy (DbCM) in adults with diabetes or pre-diabetes. The studies, which were performed by independent investigators under research grants sponsored by Applied Therapeutics, will be presented at the 81st Scientific Sessions of the annual 2021 American Diabetes Association meeting taking place virtually June 25-29.

Presentation Details

978-P: "***Prevalence, Optimal Screening Approaches, and Prognostic Implications of Diabetic Cardiomyopathy in Community-Dwelling Adults.***"

- Individuals with diabetes or pre-diabetes have abnormalities in several measures of cardiac structure, function and biomarkers
- Based on analyses of 3 studies comprising 16,653 participants without cardiovascular disease or heart failure at baseline, the prevalence of DbCM was 17% in people with diabetes or pre-diabetes and two or more cardiac abnormalities on echocardiogram (left atrial enlargement, left ventricular hypertrophy, diastolic dysfunction), representing a prevalence of ~1 in 5 people with diabetes

971-P: ***"Prevalence of Diabetic Cardiomyopathy in real-world practice: a longitudinal cohort study"***

- To determine the prevalence of DbCM, an analysis was completed among Type 2 Diabetic patients who had not yet progressed to overt Heart Failure and who had echocardiography at the University of California San Diego Medical Center in the period from 2010 to 2015
- As Left Atrial Enlargement (LAVI) represents a widely used and documented echocardiographic criteria, this was utilized in the UCSD database as the echocardiographic indicator of DbCM
- When looking at LAVI only (not including other echocardiographic indicators of DbCM), the prevalence of DbCM in this sub-population was 9%

1043-P: ***"Prevalence of Diabetic Cardiomyopathy: A systematic review of the literature"***

- A systematic literature review was conducted for studies that reported the epidemiology of DbCM
- With an estimated 61 million diagnosed diabetics across the United States, France, Germany, Italy, Spain, United Kingdom and Japan, this analysis estimates that ~ 1 in 5 patients with diabetes, or 12.9 million people in these countries meet echocardiographic criteria for DbCM, with 10.7M of this population also meeting the criteria for stage B heart failure, I.E., structural heart disease prior to development of overt heart failure

"These new data confirm the high prevalence of Diabetic Cardiomyopathy, which is a major health issue that will continue to grow as the population of people with diabetes increases," said Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics. "It is important for healthcare professionals to be aware of risk factors and to screen for Diabetic Cardiomyopathy, a serious and progressive disease that can lead to increased hospitalizations, morbidities and mortality."

"The high prevalence of Diabetic Cardiomyopathy underscores the urgent need for clinical intervention," said Shoshana Shendelman, PhD, Founder and Chief Executive Officer of Applied Therapeutics. "The ARISE-HF global registrational study evaluating AT-001 treatment in Diabetic Cardiomyopathy represents a major advancement for both patients and physicians. The study is currently enrolling at 82 sites worldwide. To learn more or to enroll or refer patients, please visit www.ARISEHF.com."

About AT-001

AT-001 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 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. 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, AT-007, 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, as well as novel dual PI3k inhibitors in preclinical development for orphan oncology indications.

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. These include, without limitation, statements regarding (i) the timing of our NDA submission for potential approval of AT-007, which will include data from the ACTION-Galactosemia Kids trial and the 90-day safety data in adults with Galactosemia, (ii) the timing of our rare disease franchise expansion programs in SORD Deficiency and PMM2-CDG, (iii) the timing of the initiation and completion of our clinical trials, (iv) the likelihood that data from our clinical trials will support future development of our product candidates and (v) the likelihood of obtaining regulatory approval of our product candidates. 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 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, (vi) our ability to maintain and establish collaborations or obtain additional funding, (vii) our ability to obtain regulatory approval of our current and future product candidates, (viii) our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates, (ix) our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources, (x) the implementation of our business model and strategic plans for our business and product candidates, (xi) our intellectual property position and the duration of our patent rights, (xii) developments or disputes concerning our intellectual property or other proprietary rights, (xiii) our expectations regarding government and third-party payor coverage and reimbursement, (xiv) our ability to compete in the markets we serve, (xv) the impact of government laws and regulations and liabilities thereunder, (xvi) developments relating to our competitors and our industry, (xvii) the impact of the COVID-19 pandemic on the timing and progress of our ongoing clinical trials and our business in general and (xviii) 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.

Investors:
Maghan Meyers
(212) 600-1902 or
appliedtherapeutics@argotpartners.com

Media:
media@appliedtherapeutics.com