# Applied Therapeutics Announces Presentation of Clinical Data Highlighting AT-001 for the Treatment of Diabetic Cardiomyopathy at the American Heart Association (AHA) Scientific Sessions 2019

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NEW YORK, Nov. 15, 2019 (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 the presentation of data at the American Heart Association (AHA) Scientific Sessions 2019 in Philadelphia (November 16-18, 2019) on AT-001, a novel, potent and selective aldose reductase inhibitor (ARI) in Phase 3 clinical development for Diabetic Cardiomyopathy (DbCM).

"We are pleased to present additional data at AHA supporting our clinical rationale for development of AT-001 in Diabetic Cardiomyopathy, a fast-moving form of heart failure for which no treatments exist," said Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics. "Reduction in NTproBNP – an important cardiac stress biomarker shown to correlate with long term heart failure outcomes – is a strong preliminary indicator of efficacy in this patient population. Our ongoing Phase 3 study, ARISE-HF, represents an important step forward for patients as the first pivotal study to date in DbCM."

**Clinical Assessment of AT-001, an Aldose Reductase Inhihibitor in Development for Diabetic Cardiomyopathy: a 28 day proof of concept study**
(poster presentation Monday, Nov 18, from 1:30-2:00pm)

- AT-001 selectivity and affinity for AR has resulted in potent AR inhibition within a favorable safe dosing range
- Observed reductions NT-proBNP, a validated cardiac stress biomarker, over 28 days of treatment with AT-001 support further investigation of the therapeutic potential of this novel agent in subjects with DbCM

**About Diabetic Cardiomyopathy**
Diabetic Cardiomyopathy (DbCM) is a rapidly progressing degenerative disorder of the heart in patients with both type 1 and type 2 diabetes. There are no approved therapies for this fatal condition, which affects 17 – 24 percent of people with diabetes, or approximately 77 million patients worldwide. Hyperglycemia, a symptom that characterizes diabetes, triggers the enzyme Aldose Reductase to convert excess glucose into sorbitol and fructose, both of which can lead to cell death in the heart muscle. When this happens, the heart fibroses, or "hardens," such that the organ is unable to circulate blood through the body effectively. Approximately 25 percent of patients with DbCM progress to overt heart failure or death within 1.5 years of diagnosis.

**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. 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-001, is a novel aldose reductase inhibitor (ARI) that is being developed for the treatment of Diabetic Cardiomyopathy, or DbCM, a fatal fibrosis of the heart. The company initiated a Phase 3 registrational study in DbCM in September 2019. Applied Therapeutics is also developing AT-007, a central nervous system penetrant ARI, for the treatment of Galactosemia, a rare pediatric metabolic disease, and initiated a Phase 1/2 clinical trial in June 2019. 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, expected to advance into a Phase 1 study in 2020.

**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 design, scope and results of our clinical trials, (ii) the timing of the initiation and completion of our clinical trials, (iii) the likelihood that data from our clinical trials will support future development of our product candidates, (iv) the likelihood of obtaining regulatory approval of our product candidates and qualifying for any special designations, such as orphan drug designation, (v) our cash runway and the timing of our clinical development plan. 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, the uncertainties inherent in the initiation, execution and completion of clinical trials, in the timing of availability of trial data, in the results of the clinical trials, in the actions of regulatory agencies, in the commercialization and acceptance of new therapies. 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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