# Applied Therapeutics Announces Presentation of Pre-Clinical Data Highlighting AT-001 for Treatment of Diabetic Cardiomyopathy at the World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC)

December 6, 2019

NEW YORK, Dec. 06, 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 World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC) in Los Angeles (December 4-7, 2019) on AT-001, a novel, potent and selective aldose reductase inhibitor (ARI) in Phase 3 clinical development for Diabetic Cardiomyopathy (DbCM).

“The Aldose Reductase enzyme has long been known to play a key role in several diabetic complications, including DbCM," said Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics. "Unfortunately, past attempts to inhibit Aldose Reductase failed due to lack of selectivity and off-target toxicity. AT-001 was designed based on new structural understanding of the AR enzymatic site, resulting in significantly increased potency and selectivity. The pre-clinical data we are presenting at WCIRDC shows the head to head comparison of AT-001 vs. a first-generation Aldose Reductase inhibitor and highlights the improvements over these prior ARIs.”

**Overcoming the Safety Challenges of Aldose Reductase Inhibition: Development of AT-001 for Diabetic Cardiomyopathy (#068)**
(poster presentation Thursday, Dec 5th, from 6:30-7:30pm; oral presentation Friday, Dec 6th, from 6:45-8:15pm)

- AT-001 is logarithmically more potent than zopolrestat in inhibiting Aldose Reductase
- The unique structure and activity of AT-001 provide selectivity for Aldose Reductase and avoid off-target inhibition of Aldehyde Reductase
- The in vitro safety of this agent together with the positive safety data from the phase 1/2 program, support the ongoing pivotal study in DbCM

The presentation will be available on the Applied Therapeutics website following the oral session.

**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 hallmark of 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.

**Contacts**

Investors:
Maeve Conneighton
(212) 600-1902 or
appliedtherapeutics@argotpartners.com

Media:
media@appliedtherapeutics.com

Source: Applied Therapeutics