



Applied Therapeutics to Present Data Highlighting AT-001 for the Treatment of Diabetic Cardiomyopathy at the Heart Failure Society of America (HFSA) 23rd Annual Scientific Meeting

September 13, 2019

NEW YORK, Sept. 13, 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 presentation of data at the Heart Failure Society of America (HFSA) 23rd Annual Scientific Meeting in Philadelphia (September 13-16, 2019) on AT-001, a novel, potent and selective aldose reductase inhibitor (ARI) in Phase 3 clinical development for Diabetic Cardiomyopathy (DbCM). The presentation, titled "Preclinical and Clinical Proof of Concept for Metabolic Intervention in Diabetic Cardiomyopathy," further supports the development rationale and clinical proof of concept for AT-001 in DbCM.

"We are pleased to share additional data from our Phase 1/2 study of AT-001 in diabetic patients with the heart failure community," said Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics. "DbCM is a debilitating disease with no treatments available. We recently initiated our registrational Phase 3 trial of AT-001 in DbCM (ARISE-HF), and we are excited about the potential to provide a new treatment option to patients with this fast-moving form of heart failure."

Preclinical and Clinical Proof of Concept for Metabolic Intervention in Diabetic Cardiomyopathy (poster presentation Friday, September 13, 6:15-7:15pm)

- AT-001 significantly reduced cardiac damage in a relevant mouse model of DbCM
- AT-001 potently inhibited AR within a favorable safe dosing range
- In humans, single and multiple ascending doses were well-tolerated with no safety concerns identified, and proof of biological activity was obtained in all patients dosed

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 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