



Applied Therapeutics to Present Data at ESC-HF Highlighting AT-001, a Novel, Potent and Selective Aldose Reductase Inhibitor for Treatment of Diabetic Cardiomyopathy

May 24, 2019

Robust clinical and preclinical data featured in prominent Late Breaking Science and Basic and Translational Hot Line sessions

NEW YORK, May 24, 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 that it will present data at the European Society for Cardiology 6th World Congress on Acute Heart Failure in Athens, Greece (May 25-May 28, 2019). Two data presentations will be displayed at the Clinical Forum – one as a “Late Breaking Clinical Trial” and the other as a part of the “Basic and Translational Hot Line.” Both presentations highlight AT-001, a novel, potent and selective aldose reductase inhibitor (ARI) in clinical development for Diabetic Cardiomyopathy (DbCM). Key data from a recently completed Phase 1/2 study in approximately 120 type 2 diabetic patients will be presented, describing AT-001 safety, pharmacokinetics and proof of biological activity. Supporting preclinical data from an animal model of DbCM will also be presented, demonstrating that AT-001 prevents or reduces cardiac damage in a relevant disease model.

“We are excited to be presenting this data in a peer reviewed setting for the first time and are thrilled by the recognition from the congress and the clinical community,” said Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics. “Diabetic Cardiomyopathy is a fatal and debilitating form of heart failure that occurs in diabetics. There are no therapies approved to treat DbCM, and it affects 77 million patients worldwide. Targeting indications of high unmet medical need, such as DbCM, where patients are in urgent need of new therapies, is critical to our mission at Applied. We look forward to initiating our pivotal Phase 2/3 clinical trial for AT-001 in DbCM later this year.”

Safety and Proof of Biological Activity Support Clinical Development of AT-001 for Diabetic Cardiomyopathy: a Phase 1/2 Study (Clinical Forum, Late-Breaking Clinical Trial, poster #12 – Sat May 258:30am - Tues May 2812:30pm)

- AT-001 was well tolerated at all doses tested
- Target engagement was confirmed by potent aldose reductase (AR) inhibition as evidenced by significant reductions in sorbitol, a pharmacodynamic biomarker of AR activity
- AT-001 improved selectivity and affinity for AR resulted in potent AR inhibition

Beneficial Effects of AT-001, an Aldose Reductase Inhibitor, in Rodent Models of Diabetic Cardiomyopathy (Clinical Forum, Basic and Translational Science Hot Line, poster #11 – Sat May 258:30am - Tues May 2812:30pm)

- AT-001 significantly reduced cardiac damage in a relevant mouse model of DbCM, confirming biological activity
- AT-001 normalized sorbitol levels, a biomarker of AR activity, demonstrating effective inhibition of AR
- Data evidences the role of AR inhibition in significantly reducing or preventing cardiac damage and supports clinical investigation of AT-001 in DbCM

About Diabetic Cardiomyopathy

Diabetic Cardiomyopathy (DbCM) is a rapidly progressing degenerative disorder of the heart muscle in people with 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 clinical development for the treatment of Diabetic Cardiomyopathy. AT-001 has been studied in an investigational 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 plans to initiate a Phase 2/3 pivotal study in DbCM in 2019. Applied Therapeutics is also developing AT-007, a central nervous system penetrant ARI, for the treatment of Galactosemia, a rare pediatric metabolic disease, which is expected to advance into a Phase 1 clinical trial in 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 the likelihood data will support future development and the expected timing of initiation of our clinical trials. 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. Other 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 section titled "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