



Applied Therapeutics to Present Data on AT-001 for the Treatment of Diabetic Cardiomyopathy at 2020 American Diabetes Association Virtual Scientific Sessions

June 8, 2020

NEW YORK, June 08, 2020 (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, announced today that three abstracts have been selected, including one oral presentation, at the upcoming American Diabetes Association's (ADA) 80th Scientific Sessions: A Virtual Experience taking place June 12-16, 2020. The abstracts and presentation include data on the safety and tolerability of Applied Therapeutics' investigational candidate for Diabetic Cardiomyopathy (DbCM), AT-001, a next generation aldose reductase inhibitor (ARI).

"This year at ADA we are pleased to present comprehensive data on our aldose reductase inhibitor program, including technological advancements that enabled us to overcome off-target safety and efficacy hurdles of the past, and mechanistic data on the role of aldose reductase toxicity during hyperglycemia," said Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics. "We will present the structural basis and rational drug design behind our next generation aldose reductase inhibitors, including side by side data on AT-001 vs. zopolrestat, the prior best in class 'old' ARI, demonstrating AT-001 improved potency, selectivity and safety in vitro and in vivo. Additionally, we'll present data elucidating the mechanisms by which aldose reductase causes cell damage responsible for diabetic complications, and our ability to prevent this damage through selective inhibition with AT-001. We are excited to share this data with the scientific community."

Abstracts and presentations will be available as of June 9, 2020 at <https://professional.diabetes.org/> through the ADA Events app and Online Planner.

Presentation Details

Abstract 1080-P: Addressing the Safety Challenges of Aldose Reductase Inhibition: Development of AT-001 for Diabetic Cardiomyopathy, a Potent and Selective Next Generation Aldose Reductase Inhibitor

Presenter: Riccardo Perfetti, M.D., Ph.D.

(Poster Presentation, Saturday, June 13, 10:00-11:00 a.m. CT)

Abstract 462-P: AT-001, a Next Generation Aldose Reductase Inhibitor with Improved Selectivity and Specificity, Protects from Cellular Damage Associated with Hyperglycemia

Presenter: Riccardo Perfetti, M.D., Ph.D.

(Poster Presentation, Saturday, June 13, 10:00-11:00 a.m. CT)

Abstract 186-OR: Safety and Tolerability of the Next Generation Aldose Reductase Inhibitor (ARI) AT-001 Supports Initiation of the Pivotal Trial in Diabetic Cardiomyopathy (DbCM)

Presenter: Riccardo Perfetti, M.D., Ph.D.

(Oral Presentation, Sunday, June 14, 9:45-10:00 a.m. CT)

About Applied Therapeutics, Inc.

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 Galactosemia, a rare pediatric metabolic disease. The Company initiated a pivotal Phase 1/2 clinical trial in June 2019, read out positive top-line biomarker data in adult Galactosemia patients in January 2020 and announced full data from the trial in April 2020. The Company is also developing AT-001, a novel potent 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. 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.

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.

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.

Investors:

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

Media:

Gleb Sagitov
media@appliedtherapeutics.com



Source: Applied Therapeutics