Applied Therapeutics to Present Data Highlighting AT-007 for the Treatment of Galactosemia at the American Society of Human Genetics (ASHG) 2019 Annual Meeting

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NEW YORK, Oct. 16, 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 Company will give an oral presentation of data at the American Society of Human Genetics (ASHG) 2019 Annual Meeting in Houston (October 15-19) on AT-007, a central nervous system (CNS) penetrant Aldose Reductase inhibitor (ARI) in Phase 1/2 development for treatment of Galactosemia. In addition, the Company will host an ASHG Educational Symposium featuring a panel of Galactosemia experts.

Details on the Oral Presentation and Educational Symposium are below:

Oral Presentation

Title: AT-007, a Novel CNS Penetrant Aldose Reductase Inhibitor Prevents the Metabolic and Tissue Specific Abnormalities of Galactosemia, in a GALT Deficient Rat Model of Disease
Date and Time: Saturday, October 19, 2019, 8:30-8:45am CT
Presenter: Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics
Session: 99
Location: Room 370A – Level 3/Convention Center

The presentation will be available on the ASHG conference website as well as the Applied Therapeutics website following the session.

Galactosemia Educational Symposium

Title: Development of an Oral Treatment for Galactosemia
Date and Time: Thursday, October 17, 2019, 12:45-2:00pm CT
Location: Marriott Marquis Houston, Room Briargrove AB, Level 3
Key Topics:

- Clinical presentation of Classic Galactosemia
  Jerry Vockley, MD, PhD, UMPC Children's Hospital, Pittsburgh University
- Biology and biochemistry of Classic Galactosemia
  Gerard Berry, MD, Boston Children's Hospital and Harvard Medical School
- Preclinical evidence and clinical development for a novel oral compound to prevent complications of Classic Galactosemia
  Riccardo Perfetti, MD, PhD, Chief Medical Officer of Applied Therapeutics

Additional details for the event can be found here.

About Galactosemia
Galactosemia is a rare metabolic disease that affects how the body processes a simple sugar called galactose, and for which there is no known cure or approved treatment available. Galactose is found in foods, but the human body also naturally produces galactose on its own, so dietary restriction can't prevent complications of disease. It is estimated that the U.S. Galactosemia population is approximately 2,800 patients, based on newborn screening data identifying 2,500 infants through 2014, and the estimated birth rate of 80 patients per year. High levels of galactose circulating in the blood and tissues of Galactosemia patients enables Aldose Reductase to convert galactose to a toxic metabolite, called galactitol, which causes long-term complications ranging from CNS dysfunction to cataracts.

About AT-007
AT-007 is a central nervous system (CNS) penetrant Aldose Reductase inhibitor (ARI) in Phase 1/2 development for treatment of Galactosemia. AT-007 has been studied in in an animal model of Galactosemia, which demonstrated that AT-007 reduces toxic galactitol levels and prevents disease complications. Applied Therapeutics is conducting a biomarker based development program in patients with Galactosemia, based on the recently released draft industry guidance on drug development for low prevalence, slowly progressing rare metabolic diseases. The company received Orphan Designation for AT-007 for Galactosemia in May 2019.

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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