Applied Therapeutics to Present Data on AT-007 for Treatment of Galactosemia at the Galactosemia Foundation 2020 Virtual Conference

July 17, 2020

NEW YORK, July 17, 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 presentations covering the AT-007 Galactosemia development program at the Galactosemia Foundation 2020 Virtual Conference, July 17-19. The Galactosemia Foundation Conference is a unique platform that brings together patients and families with Galactosemia alongside researchers and physicians.

“We are excited to share our development progress with the Galactosemia community,” said Shoshana Shendelman, PhD, Founder and CEO of Applied Therapeutics. “Our long-term partnership with the Galactosemia Foundation, families and physicians is essential to bringing treatment to patients.”

Oral Presentation Details

Title: AT-007: Development of an Oral Treatment for Patients with Galactosemia
Presenter: Shoshana Shendelman, PhD, Chief Executive Officer of Applied Therapeutics
Time: Saturday, July 18 10:00 – 11:00 a.m. ET

Title: ACTION-Galactosemia: Clinical Experience with Adult Galactosemia Patients and Path Forward
Presenter: Riccardo Perfetti, M.D., Ph.D., Chief Medical Officer of Applied Therapeutics
Time: Saturday, July 18 4:15 – 5:00 p.m. ET

Title: ACTION-Galactosemia Kids: Pediatric Study of AT-007 in Children with Galactosemia
Presenter: Shoshana Shendelman, PhD, Chief Executive Officer of Applied Therapeutics
Time: Saturday, July 18 5:30 – 6:15 p.m. ET

Slides will be available on the presentations and publications section of the Applied Therapeutics website following the conference.

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. A pediatric Galactosemia study commenced in June 2020 and is currently ongoing. 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-007

AT-007 is a central nervous system (CNS) penetrant Aldose Reductase inhibitor (ARI) in clinical development for treatment of Galactosemia. AT-007 has been studied 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 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 and Pediatric Rare Disease Voucher (PRV) designation 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) our plan to move quickly towards regulatory filing following our pivotal Phase 2 ACTION-Galactosemia study, while preparing for Galactosemia commercial launch and growing our organization, (ii) the design, scope and results of our clinical trials, (iii) the timing of the initiation and completion of our clinical trials, (iv) the likelihood that data from our clinical trials will support future development of our product candidates, and (v) the likelihood of obtaining regulatory approval of our product candidates and qualifying for any special designations, such as orphan drug designation. 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, (i) our plans to develop and commercialize our product candidates, (ii) the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs, (iii) our ability to take advantage of expedited regulatory pathways for any of our product

candidates, (iv) our estimates regarding expenses, future revenue, capital requirements and needs for additional financing, (v) our ability to successfully acquire or license additional product candidates on reasonable terms, (vi) our ability to maintain and establish collaborations or obtain additional funding, (vii) our ability to obtain regulatory approval of our current and future product candidates, (viii) our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates, (ix) our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources, (x) the implementation of our business model and strategic plans for our business and product candidates, (xi) our intellectual property position and the duration of our patent rights, (xii) developments or disputes concerning our intellectual property or other proprietary rights, (xiii) our expectations regarding government and third-party payor coverage and reimbursement, (xiv) our ability to compete in the markets we serve, (xv) the impact of government laws and regulations and liabilities thereunder, (xvi) developments relating to our competitors and our industry, (xvii) the impact of the COVID-19 pandemic on the timing and progress of our ongoing clinical trials and our business in general and (xviii) other factors that may impact our financial results. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. 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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