Applied Therapeutics Reports First Quarter 2019 Financial Results

June 21, 2019

-Strengthened Financial Position with Recent Initial Public Offering-

- Phase 1/2 Trial AT-007 in Adults with Galactosemia Expected to Start This Month -

- Pivotal Phase 2/3 Trial for AT-001 in Diabetic Cardiomyopathy Expected to Start Later This Year -

NEW YORK, June 21, 2019 (GLOBE NEWSWIRE) -- Applied Therapeutics, Inc. (Nasdaq: APLT), a clinical-stage biopharmaceutical company developing novel drug candidates in indications of high unmet medical need, today reported financial results for the first quarter ended March 31, 2019.

"Since the launch of Applied Therapeutics just three years ago, we have built a robust pipeline of novel drug candidates with the potential to deliver a meaningful impact in multiple disease areas of high unmet medical need," said Shoshana Shendelman, PhD, President and Chief Executive Officer of Applied Therapeutics. "With the recent completion of our initial public offering, we have strengthened our cash position, extending our runway and providing additional resources to accelerate our clinical development plan. This includes our lead asset, AT-001, which is on track to enter a pivotal Phase 2/3 clinical trial in diabetic cardiomyopathy (DbCM) later this year and advance AT-007 into Phase 1/2 study into adults with Galactosemia this month."

Recent Highlights

- **Received FDA Orphan Drug Designation for AT-007 in Galactosemia.** In May 2019, we received orphan drug designation for AT-007 in Galactosemia. The designation allows Applied Therapeutics to qualify for a number of incentives, including: seven years of market exclusivity upon regulatory approval, if received; exemption from FDA application fees for Galactosemia; and tax credits for qualified clinical trials.

- **Presented Phase 1/2 Data Highlighting Safety and Efficacy for AT-001 in DbCM at the American Diabetes Association (ADA) 79th Annual Scientific Sessions in San Francisco.** In June 2019, we presented Phase 1/2 Data Highlighting Safety and Efficacy for AT-001 in DbCM at the ADA Annual Scientific Sessions. The data, presented as part of the Late Breaking session, demonstrated that AT-001 was well tolerated at all dose levels, and 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 also improved selectivity and affinity for AR and resulted in potent AR inhibition.

- **Presented Phase 1/2 Data Highlighting Safety and Proof of Biological Activity for AT-001 in DbCM at The European Society for Cardiology (ESC) 6th World Congress in Athens, Greece.** In May 2019, we presented two posters at ESC, the first of which was presented in the Late Breaking session and highlighted key data from a recently completed Phase 1/2 study in approximately 120 type 2 diabetic patients demonstrating the safety and proof of biological activity for AT-001 in DbCM. Supporting preclinical data from an animal model of DbCM was also presented, demonstrating that AT-001 prevents or reduces cardiac damage in a relevant disease model.

- **Completed Initial Public Offering.** In May 2019, we completed our IPO, generating approximately $34.0 million in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

- **Announced Appointment of Mark Vignola, PhD, as Chief Financial Officer.** In April 2019, we announced the appointment of Mark Vignola, PhD, as Chief Financial Officer. Dr. Vignola served most recently as Head of Corporate Development & Investor Relations at Intercept Pharmaceuticals.

Financial Results

- **Cash and cash equivalents** totaled $14.7 million as of March 31, 2019, compared with $18.7 million at December 31, 2018. Subsequent to the close of the quarter, we completed an initial public offering resulting in net proceeds of approximately $34.0 million.

- **Research and development expenses** for the three months ended March 31, 2019 were $6.9 million, compared to $1.5 million for the three months ended March 31, 2018. The increase of approximately $5.4 million was primarily related to the progressing of our clinical trials through development, including an increase in clinical and pre-clinical expenses of $4.1 million and drug manufacturing and formulation expenses of $0.7 million, and personnel expenses of $0.7 million due to

the hiring of research and development personnel, including the Chief Medical Officer in August 2018.

- **General and administrative expenses** were $1.9 million for the three months ended March 31, 2019, compared to $0.4 million for the three months ended March 31, 2018. The increase of approximately $1.4 million was primarily related to professional fees of $0.7 million due to increased legal and consulting fees, personnel expenses of $0.4 million due to the hiring of other personnel, including the interim Chief Financial Officer and the Controller, and other expenses of $0.3 million, primarily due to public relations efforts, travel expenses and rent.

- **Net loss** for the first quarter of 2019 was $8.7 million, or $1.58 per basic and diluted common share, compared to a net loss of $2.3 million, or $.43 per basic and diluted common share, for the first quarter of 2018.

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 product 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 Phase 1 in 2020. For more information, visit www.appliedtherapeutics.com.

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 (i) our cash runway and acceleration of our clinical development plan, (ii) the likelihood data will support future development of our product candidates, (iii) qualification for exemptions resulting from the receipt of orphan drug designation and (iii) the expected timing of the 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. 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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Applied Therapeutics, Inc.
Condensed Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
OPERATING EXPENSES:		
Research and development	$ 6,874	$ 1,448
General and administrative	1,855	$ 420
Total operating expenses	8,729	$ 1,868
LOSS FROM OPERATIONS	(8,729)	$ (1,868)
OTHER INCOME (EXPENSE), NET:		
Interest income (expense), net	(1)	$ (281)
Other expense	-	$ (186)
Total other income (expense), net	(1)	$ (467)

Net loss	$ (8,730)	$ (2,335)
Net loss attributable to common stockholders—basic and diluted	$ (8,730)	$ (2,335)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.58)	$ (0.43)
Weighted-average common stock outstanding—basic and diluted	5,513,531	5,458,450

Applied Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)

	As of March 31, 2019 (Unaudited)	As of December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,686	$ 18,748
Prepaid expenses and other current assets	2,186	1,498
Total current assets	16,872	20,246
TOTAL ASSETS	$ 16,872	$ 20,246
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable	2,649	3,015
Accrued expenses and other current liabilities	3,679	1,413
Total current liabilities	6,328	4,428
Total liabilities	6,328	4,428
Series A convertible preferred stock, $0.0001 par value; 3,093,898 shares authorized at March 31, 2019 and December 31, 2018; 3,093,898 shares issued and outstanding at March 31, 2019 and December 31, 2018; liquidation preference of $7,000 at March 31, 2019 and December 31, 2018;	6,254	6,254
Series B convertible preferred stock, $0.0001 par value; 7,790,052 shares authorized as of March 31, 2019 and December 31, 2018; 4,444,773 and 4,001,848 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively; liquidation preference of $33,281 and $29,964 as of March 31, 2019 and December 31, 2018, respectively;	32,207	29,156
STOCKHOLDERS' DEFICIT:		
Common stock, $0.0001 par value; 20,441,982 shares authorized as of March 31, 2019 and December 31, 2018; 5,513,531 shares issued and outstanding as of March 31, 2019 and December 31, 2018	-	-
Additional paid-in capital	2,070	1,665

Accumulated deficit	(29,987)	(21,257)
Total stockholders' deficit	(27,917)	(19,592)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT	$ 16,872	$ 20,246

Source: Applied Therapeutics