Cytokinetics, Inc. Reports Second Quarter 2018 Financial Results

July 26, 2018 8:00 PM EDT

Phase 2 Study of Reldesemtiv in Patients with SMA
Showed Potentially Clinically Meaningful Effects
on Six Minute Walk Distance and Maximal Expiratory Pressure

Results from Phase 2 Clinical Trial of Reldesemtiv in Patients with COPD Expected in Q3

Finalizing Preparations to Initiate Second Phase 3 Clinical Trial of Omecamtiv Mecarbil

SOUTH SAN FRANCISCO, Calif., July 26, 2018 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) reported financial results for the second quarter of 2018. Net loss for the second quarter was $27.5 million, or $0.51 per share, compared to a net loss for the second quarter of 2017 of $29.1 million, or $0.60 per share. Cash, cash equivalents and investments totaled $232.0 million at June 30, 2018.

"We made substantial progress in the second quarter of 2018 advancing programs in both our cardiac and skeletal muscle verticals," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Following the recent presentation of positive data from our Phase 2 study of *reldesemtiv* in patients with SMA, we are now working with our partner, Astellas, as well as advocacy partners and clinical advisors, to consider a potential path forward in this indication, and potentially others, as we expect additional results this year. In the past quarter, we also received feedback from FDA regarding the planned second Phase 3 clinical trial of *omecamtiv mecarbil* in patients with heart failure, under our collaboration with Amgen; we are working toward the objective of initiating this trial before the end of the year. Finally, we continued the preclinical development of several new compounds, independently and within our collaborations, and we expect to move one or more potential drug candidates into Phase 1 clinical studies later this year."

Recent Highlights and Upcoming Milestones

Cardiac Muscle Program

omecamtiv mecarbil (cardiac myosin activator)

- Continued patient enrollment in GALACTIC-HF (**G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac Outcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure), the Phase 3 cardiovascular outcomes clinical trial of *omecamtiv mecarbil.* Enrollment has surpassed 50 percent completion with over 4,000 patients randomized to date having a risk profile consistent with the trial design. We expect completion of patient enrollment into GALACTIC-HF to occur during the first half of 2019.

- Conducted further interactions with FDA and finalized the protocol for a second Phase 3 clinical trial of *omecamtiv mecarbil*. This trial is intended to evaluate the potential effect of *omecamtiv mecarbil* on exercise performance in patients with heart failure and will be conducted by Cytokinetics in collaboration with Amgen. We continue to work toward the objective of beginning this clinical trial by the end of the year.

Skeletal Muscle Program

reldesemtiv (next-generation FSTA)

- Announced that data from the Phase 2 clinical study of *reldesemtiv* in patients with spinal muscular atrophy (SMA) were presented by John W. Day, M.D., Ph.D., Professor of Neurology and Pediatrics (Genetics), Stanford University, at the 2018 Annual Cure SMA Conference in Dallas. The study showed dose- and concentration-dependent increases in time to muscle fatigue as measured by changes from baseline in Six Minute Walk Distance, a sub-maximal exercise test of aerobic capacity and endurance, and Maximal Expiratory Pressure, a measure of strength of respiratory muscles, after eight weeks of treatment with *reldesemtiv*.

- Continued site activation and patient enrollment in FORTITUDE-ALS (**F**unctional **O**utcomes in a **R**andomized **T**rial of **I**nvestigational **T**reatment with CK-2127107 to **U**nderstand **D**ecline in **E**ndpoints – in **ALS**), the Phase 2 clinical trial of *reldesemtiv* which is designed to assess the

change from baseline in percent predicted slow vital capacity and other measures of skeletal muscle function after 12 weeks of treatment with *reldesemtiv* in patients with ALS. This trial has enrolled over 250 patients toward the objective of 445 patients in the trial and is being conducted by Cytokinetics in collaboration with Astellas. We expect to complete enrollment in FORTITUDE-ALS in Q4 2018 with results from this clinical trial now expected in the first half of 2019.

- Completed patient enrollment in the Phase 2 clinical trial of *reldesemtiv* in patients with chronic obstructive pulmonary disease (COPD) which is designed to assess its effect on physical function. This trial is being conducted by Astellas in collaboration with Cytokinetics. We expect results from this clinical trial in Q3 2018.

- Continued patient enrollment in the Phase 1b clinical trial of *reldesemtiv* in elderly subjects with limited mobility which is designed to assess its effect on measures of physical function. This trial is being conducted by Astellas in collaboration with Cytokinetics. We expect Astellas will conduct an interim analysis of data from this clinical trial in Q3 2018.

Pre-Clinical Research and Development

- Continued research in collaboration with Astellas directed to the discovery of next-generation skeletal muscle activators; jointly advanced a potential drug candidate into IND-enabling studies.

- Continued pre-clinical development of a next-generation cardiac muscle activator in collaboration with Amgen; we expect to submit an IND in 2018 and plan to initiate Phase 1 studies for this potential drug candidate by year-end or in early 2019.

- Continued IND-enabling studies with an unpartnered cardiac sarcomere directed compound and engaged FDA in preparation for potential advancement to Phase 1 studies expected in Q4 2018.

- Continued independent research activities directed to our other muscle biology research programs.

Corporate

- Announced the continuation of our partnership with The ALS Association in the fight against ALS with renewal of Gold Level Sponsorship of the National Walks to Defeat ALS® and Premier Level National ALS Advocacy Conference Sponsorship as well as Platinum Level Sponsorship for initiatives led by The ALS Association Golden West Chapter, including grant funding for care services for people living with ALS in the San Francisco Bay Area.

- Announced an expanded partnership with Cure SMA to increase education, awareness and fundraising for SMA. As a National Platinum Partner for 2018, Cytokinetics will lend support to several of Cure SMA's initiatives at both the local and national level to advance understanding of, and research toward potential treatments for SMA.

Financials

Revenues for the three and six months ended June 30, 2018 were $6.2 million and $11.5 million, respectively, compared to $3.1 million and $7.2 million for the corresponding periods in 2017. Revenues for the first six months of 2018 stemmed from our strategic alliance with Astellas.

Research and development expenses for the three months ended June 30, 2018 increased to $21.6 million and $43.7 million, respectively from $19.8 million and $39.1 million for the same periods in 2017, respectively, primarily due to increases in clinical trial expenses for *reldesemtiv* and preclinical

expenses for our cardiac sarcomere directed program, offset in part by lower clinical trial and other development expenses for *tirasemtiv*.

General and administrative expenses for the three months ended June 30, 2018 decreased to $8.0 million from $8.4 million in 2017 primarily because of reduced precommercial and general outside services and increased to $17.3 million for the six months ended June 30, 2018 from $16.6 million for the same period in 2017, primarily due to increased general facilities-related costs.

Financial Guidance

The Company also updated financial guidance for 2018. The Company has reduced spending and revenue guidance by $5 million because of a delay in enrollment of FORTITUDE-ALS, with a corresponding reduction in cash revenues as the cost of that trial is being reimbursed by Astellas. The Company does not anticipate any change in net cash utilization. The Company estimates cash revenue will be in the range of $12 to $18 million, operating expenses will be in the range of $100 to $110 million, and net cash utilization will be approximately $100 million.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's second quarter results via a webcast and conference call today at 4:30 PM Eastern Time. The webcast can be accessed through the Investors & Media section of the Cytokinetics website at www.cytokinetics.com. The live audio of the conference call can also be accessed by telephone by dialing either (866) 999-CYTK (2985) (United States and Canada) or (706) 679-3078 (international) and typing in the passcode 9599438.

An archived replay of the webcast will be available via Cytokinetics' website until August 2, 2018. The replay will also be available via telephone by dialing (855) 859-2056 (United States and Canada) or (404) 537-3406 (international) and typing in the passcode 9599438 from July 26, 2018 at 7:30 PM Eastern Time until August 2, 2018.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators as potential treatments for debilitating diseases in which muscle performance is compromised and/or declining. As a leader in muscle biology and the mechanics of muscle performance, the company is developing small molecule drug candidates specifically engineered to increase muscle function and contractility. Cytokinetics is collaborating with Amgen Inc. ("Amgen") to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omecamtiv mecarbil* is the subject of GALACTIC-HF, an international Phase 3 clinical trial in patients with heart failure. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Cytokinetics is collaborating with Astellas Pharma Inc. ("Astellas") to develop *reldesemtiv* (CK-2127107), a next-generation FSTA. *Reldesemtiv* has been granted orphan drug designation by the FDA for the potential treatment of spinal muscular atrophy (SMA). *Reldesemtiv* was the subject of a positive Phase 2 clinical study in patients with SMA which showed increases in measures of endurance and stamina consistent with the mechanism of action. *Reldesemtiv* is currently the subject of two ongoing Phase 2 clinical trials in patients with chronic obstructive pulmonary disease and amyotrophic lateral sclerosis. Astellas is also conducting a Phase 1b clinical trial of *reldesemtiv* in elderly adults with limited mobility. Astellas holds an exclusive worldwide license to develop and commercialize *reldesemtiv*. Licenses held by Amgen and Astellas are subject to Cytokinetics' specified co-development and co-commercialization rights. Cytokinetics continues its 20-year history of innovation with three new muscle biology directed compounds advancing from research to development in 2018. For additional information about Cytokinetics, visit www.cytokinetics.com.

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Cytokinetics claims the protection of the Act's Safe Harbor for forward-looking statements. Examples of such statements include, but are not limited to, statements relating to Cytokinetics' and its partners' research and development activities, including the initiation, conduct, design, enrollment, progress, continuation, completion, timing and results of clinical trials; the significance and utility of pre-clinical study and clinical trial results; and the properties and potential benefits of Cytokinetics' drug candidates. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including, but not limited to, potential difficulties or delays in the development, testing, regulatory approvals for trial commencement, progression or product sale or manufacturing, or production of Cytokinetics' drug candidates that could slow or prevent clinical development or product approval; patient enrollment for or conduct of clinical trials may be difficult or delayed; the FDA or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials; Amgen's and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil* and *reldesemtiv*, respectively; Cytokinetics may incur unanticipated research and development and other costs; standards of care may change, rendering Cytokinetics' drug candidates obsolete; and competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and Cytokinetics' actual results of operations, financial condition and liquidity, and the development of the industry in which it operates, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that Cytokinetics makes in this press release speak only as of the date of this press release. Cytokinetics assumes no obligation to update its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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Cytokinetics, Incorporated
Condensed Consolidated Statements of Operations
(in thousands, except per share data, unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2018	June 30, 2017	June 30, 2018	June 30, 2017
Revenues:				

Research and development, milestone, grant and other revenues, net	$ 4,680	$ (1,889)	$ 8,265	$ 818
License revenues	1,535	4,942	3,218	6,388
Total revenues	6,215	3,053	11,483	7,206
Operating expenses:				
Research and development	21,582	19,809	43,717	39,098
General and administrative	8,046	8,438	17,310	16,553
Total operating expenses	29,628	28,247	61,027	55,651
Operating loss	(23,413)	(25,194)	(49,544)	(48,445)
Interest expense	(898)	(782)	(1,761)	(1,540)
Non-cash interest expense on liability related to sale of future royalties	(4,338)	(3,717)	(8,467)	(6,012)
Interest and other income, net	1,126	612	1,968	1,049
Net loss	$ (27,523)	$ (29,081)	$ (57,804)	$ (54,948)
Net loss per share - basic and diluted	$ (0.51)	$ (0.60)	$ (1.07)	$ (1.22)
Weighted-average shares in net loss per share — basic and diluted	54,293	48,218	54,178	44,910
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net - UPDATE	107	(78)	107	(223)
Comprehensive loss	$ (27,416)	$ (29,159)	$ (57,697)	$ (55,171)

Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2018	December 31, 2017[(1)]
	(unaudited)	
ASSETS		
Current assets:		
Cash and short term investments	$ 231,941	$ 268,891
Other current assets	12,288	5,404
Total current assets	244,229	274,295
Long-term investments	—	16,518
Property and equipment, net	2,598	3,568
Other assets	412	429
Total assets	$ 247,239	$ 294,810
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 17,426	$ 22,645
Deferred revenue, current	—	9,572
Current portion of long-term debt	1,703	—
Other current liabilities	8,159	227
Total current liabilities	27,288	32,444
Long-term debt, net	30,662	31,777
Liability related to the sale of future royalties, net	113,144	104,650
Deferred revenue, non-current	—	15,000
Other long-term liabilities	974	1,097
Total liabilities	172,068	184,968
Stockholders' equity:		
Common stock	55	54
Additional paid-in capital	762,887	755,526
Accumulated other comprehensive income	450	343
Accumulated deficit	(688,222)	(646,081)
Total stockholders' equity	75,170	109,842

Total liabilities and stockholders' equity	$ 247,238	$ 294,810

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Source: Cytokinetics, Incorporated