Cytokinetics, Inc. Reports Second Quarter 2017 Financial Results

August 2, 2017 8:00 PM EDT

Results Expected from VITALITY-ALS, Our Phase 3 Clinical Trial of Tirasemtiv, in Q4 2017

CK-2127107 Advancing in Four Clinical Trials Under Our Collaboration with Astellas

Omecamtiv Mecarbil Phase 3 Clinical Trial Proceeding on Plan in GALACTIC-HF Under Our Collaboration with Amgen

SOUTH SAN FRANCISCO, Calif., Aug. 02, 2017 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) reported total revenues for the second quarter of 2017 were $3.1 million, compared to $5.8 million, during the same period in 2016. Net loss for the second quarter was $29.1 million, or $0.60 per share, respectively, compared to a net loss for the same period in 2016 of $11.6 million, or $0.29 per share. As of June 30, 2017, cash, cash equivalents and investments totaled $332.1 million.

"We made key progress during the second quarter in anticipation of results from VITALITY-ALS expected later this year and recently initiated two additional clinical trials of CK-2127107 – one in ALS and one in elderly people with frailty under our collaboration with Astellas – underscoring the broad potential of fast skeletal muscle troponin activation across multiple diseases and conditions of impaired muscle function and weakness," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "With similar progress made for *omecamtiv mecarbil* under our collaboration with Amgen, we believe that Cytokinetics is executing well across the breadth of our business, advancing late-stage development of several first-in-class programs while also readying for the potential registration and commercialization of *tirasemtiv* in North America and Europe."

Recent Highlights and Upcoming Milestones

Skeletal Muscle Program

tirasemtiv (fast skeletal muscle troponin activator)

- Continued conduct of VITALITY-ALS (**V**entilatory **I**nvestigation of ***T****irasemtiv* and **A**ssessment of **L**ongitudinal **I**ndices after **T**reatment for a **Y**ear in **ALS**) and enrollment in VIGOR-ALS (**V**entilatory **I**nvestigations in **G**lobal **O**pen-Label **R**esearch in **ALS**), an open-label extension clinical trial designed to assess the long-term safety and tolerability of *tirasemtiv* in patients with ALS who have completed participation in VITALITY-ALS.

- Conducted clinical, regulatory, non-clinical and other activities intended to support potential regulatory filings and registration of *tirasemtiv* in North America and Europe.

- Conducted manufacturing, market research, market access and other commercial readiness activities in support of potential registration and commercialization of *tirasemtiv* in North America and Europe.

- Expect to continue to enroll patients who complete VITALITY-ALS into VIGOR-ALS throughout 2017.

- Expect results from VITALITY-ALS in Q4 2017.

CK-2127107 (next generation fast skeletal muscle troponin activator)

- Announced that the Office of Orphan Products Development of the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to CK-2127107 for the potential treatment of spinal muscular atrophy (SMA).

- Recently announced data relating to patient baseline characteristics and the reasons for patient screen failure, both from the first cohort of the Phase 2 clinical trial of CK-2127107 in patients with SMA, presented at the CureSMA 2017 Annual SMA Conference in Orlando, FL.

- Recently announced the start of a Phase 1b, double-blind, randomized, placebo-controlled,

multiple dose, two-period crossover study to assess the effect of CK-2127107 on measures of physical function in elderly adults with limited mobility. This study is being conducted by Astellas, in collaboration with Cytokinetics.

- Recently announced the start of 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**). This Phase 2 clinical trial is designed to assess the change from baseline in the percent predicted slow vital capacity (SVC) and other measures of skeletal muscle function after 12 weeks of treatment with CK-2127107.

- Expect to complete enrollment of Cohort 2 of the Phase 2 clinical trial of CK-2127107 in patients with SMA in 2017.

- Expect data from the Phase 2 clinical trial of CK-2127107 in patients with SMA in Q1 2018.

- Expect Astellas to continue enrollment in a Phase 2 clinical trial of CK-2127107 in patients with COPD in 2017.

Cardiac Muscle Program

omecamtiv mecarbil (cardiac muscle myosin activator)

- Announced that results from the dose escalation phase of COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yosin Activation to **I**ncrease **C**ontractility in **H**eart **F**ailure), a Phase 2 trial evaluating *omecamtiv mecarbil* in patients with chronic heart failure, were presented in a Rapid Fire Abstract Presentation at Heart Failure 2017, the annual congress of the Heart Failure Association of the European Society of Cardiology.

- Continued to activate sites and enroll patients 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* which is being conducted by Amgen, in collaboration with Cytokinetics.

- Recently announced topline data from a Phase 2 clinical trial of *omecamtivmecarbil* in Japanese patients with chronic heart failure. The trial met its pharmacokinetic primary endpoint and demonstrated statistically significant improvements in systolic ejection time (SET).

- Expect continued enrollment of patients with chronic heart failure in GALACTIC-HF throughout 2017.

Pre-Clinical Research

- Continued research activities under our joint research program with Amgen directed to the discovery of next-generation cardiac muscle activators and under our joint research program with Astellas directed to the discovery of next-generation skeletal muscle activators. In addition, company scientists continued independent research activities directed to our other muscle biology programs.

- Expect to nominate at least one potential drug candidate from research programs for development in 2017.

Corporate

- Raised $83 million in net proceeds, after deducting underwriting discounts and commissions, from an underwritten public offering of 6,049,000 shares of common stock including the underwriter's exercise of their overallotment option. Morgan Stanley LLC acted as the sole underwriter of the offering.

- Raised an additional $12 million from sales of common stock through an at-the-market equity vehicle.

- Received an additional $11 million from the exercise of warrants issued in connection with our June 2012 equity offering.

- Announced that Cytokinetics has been selected for addition to the S&P SmallCap 600 GICS Biotechnology Sub-Industry Index.

- Announced with The ALS Association (ALSA) the continuation of our partnership in the fight against ALS which includes Cytokinetics' renewal of its 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.

Financials

Revenues for the three and six months ended June 30, 2017 were $3.1 million and $7.2 million, respectively, compared to $5.8 million and $14.2 million for the corresponding periods in 2016. Revenues for the first six months of 2017 included $6.7 million of research and development revenues and $6.4 million of license revenues from our collaboration with Astellas, and $1.3 million of research and development revenues from our collaboration with Amgen. Revenues for the first six months of 2017 were offset by $7.5 million (out of the total of $40 million) for payments to Amgen related to our option to co-fund the Phase 3 development program of *omecamtivmecarbil* in exchange for an increased royalty upon potential commercialization.

Research and development expenses for the three and six months ended June 30, 2017 increased to $19.8 million and $39.1 million, respectively, from $9.7 million and $23.3 million for the same periods in 2016, primarily due to increased clinical activity, including activity for VITALITY-ALS and other activities intended to support potential regulatory filings and registration of *tirasemtiv* in North America and Europe, as well as increased personnel.

General and administrative expenses for the three and six months ended June 30, 2017 increased to $8.4 million and $16.6 million from $7.1 million and $13.9 million for the same periods in 2016, primarily due to increased personnel, non-cash stock compensation expense and increased commercial readiness activities.

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 46688062.

An archived replay of the webcast will be available via Cytokinetics' website until August 9, 2017. 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 46688062 from August 2, 2017 at 7:30 PM Eastern Time until August 9, 2017.

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' lead drug candidate is *tirasemtiv*, a fast skeletal muscle troponin activator (FSTA). *Tirasemtiv* is the subject of VITALITY-ALS, an international Phase 3 clinical trial in patients with ALS. *Tirasemtiv* has been granted orphan drug designation and fast track status by the U.S. Food and Drug Administration (FDA) and orphan medicinal product designation by the European Medicines Agency for the potential treatment of ALS. Cytokinetics is preparing for the potential commercialization of *tirasemtiv* in North America and Europe and has granted an option to Astellas Pharma Inc. ("Astellas") for development and commercialization in other countries. Cytokinetics is collaborating with Astellas to develop CK-2127107, a next-generation FSTA. CK-2127107 has been granted orphan drug designation by the FDA for the potential treatment of SMA. CK-2127107 is the subject of three ongoing Phase 2 clinical trials enrolling patients with spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. Astellas is also conducting a Phase 1b clinical trial of CK-2127107 in elderly adults with limited mobility. 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. Astellas holds an exclusive worldwide license to develop and commercialize CK-2127107. Licenses held by Amgen and Astellas are subject to Cytokinetics' specified co-development and co-commercialization rights. For additional information about Cytokinetics, visit http://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 disclaims any intent or obligation to update these forward-looking statements, and 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 and results of clinical trials; the significance and utility of pre-clinical study and clinical trial results, the expected availability of clinical trial results; planned interactions with regulatory authorities and the outcomes of such interactions; the significance and utility of pre-clinical study and clinical trial results; the potential benefits of Cytokinetics' expanded collaboration with Astellas; the expected timing of events and milestones; 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 Cytokinetics need for additional funding and such additional funding may not be available on acceptable terms, if at all; the FDA and/or other regulatory authorities may not accept effects on slow vital capacity as a clinical endpoint to support registration of *tirasemtiv* for the treatment of ALS; 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, including risks that current and past results of clinical trials or pre-clinical studies may not be indicative of future clinical trials results; 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 CK-2127107, respectively; Cytokinetics may incur unanticipated research and development and other costs; Cytokinetics may be unable to enter into future collaboration agreements for its drug candidates and programs on acceptable terms, if at all; 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.

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

	Three Months Ended		Six Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Revenues:				
Research and development, grant and other revenues, net	$ (1,889)	$ 3,852	$ 818	$ 8,299
License revenues from related parties	4,942	1,950	6,388	5,923
Total revenues	3,053	5,802	7,206	14,222
Operating Expenses:				
Research and development	19,809	9,723	39,098	23,256
General and administrative	8,438	7,090	16,553	13,931
Total operating expenses	28,247	16,813	55,651	37,187
Operating loss	(25,194)	(11,011)	(48,445)	(22,965)
Interest and other income (expense), net	(3,887)	(600)	(6,503)	(1,101)
Net loss	$ (29,081)	$ (11,611)	$ (54,948)	$ (24,066)
Net loss per share – basic and diluted	$ (0.60)	$ (0.29)	$ (1.22)	$ (0.61)
Weighted average shares used in computing net loss per share – basic and diluted	48,218	39,666	44,910	39,629

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2017 (unaudited)	December 31, 2016[1]
Assets		
Cash and cash equivalents	$ 100,711	$ 66,874
Short term investments	211,340	89,375
Accounts receivable	-	24
Other current assets	4,945	2,360
Total current assets	316,996	158,633
Property and equipment, net	3,268	3,637
Long-term investments	20,087	7,672
Other assets	279	200
Total assets	$ 340,630	$ 170,142
Liabilities and stockholders' equity		
Deferred revenue, current	$ 7,942	$ 8,060
Other current liabilities	23,117	25,198
Total current liabilities	31,059	33,258
Long-term debt	22,844	27,381
Deferred revenue, non-current	15,067	15,000
Liability related to sale of future royalties	96,657	-
Other non-current liabilities	2	142
Stockholders’ equity	175,001	94,361
Total liabilities and stockholders' equity	$ 340,630	$ 170,142

[1] Derived from the audited financial statements, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2016.

Contact:
Diane Weiser
Vice President, Corporate Communications, Investor Relations
(650) 624-3000

Cytokinetics, Inc