Cytokinetics, Inc. Reports Third Quarter 2016 Financial Results

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Omecamtiv Mecarbil Advancing to Phase 3 With Agreement from FDA on Key Elements of Special Protocol Assessment

VIGOR-ALS Enrolling Patients with ALS Who Have Completed VITALITY-ALS

$65 Million Recently Received From Astellas Related to Expanded Collaboration

SOUTH SAN FRANCISCO, Calif., Oct. 27, 2016 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) reported total revenues for the third quarter of 2016 were $59.0 million, compared to $7.9 million, during the same period in 2015. The net income for the third quarter was $31.9 million, or $0.80 and $0.74 per basic and diluted share, respectively. This is compared to the net loss for the same period in 2015 of $(8.8) million, or $(0.23) per basic and diluted share. As of September 30, 2016, cash, cash equivalents and investments totaled $86.3 million and the Company received an additional $65.0 million in October 2016, from the expanded collaboration with Astellas Pharma, Inc. ("Astellas"), which was effective in September 2016.

“We had a very productive quarter advancing our growing portfolio of novel mechanism drug candidates,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “We are especially pleased to be moving *omecamtiv mecarbil* into GALACTIC-HF with agreement from FDA on key elements of a SPA and look forward to finalizing the protocol in collaboration with Amgen. We also made great progress completing enrollment in VITALITY-ALS and initiating VIGOR-ALS, the open-label extension trial for patients with ALS who have completed VITALITY-ALS. Finally, it’s gratifying to have again expanded our collaboration with Astellas and to align our interests for *tirasemtiv* and CK-2127107 in ALS and other indications, while advancing another next-generation fast skeletal muscle activator into pre-clinical development. We believe the activities of the past quarter demonstrate the power of our muscle biology platform and the promise of innovations arising from our pioneering research and development.”

Recent Highlights and Upcoming Milestones

Cardiac Muscle Program

omecamtiv mecarbil

- Announced the advancement of *omecamtiv mecarbil* to a Phase 3 clinical trials program. The first Phase 3 trial, 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), to be conducted by Amgen in collaboration with Cytokinetics, is designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared with placebo on the time to cardiovascular death or first heart failure event, whichever comes first, in approximately 8,000 subjects with chronic heart failure with reduced ejection fraction receiving standard of care therapy.

- Announced additional results from 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, showing that *omecamtiv mecarbil* may improve symptoms versus placebo in patients with moderate to severe heart failure symptoms at baseline after 20 weeks of double-blind treatment, as measured by the Kansas City Cardiomyopathy Questionnaire Total Symptom Score, one of the sub-domains of a self-administered questionnaire that measures quality-of-life in patients with heart failure. The results were presented at the 20th Annual Heart Failure Society of America Scientific Meeting in Orlando, FL.

- Reached agreement with FDA on key elements of GALACTIC-HF through a Special Protocol Assessment (SPA). Details of the protocol are being finalized with regulators.

- Expect to initiate sites for GALACTIC-HF in the fourth quarter of 2016.

Skeletal Muscle Program

tirasemtiv

- Announced the completion of patient enrollment in 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**), an international Phase 3 clinical trial of *tirasemtiv* in patients with ALS. VITALITY-ALS is designed to assess the effects of *tirasemtiv* versus placebo on slow vital capacity (SVC) and other measures of skeletal muscle strength in patients with ALS. VITALITY-ALS enrolled more than 700 patients.

- Convened the second Data Monitoring Committee Meeting for VITALITY-ALS to review unblinded safety and efficacy data; the Committee recommended continuing the trial without modifications to the protocol.

- Amended our collaboration agreement with Astellas to provide an option right for the development and commercialization of *tirasemtiv* outside of North America, Europe and select other countries.

- Announced the first patient has been enrolled 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 their participation in VITALITY-ALS.

- Expect data from VITALITY–ALS in the fourth quarter of 2017.

CK-2127107

- Amended our collaboration agreement with Astellas to enable the development of CK-2127107, under an agreed plan for the potential treatment of patients with ALS.

- Continued enrollment of the ongoing Phase 2 clinical trial of CK-2127107 in patients with spinal muscular atrophy (SMA) in collaboration with Astellas.

- Expect to complete enrollment of Cohort 1 in the Phase 2 clinical trial of CK-2127107 in patients with SMA in the fourth quarter of 2016. Expect data from this clinical trial in first half of 2017.

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

Pre-Clinical Research

- Announced the initiation of IND-enabling studies for a next-generation fast skeletal muscle activator under our collaboration with Astellas.

- Extended our joint research program with Astellas focused on the discovery of next-generation skeletal muscle activators through 2017.

- 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.

Corporate

- Announced that the Federal Trade Commission granted early termination of the waiting period

under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act) in connection with the 2016 amendment to the License and Collaboration Agreement initially executed between Cytokinetics and Astellas Pharma Inc., in 2013 and amended in 2014.

- Recently received the upfront payment of $65 million from Astellas related to the amendment to our collaboration agreement.

- Received a $2 million milestone payment related to the initiation of IND-enabling studies for a next-generation fast skeletal muscle activator under our collaboration with Astellas.

- Earned a $150,000 milestone payment related to our collaboration with MyoKardia.

- Announced the continuation and expansion of our partnership with The ALS Association in the fight against ALS, including renewal of our Gold Level Sponsorship of the National Walks to Defeat ALS® and Platinum Level Sponsorship for initiatives led by The ALS Association's Golden West Chapter.

Financials

Revenues for the third quarter of 2016 were $59.0 million, compared to $7.9 million during the same period in 2015. Revenues for the third quarter of 2016 included $53.0 million of license revenues, $3.0 million of research and development revenues and $2.0 million of milestone payments from our collaboration with Astellas, $0.6 million in research and development revenues from our collaboration with Amgen, $0.3 million in research and development revenues from our collaboration with ALSA and $0.2 million in milestone revenue from our collaboration with MyoKardia. Revenues for the same period in 2015 were comprised of $4.1 million of license revenues and $3.2 million of research and development revenues from our collaboration with Astellas, and $0.6 million of research and development revenues from our collaboration with Amgen. The increase in revenues for the third quarter of 2016, compared with the same period in 2015, was mainly due to the license revenue associated with the expansion of the Astellas collaboration agreement, which was effective in September 2016.

Total research and development (R&D) expenses for the third quarter of 2016 were $19.3 million, compared to $11.6 million for the same period in 2015. The $7.7 million increase in R&D expenses for the third quarter of 2016, compared with the same period in 2015, was primarily due to an increase of $6.6 million in outsourced pre-clinical and clinical costs mainly associated with the ongoing VITALITY-ALS trial, and an increase of $1.1 million in personnel related expenses due to increased headcount costs and increased non-cash stock compensation expense.

Total general and administrative (G&A) expenses for the third quarter of 2016 were $7.2 million compared to $5.3 million for the same period in 2015. The $1.9 million increase in G&A expenses for the third quarter of 2016, compared to the same period in 2015, was primarily due to an increase of $1.3 million in personnel related expenses due to increased headcount and increased non-cash stock compensation expense, an increase of $0.4 million in outsourced costs related to commercial development and information technology, and an increase of $0.2 million in corporate and patent legal fees.

Revenues for the nine months ended September 30, 2016 were $73.3 million, compared to $18.9 million for the same period in 2015. Revenues for the first nine months of 2016 included $59.0 million of license revenues, $9.5 million of research and development revenues and $2.0 million of milestone payments from our collaboration with Astellas, $1.8 million of research and development revenues from our collaboration with Amgen, $0.8 million in research and development revenues from our collaboration with ALSA and $0.2 million in milestone payment revenue from our collaboration with MyoKardia. Revenues for the same period in 2015 included $8.8 million of license revenues and $8.2 million of research and development revenues from our collaboration with Astellas, and $1.9 million of research and development revenues from our collaboration with Amgen.

Total R&D expenses for the nine months ended September 30, 2016 were $42.6 million, compared to $33.1 million for the same period in 2015. The $9.5 million increase in R&D expenses in the first nine months of 2016, over the same period in 2015, was primarily due to an increase of $9.5 million in outsourced clinical costs, an increase of $3.5 million in personnel related expenses due to increased headcount costs and increased non-cash stock compensation expense, partially offset by a decrease of $3.6 million in outsourced preclinical costs mainly associated with clinical manufacturing activities. The increase in outsourced clinical costs was comprised of an increase of $14.0 million in outsourced clinical costs mainly associated with VITALITY-ALS, offset by a $4.5 million litigation settlement in June 2016 from a contract research organization for BENEFIT-ALS, our Phase 2 clinical trial which was concluded in 2014.

Total G&A expenses for the nine months ended September 30, 2016 were $21.1 million, compared to $14.1 million for the same period in 2015. The $7.0 million increase in G&A spending in the first nine months of 2016 compared to the same period in 2015, was primarily due to an increase of $3.3 million in personnel related expenses due to increased headcount costs and increased non-cash stock compensation expense, an increase of $1.9 million in outsourced costs related to commercial development, grants and sponsorships, and accounting and finance, and an increase of $1.6 million in corporate and patent legal fees.

The net income for the nine months ended September 30, 2016, was $7.8 million, or $0.20 and $0.19 per basic and diluted share, respectively, compared to a net loss of $(28.3) million, or $(0.73) per basic and diluted share, for the same period in 2015.

Financial Guidance

Cytokinetics also updated its financial guidance for 2016. The company anticipates cash revenue will be in the range of $84 to $87 million, cash R&D expenses will be in the range of $65 to $67 million, and cash G&A expenses will be in the range of $23 to $26 million. This guidance excludes approximately $13.5 million in unearned revenue from the 2014 amendment of our collaboration with Astellas, which will be recognized in 2016 under generally accepted accounting principles, as well as any potential future milestones that may be achieved in accordance with our collaboration agreements with our partners Amgen and Astellas. We expect a milestone payment from Amgen of approximately $27 million relating to the start of GALACTIC-HF in the fourth quarter 2016. The guidance includes $15 million in cash revenue under the 2016 amendment to our collaboration with

Astellas, which will be recorded under generally accepted accounting principles once Astellas exercises its option to add *tirasemtiv* to the collaboration. This guidance also excludes an estimated $7.2 million in non-cash related operating expenses primarily related to stock compensation expense.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's third 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 29639748.

An archived replay of the webcast will be available via Cytokinetics' website until November 3, 2016. 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 29639748 from October 27, 2016 at 5:30 PM Eastern Time until November 3, 2016.

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, for the potential treatment of ALS. *Tirasemtiv* has been granted orphan drug designation and fast track status by the U.S. Food and Drug Administration and orphan medicinal product designation by the European Medicines Agency for the potential treatment of ALS. Cytokinetics retains the right to develop and commercialize *tirasemtiv*, subject to an option held by Astellas Pharma Inc. Cytokinetics is also collaborating with Astellas to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator, for the potential treatment of heart failure. Amgen holds an exclusive license worldwide to develop and commercialize *omecamtiv mecarbil* and Astellas holds an exclusive license worldwide to develop and commercialize CK-2127107. Both licenses are subject to Cytokinetics' specified development and commercialization participation 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 preclinical study and clinical trial results, the expected availability of clinical trial results; planned interactions with regulatory authorities and the outcomes of such interactions, including our discussions with the FDA regarding the key elements of GALACTIC-HF and the potential for a SPA; the significance and utility of preclinical study and clinical trial results; the potential benefits of Cytokinetics' expanded collaboration with Astellas; the expected timing of events; 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 further clinical development of *tirasemtiv* in ALS patients which will require significant additional funding, and Cytokinetics may be unable to obtain such additional funding 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 preclinical 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 or be unable to obtain additional financing necessary to conduct development of its products; 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		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Revenues:				
Research and development revenues from related parties	$ 5,573	$ 3,786	$ 13,383	$ 10,087
Research and development, grant and other				

revenues	441	27	930	27
License revenues from related parties	53,033	4,132	58,956	8,787
Total revenues	59,047	7,945	73,269	18,901
Operating Expenses:				
Research and development	19,340	11,557	42,596	33,149
General and administrative	7,217	5,276	21,149	14,138
Total operating expenses	26,557	16,833	63,745	47,287
Operating income (loss)	32,490	(8,888)	9,524	(28,386)
Interest and other income (expense), net	(603)	39	(1,703)	114
Net income (loss)	$ 31,887	$ (8,849)	$ 7,821	$ (28,272)
Net income (loss) per share – basic	$ 0.80	$ (0.23)	$ 0.20	$ (0.73)
Net income (loss) per share – diluted	$ 0.74	$ (0.23)	$ 0.19	$ (0.73)
Weighted average shares used in computing net income (loss) per share – basic	39,926	38,752	39,729	38,718
Weighted average shares used in computing net income (loss) per share – diluted	43,217	38,752	42,247	38,718

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands) (unaudited)

	September 30, 2016	December 31, 2015[(1)]
Assets		
Cash and cash equivalents	$ 30,300	$ 65,076
Short term investments	48,309	46,366
Related party accounts receivable	67,000	12
Prepaid and other current assets	2,575	1,653
Total current assets	148,184	113,107
Property and equipment, net	2,049	1,751
Long-term investments	7,737	179
Other assets	200	200
Total assets	$ 158,170	$ 115,237

Liabilities and stockholders' equity		
Deferred revenue, current	$ 10,497	$ 20,858
Other current liabilities	18,837	10,791
Total current liabilities	29,334	31,649
Long-term debt	29,742	14,639
Deferred revenue, non-current	15,635	—
Other non-current liabilities	209	359
Stockholders’ equity	83,250	68,590
Total liabilities and stockholders' equity	$ 158,170	$ 115,237

(1) Derived from the audited financial statements, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015.

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

Cytokinetics, Inc