

## Endocyte Reports Third Quarter 2016 Financial Results

**- Confirmed Maximum Dose for EC1169 and Initiated Expansion Phase in Prostate Cancer Patients -**

**- First Confirmed RECIST Partial Response Observed in EC1169 Dose Escalation Reported at European Society for Medical Oncology (ESMO) in October -**

**- Conference Call Today at 4:30 p.m. EST -**

WEST LAFAYETTE, Ind., Nov. 09, 2016 (GLOBE NEWSWIRE) -- Endocyte, Inc. (NASDAQ:ECYT), a leader in developing targeted small molecule drug conjugates (SMDCs) and companion imaging agents for personalized therapy, today announced financial results for the third quarter ending September 30, 2016, and provided a clinical and business update.

"Our clinical pipeline made critical progress during the quarter as we have moved both lead SMDC product candidates, EC1456 and EC1169, into the expansion phases of their trials, and confirmed the maximum clinical doses for each," commented Mike Sherman, president and CEO at Endocyte. "We are focused on accelerating progress of both trials to assess the performance of these therapeutic SMDCs along with their companion imaging agents in the targeted indications, and look forward to reporting data on both product candidates at medical conferences in the first half of 2017."

"Key unmet medical needs remain in both prostate cancer and non-small cell lung cancer (NSCLC), which we hope to address with our lead SMDCs. Prostate cancer patients who progress following hormone therapy remain difficult to treat and many NSCLC patients do not respond to immuno-oncology agents and other therapies," commented Alison A. Armour, MD, chief medical officer of Endocyte. "During the EC1169 dose-escalation, we were pleased to see total tumor burden reduction in four out of six patients with measurable disease treated at higher doses, along with our first confirmed RECIST partial tumor response."

### **EC1169 (PSMA-tubulysin)**

- | Data from the dose escalation phase of the EC1169 trial reported at ESMO in October showed that total target tumor burden reduction was observed in 4 of the 6 patients with measurable soft tissue disease treated at doses of 3.8 mg/m<sup>2</sup> and higher.
- | One of these patients demonstrated the first confirmed radiologic partial tumor response (PR) as measured by RECIST 1.1 criteria.
- | Two patients demonstrated confirmed prostate specific antigen reductions of greater than 50%, one of whom went on to demonstrate the PR.
- | EC1169 was well tolerated without causing dose-limiting hematologic toxicity frequently associated with traditional chemotherapy. Primary toxicities included fatigue and gastrointestinal (GI) toxicity; predominantly grade 1 and 2, reversible and responsive to simple medication.
- | The company has confirmed 6.5 mg/m<sup>2</sup> once per week, administered 2 weeks out of a 3 week cycle, as the maximum clinical dose and is moving into the expansion phase where 2 cohorts of metastatic castration resistant prostate cancer (mCRPC) patients will be evaluated. One cohort will include patients who previously received a taxane-based therapy and the other cohort will include taxane-naïve patients. Initial patients in this expansion phase have consented to participate and are expected to be treated this month.

### **EC1456 (Folate-tubulysin)**

- | A dose of 6.0 mg/m<sup>2</sup> was established as the maximum twice per week dose, administered 2 weeks out of a 3 week cycle, which is being used in the expansion phase of the trial where the company will evaluate EC1456 in select folate receptor (FR)-positive NSCLC patients, identified by the companion imaging agent etarfolatide.
- | Patients included in this phase of the trial will have received first-line chemotherapy and may have also been treated with anti-PD-1 therapy.
- | EC1456 was well tolerated during dose escalation, with primary toxicities including fatigue, GI toxicity, and electrolyte disturbance; predominantly grade 1 and 2, reversible and responsive to simple medication.
- | In spite of the inclusion of patients in the dose escalation phase who were not selected as positive for the targeted FR, most patients demonstrated stable disease as best response and several patients demonstrated a reduction in target tumor volume.

## Upcoming Expected Milestones for the First Half of 2017

- 1 Efficacy and safety data from expansion cohorts for both EC1456 and EC1169 are expected to be reported at medical conferences.
- 1 Data from an EC1456 surgical debulking study. This study is designed to assess various metrics related to cell targeting and intratumoral delivery of drug payload.
- 1 Data from an EC1169 receptor occupancy study. This study is designed to provide insight into the drug's interaction with the target receptor.
- 1 New pre-clinical data on the CAR-T program are expected to be reported at a scientific conference.

## Third Quarter 2016 Financial Results

Endocyte reported a net loss of \$8.7 million, or \$0.21 per basic and diluted share, for the third quarter of 2016, compared to a net loss of \$10.0 million, or \$0.24 per basic and diluted share for the same period in 2015.

Research and development expenses were \$6.0 million for the third quarter of 2016, compared to \$6.6 million for the same period in 2015. The decrease was primarily attributable to a decrease in compensation expense and a decrease in expenses related to the TARGET trial, which is now complete. The net effect of these decreases was partially offset by increases related to the EC1456 and EC1169 dose escalation trials and increases in manufacturing and other research expenses related to EC1456 and EC1169.

General and administrative expenses were \$3.0 million for the third quarter of 2016, compared to \$3.8 million for the same period in 2015. The decrease was primarily attributable to a decrease in compensation expense and a decrease in expenses related to professional fees and employee benefits.

Cash, cash equivalents and investments were \$146.7 million at September 30, 2016, compared to \$180.3 million at September 30, 2015, and \$173.6 million at December 31, 2015.

## Financial Expectations

The company updated its financial expectations and now anticipates its cash balance at the end of 2016 to be above \$135 million.

## About EC1456 and the Phase 1 Trial

EC1456 is an investigational therapeutic SMDC constructed of a high affinity FR-targeting ligand conjugated through a spacer and bioreleasable linker system to a potent cytotoxic microtubule inhibitor, TubBH. Patient FR-status will be determined using the investigational companion imaging agent, etarfolatide. EC1456 and etarfolatide are currently being evaluated in a phase 1 study in patients with advanced solid tumors ([ClinicalTrials.gov](http://ClinicalTrials.gov) Identifier: [NCT01999738](https://clinicaltrials.gov/ct2/show/study/NCT01999738)).

The open-label, multicenter, non-randomized, study is divided into two parts. The first part of the study was designed to determine the maximum clinical dose and recommended Phase 2 dose of EC1456 in patients with metastatic or locally advanced solid tumors.

Endocyte has now initiated the expansion phase of the study which is designed to evaluate the efficacy of EC1456 in patients with NSCLC known to express the FR and treated with the maximum clinical dose of EC1456. The twice weekly (BIW) dosing schedule at a 6.0 mg/m<sup>2</sup> dose will be evaluated and then upon completion of this dosing schedule, additional patients will be enrolled in a once per week dosing schedule cohort. Single agent anti-tumor response will be evaluated, which will inform and may trigger additional work in combination therapies and indications such as triple-negative breast cancer, ovarian cancer and endometrial cancer.

## About EC1169 and the Phase 1 Trial

EC1169 is an investigational therapeutic SMDC constructed of a high affinity prostate specific membrane antigen (PSMA)-targeting ligand conjugated through a bioreleasable linker system to a potent microtubule inhibitor, tubulysin B hydrazide (TubBH). Patient PSMA-status will be determined using the investigational companion imaging agent, EC0652. EC1169 and EC0652 are currently being evaluated in a phase 1 study in patients with mCRPC ([ClinicalTrials.gov](http://ClinicalTrials.gov) Identifier: [NCT02202447](https://clinicaltrials.gov/ct2/show/study/NCT02202447)).

The open-label, multicenter, non-randomized, study is divided into two parts. The first part of the study, now complete, was designed to determine the maximum clinical dose and recommended Phase 2 dose of EC1169 in patients with prostate

cancer.

Endocyte has now initiated the second part of the study which is designed to evaluate the efficacy of EC1169 in taxane-exposed and taxane-naïve mCRPC, with a primary study endpoint of radiographic progression free survival in patients selected as PSMA-positive.

### **Conference Call**

Endocyte management will host a conference call today at 4:30 p.m. EST.

U.S. and Canadian participants: (877) 845-0711  
International: (760) 298-5081

A live, listen-only webcast of the conference call may also be accessed by visiting the Investors & News section of the Endocyte website, [www.endocyte.com](http://www.endocyte.com).

The webcast will be recorded and available on the company's website for 90 days following the call.

### **Website Information**

Endocyte routinely posts important information for investors on its website, [www.endocyte.com](http://www.endocyte.com), in the "Investors & News" section. Endocyte uses this website as a means of disclosing material information in compliance with its disclosure obligations under Regulation FD. Accordingly, investors should monitor the "Investors & News" section of Endocyte's website, in addition to following its press releases, SEC filings, public conference calls, presentations and webcasts. The information contained on, or that may be accessed through, Endocyte's website is not incorporated by reference into, and is not a part of, this document.

### **About Endocyte**

Endocyte is a biopharmaceutical company and leader in developing targeted therapies for the treatment of cancer and other serious diseases. Endocyte uses its proprietary drug conjugation technology to create novel SMDCs and companion imaging agents for personalized targeted therapies. The company's SMDCs actively target receptors that are over-expressed on diseased cells relative to healthy cells. This targeted approach is designed to enable the treatment of patients with highly active drugs at greater doses, delivered more frequently and over longer periods of time than would be possible with the untargeted drug alone. The companion imaging agents are designed to identify patients whose disease over-expresses the target of the therapy and who are therefore more likely to benefit from treatment. For additional information, please visit Endocyte's website at [www.endocyte.com](http://www.endocyte.com).

### **Forward Looking Statements**

*Certain of the statements made in this press release are forward looking, such as those, among others, relating to future spending, future cash balances, the successful completion of current and future clinical trials, the enrollment period for, and availability and reporting, of data from ongoing and future clinical trials, and the company's future development plans including those relating to the completion of preclinical development in preparation for possible future clinical trials. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include risks that the company may experience delays in the completion of its clinical trials (whether caused by competition, adverse events, patient enrollment rates, shortage of clinical trial materials, regulatory issues or other factors); risks that data from its clinical trials may not be indicative of subsequent clinical trial results; risks related to the safety and efficacy of the company's product candidates; risks that early stage preclinical data may not be indicative of subsequent data when expanded to additional preclinical models or to subsequent clinical data; risks that evolving competitive activity and intellectual property landscape may impair the company's ability to capture value for the technology; risks that expectations and estimates turn out to be incorrect, including estimates of the potential markets for the company's product candidates, estimates of the capacity of manufacturing and other facilities required to support its product candidates, projected cash needs, and expected future revenues, operations, expenditures and cash position. More information about the risks and uncertainties faced by Endocyte, Inc. is contained in the company's periodic reports filed with the Securities and Exchange Commission. Endocyte, Inc. disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*

## **Endocyte, Inc.**

### **Statements of Operations**

(dollars in thousands, except per share amounts)

(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2016	2015	2016
Collaboration revenue	\$ 33	\$ 33	\$ 58	\$ 58
Costs and expenses:				
Research and development	6,582	5,985	19,923	19,304
General and administrative	3,776	2,988	12,207	14,202
Total costs and expenses	10,358	8,973	32,130	33,506
Loss from operations	(10,325)	(8,940)	(32,072)	(33,448)
Interest income, net	153	232	490	629
Other income (expense), net	170	—	106	(4)
Net loss	\$ (10,002)	\$ (8,708)	\$ (31,476)	\$ (32,823)
Net loss per share - basic and diluted	\$ (0.24)	\$ (0.21)	\$ (0.75)	\$ (0.78)
Comprehensive loss	\$ (9,950)	\$ (8,772)	\$ (31,308)	\$ (32,712)
Weighted average number of common shares used in net loss - basic and diluted per share:	41,974,518	42,263,311	41,924,252	42,184,182

**Endocyte, Inc.**  
**Balance Sheets**  
(in thousands)

	As of December 31, 2015	As of September 30, 2016 (unaudited)
<b>Assets</b>		
Cash, cash equivalents and investments	\$ 173,600	\$ 146,717
Other assets	4,786	5,269
Total assets	\$ 178,386	\$ 151,986
<b>Liabilities and stockholders' equity</b>		
Current liabilities	\$ 6,189	\$ 4,551
Deferred revenue and other liabilities, net of current portion	851	802
Total stockholders' equity	171,346	146,633
Total liabilities and stockholders' equity	\$ 178,386	\$ 151,986

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