August 4, 2016

Endocyte Reports Second Quarter 2016 Financial Results

- Reached Maximum Tolerated Dose in Twice Weekly Dosing Schedule with EC1456 -

- Initiating EC1456 Expansion Cohort in Targeted Population of Folate Receptor-Positive Non-Small Cell Lung Cancer Patients -

- Data Presentations Expected for EC1456 and EC1169 in the Second Half of 2016 -

- Conference Call Today at 4:30 p.m. EDT -

WEST LAFAYETTE, Ind., Aug. 04, 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 second quarter ending June 30, 2016, and provided a clinical update.

"Excitement is building around our lead assets, EC1456 and EC1169, as data to date has demonstrated attractive safety profiles and signs of anti-tumor activity for both agents. Later this month, we will advance EC1456 into targeted patients with non-small cell lung cancer (NSCLC) expressing the folate receptor, who are most likely to respond," said Mike Sherman, Endocyte's president and chief executive officer. "We look forward to our first visibility into efficacy data for both compounds during the second half of the year."

EC1456 (Folate-tubulysin)

The EC1456 phase 1 dose escalation data presented at the American Society of Clinical Oncology (ASCO) annual meeting in June highlighted a 45 percent rate of stable disease as best study response across a patient population that included more than a dozen cancer types. Patients are enrolled regardless of their folate receptor (FR) status during this first part of the study.

Endocyte announced today that the maximum tolerated dose (MTD) has been determined in the twice weekly (BIW) dosing schedule for EC1456 at 6.0 mg/m^2. Enrollment of FR-positive NSCLC patients in the BIW expansion cohort will begin in August. In this expansion cohort the company plans to evaluate efficacy endpoints, including tumor response, in addition to ongoing assessment of safety. Endocyte's companion imaging agent, EC20 (etarfolatide), will be utilized to select these patients. The company is continuing to evaluate the MTD in the once weekly dosing regimen.

EC1169 (PSMA-tubulysin)

The EC1169 phase 1 dose escalation study, as presented at ASCO, highlighted that all patients in the study have some level of prostate specific membrane antigen (PSMA) positivity, and the drug has been well tolerated.

"EC1169 has the potential to be a truly differentiated therapy, and it has shown signs of anti-tumor activity, even at low doses, including reductions of prostate-specific antigen levels greater than 50 percent in some patients," commented Alison Armour, M.D., Endocyte's chief medical officer. "We have worked with key opinion leaders in prostate cancer to define the expansion phase of this trial, and once we determine the MTD, we plan to begin enrolling second-line chemotherapy metastatic castrate resistant prostate cancer (mCRPC) patients, with a primary study endpoint of radiological progression free survival. We also plan to include an exploratory assessment of taxane-naïve patients, which could allow the possibility of an earlier line therapy."

Upcoming Expected Milestones

- Phase 1 updates on EC1456 and EC1169 at the European Society for Medical Oncology (ESMO) conference in October 2016
- Complete enrollment of first 15 patient cohort in EC1456 expansion trial; single agent efficacy data (tumor response) in NSCLC at a medical meeting in late 2016 or early 2017
- EC1169 single agent efficacy data in prostate cancer in late 2016 or early 2017
- Updates on plans for earlier stage programs

Second Quarter 2016 Financial Results

Endocyte reported a net loss of $14.0 million, or $0.33 per basic and diluted share, for the second quarter of 2016, compared to a net loss of $10.6 million, or $0.25 per basic and diluted share, for the same period in 2015.

Research and development expenses were $6.8 million for the second quarter of 2016, compared to $6.7 million for the same period in 2015. The slight increase was primarily attributable to an increase in expenses related to the EC1456 and EC1169 dose escalation trials, which was partially offset by a decrease in expenses related to the TARGET trial, which is now complete, and a decrease in compensation expenses, primarily related to noncash stock compensation.

General and administrative expenses were $7.4 million for the second quarter of 2016, compared to $4.1 million for the same period in 2015. The increase in expenses was primarily attributable to an increase in compensation expense related to the resignation of the company's former Chief Executive Officer, P. Ron Ellis. The company executed a separation agreement with Mr. Ellis during the three months ended June 30, 2016, and under this agreement, the company incurred additional compensation expense of $2.8 million for noncash stock compensation and $0.8 million of expense for a cash payment. The increase in general and administrative expenses was partially offset by a decrease in legal fees.

Cash, cash equivalents and investments were $154.6 million at June 30, 2016, compared to $188.6 million at June 30, 2015, and $173.6 million at December 31, 2015.

Financial Expectations

The company revised guidance for its expected cash balance at the end of 2016 to be above $130 million. Previous guidance was between $125 and $130 million cash balance at the end of 2016.

About the EC1456 Phase 1 Trial

This open-label, multicenter, non-randomized, dose-escalation study is divided into two parts. The first part of the study was designed to evaluate safety and tolerability and identify the MTD of EC1456 in patients with metastatic or locally advanced solid tumors.

The second part of the study will determine the efficacy of EC1456 in patients with FR-positive NSCLC treated with the MTD. The BIW dosing schedule at 6.0 mg/m^2 will be evaluated first. Upon the completion of this dosing schedule, additional patients will be enrolled in a once per week dosing schedule cohort. Single agent 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. Patient FR-status will be determined using the investigational companion imaging agent, EC20 (etarfolatide). EC1456 is currently being evaluated in a phase 1 study in patients with advanced solid tumors (ClinicalTrials.gov Identifier: NCT01999738).

About the EC1169 Phase 1 Trial

This open-label, multicenter, non-randomized, dose-escalation study is divided into two parts. The first part of the study was designed to evaluate safety and tolerability and identify the MTD of EC1169 in patients with prostate cancer.

The second part of the study will determine the efficacy of the MTD of EC1169 in mCRPC patients who have been previously treated with a taxane-based chemotherapy. The primary study endpoint will be radiological progression free survival in patients selected as PSMA-positive. A second cohort will include an exploratory assessment of taxane-naïve patients. Patient PSMA status will be determined using the investigational companion imaging agent, EC0652. EC1169 is currently being evaluated in a phase 1 study in mCRPC patients (ClinicalTrials.gov Identifier: NCT02202447).

Conference Call

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

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.

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, 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.

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 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; estimates of the potential markets for its 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 June 30,		For the Six Months Ended June 30,	
	2015	2016	2015	2016
Collaboration revenue	$ 13	$ 13	$ 25	$ 25
Costs and expenses:				
Research and development	6,724	6,788	13,341	13,319
General and administrative	4,071	7,394	8,431	11,214
Total costs and expenses	10,795	14,182	21,772	24,533
Loss from operations	(10,782)	(14,169)	(21,747)	(24,508)
Interest income, net	185	208	337	397
Other expense, net	(7)	(1)	(64)	(4)
Net loss	$ (10,604)	$ (13,962)	$ (21,474)	$ (24,115)
Net loss per share - basic and diluted	$ (0.25)	$ (0.33)	$ (0.51)	$ (0.57)

Comprehensive loss	$ (10,623)	$ (13,897)	$ (21,358)	$ (23,940)
Weighted average number of common shares used in net loss per share - basic and diluted	41,939,052	42,178,537	41,898,702	42,144,182

Endocyte, Inc.
Balance Sheets
(in thousands)

	As of December 31, 2015	As of June 30, 2016 (unaudited)
Assets		
Cash, cash equivalents and investments	$ 173,600	$ 154,609
Other assets	4,786	4,798
Total assets	$ 178,386	$ 159,407
Liabilities and stockholders' equity		
Current liabilities	$ 6,189	$ 4,544
Deferred revenue and other liabilities, net of current portion	851	818
Total stockholders' equity	171,346	154,045
Total liabilities and stockholders' equity	$ 178,386	$ 159,407

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Source: Endocyte, inc