ENDOCYTE

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Endocyte Presents Data on Two Lead Clinical Programs at European Society for Medical Oncology (ESMO) 2016 Congress

Anti-tumor activity demonstrated in dose escalation trials for EC1456 and EC1169

WEST LAFAYETTE, Ind., Oct. 10, 2016 (GLOBE NEWSWIRE) -- Endocyte, Inc. (NASDAQ:ECYT), a leader in developing targeted small molecule drug conjugates (SMDCs) and companion imaging agents for personalized therapy, presented poster updates on its two lead clinical programs at the European Society for Medical Oncology (ESMO) 2016 Congress, being held in Copenhagen, Denmark October 7-11, 2016.

"We are pleased that both EC1456 and EC1169 have shown anti-tumor activity during the dose escalation phase of their respective trials, even in patients not specifically identified as positive for the drug targets," said Mike Sherman, president and CEO at Endocyte. "The activity we've seen to date with EC1169 in prostate cancer patients is particularly exciting, with our first confirmed radiologic partial response (PR). This quarter we expect to move the 6.5 mg/m^2 dose into the expansion phase of the study where we will evaluate EC1169 in patients selected as prostate specific membrane antigen (PSMA)-positive using our companion imaging agent, EC0652. We have also moved on to the expansion phase of the EC1456 trial, using our companion imaging agent etarfolatide to select folate receptor (FR)-positive non-small cell lung cancer (NSCLC) patients."

"Despite the current therapy options available for prostate cancer patients, there remains a need for safe and effective alternatives for these patients following treatment with hormone therapies," stated Michael J. Morris, M.D., Associate Professor, Genitourinary Oncology, Memorial Sloan Kettering Cancer Center, New York. "The disease is more challenging to treat at this stage, so the safety data, and at least the preliminary efficacy data, which we're seeing with Endocyte's PSMA-targeted agent is encouraging. I look forward to further exploring this novel drug in patients with metastatic prostate cancer."

EC1169 Poster #731P - Phase 1 Study of the PSMA-Targeted Tubulysin Small-Molecule Drug Conjugate EC1169 in Patients with Metastatic Castrate-Resistant Prostate Cancer (mCRPC): Study Update

Data presented in this poster 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^2 and higher. One of these patients demonstrated the first confirmed radiologic partial tumor response (PR) as measured by RECIST 1.1 criteria. Two patients also demonstrated confirmed prostate specific antigen (PSA) reductions of greater than 50%, one of whom went on to demonstrate the PR. After observing toxicity at 8.5 mg/m^2, the company is in the process of confirming 6.5 mg/m^2 as the highest clinical dose. 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.

EC1456 Poster #395P - Dose Escalation Phase 1, Safety and Pharmacokinetic Study of the Folate Receptor-Targeted Drug Conjugate EC1456 in Advanced Cancer Patients: Study Update

A dose of 6.0 mg/m2 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 in FR-positive NSCLC patients. EC1456 was well tolerated, 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 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.

About EC1169 and EC0652

EC1169 is an investigational therapeutic SMDC constructed of a high affinity PSMA-targeting ligand conjugated through a releasable linker system to a potent cytotoxic microtubule inhibitor, tubulysin B hydrazide (TubBH). The high affinity of EC1169 for PSMA allows for the active and specific delivery of TubBH to PSMA-expressing cancer cells, while minimizing exposure to normal cells. PSMA is known to be highly expressed on the majority of prostate cancers with limited expression on normal tissues.

The PSMA-targeted companion imaging agent EC0652 is being co-developed to characterize whole body PSMA expression in real time, to identify patients most likely to benefit from EC1169 therapy. EC1169 and EC0652 are currently being evaluated in a phase 1 study in patients with metastatic, castration-resistant prostate cancer (mCRPC) (ClinicalTrials.gov Identifier: NCT02202447).

About EC1456 and etarfolatide

EC1456 is an investigational therapeutic SMDC constructed of folic acid conjugated through a spacer and releasable linker system to a potent cytotoxic microtubule inhibitor, TubBH. The high affinity of the folic acid ligand for the FR allows for the active and specific targeting of EC1456 to FR-expressing cancer cells. The FR is highly expressed in several epithelial cancers (e.g. ovarian, NSCLC) but is expressed at low levels in most normal tissues.

Etarfolatide is an FR-targeted companion imaging agent being co-developed to characterize whole body FR expression in real time, to identify patients most likely to benefit from EC1456 therapy. EC1456 and etarfolatide are currently being evaluated in a phase 1 study in patients with advanced solid tumors (ClinicalTrials.gov Identifier: NCT01999738).

About Endocyte

Endocyte is a biopharmaceutical company and leader in developing personalized therapy for cancer and other serious diseases through targeted SMDCs and companion imaging agents. The company's SMDCs actively deliver highly potent payloads into targeted cells via cell surface receptors that have been identified in patients using companion imaging agents. This approach allows for selected treatment to those patients that may be the most likely to benefit from targeted therapy. EC1169, EC0652, EC1456, and etarfolatide are wholly owned by Endocyte. For more information, visit http://www.endocyte.com.

Forward Looking Statements

Certain of the statements made in this press release are forward looking, such as those relating to the company's development programs and upcoming milestones. 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.

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