

March 21, 2014

## **Endocyte Announces Phase 2b TARGET Trial Results Evaluating Vintafolide/Docetaxel Combination in Non-Small Cell Lung Cancer (NSCLC) Met the Primary Endpoint of Improved Progression Free Survival**

### **Conference Call/Webcast at 9 a.m. EDT Today**

WEST LAFAYETTE, Ind., March 21, 2014 (GLOBE NEWSWIRE) -- Endocyte, Inc. (Nasdaq:ECYT) today announced results from the Phase 2b TARGET trial, which showed that the study met the primary endpoint for the combination of vintafolide (EC145/MK-8109) and docetaxel in folate receptor (FR)-positive recurrent non-small cell lung cancer (NSCLC) patients. As a randomized Phase 2b study, the pre-defined statistical threshold for significance was a p-value of < 0.10 (one-sided test). The data showed that risk of disease worsening or death was reduced by 25 percent for patients treated with the vintafolide/docetaxel combination versus docetaxel alone (PFS HR 0.75, p-value 0.0696, one-sided test). Detailed trial results, including data regarding overall survival (OS), will be presented at an upcoming medical conference.

The TARGET Phase 2b trial was conducted in 199 patients, randomized to one of three arms: vintafolide alone, vintafolide/docetaxel combination, or docetaxel alone. Secondary endpoints, including overall response rate and OS, also showed trends in favor of the combination arm. Median OS has been reached for the vintafolide and docetaxel single-agent arms but has not yet been reached in the combination arm. In addition, the investigational combination regimen showed better activity in patients with adenocarcinoma, a subset analysis pre-specified in the trial design.

The safety profile of the combination arm was consistent with those observed with docetaxel alone and vintafolide alone, though a higher rate of hematologic and peripheral neuropathy adverse events were observed in the combination arm. There were no drug-related deaths in the combination arm. Single-agent vintafolide at the schedule evaluated in this study demonstrated less activity than single-agent docetaxel.

"We are pleased with the results of this study, as the vintafolide/docetaxel combination showed meaningful activity in patients with recurrent NSCLC, meeting the primary endpoint of the trial," said Binh Nguyen, M.D., Ph.D., vice president of medical affairs at Endocyte. "This is our second randomized study in a very challenging indication, where vintafolide has met the primary endpoint when used in patients selected with the companion imaging agent etarfolatide. These results provide further validation of our targeted approach to treatment using companion imaging and our SMDC technology. We were especially pleased with the results in the adenocarcinoma population and early OS trends, and we have learned important information about the dosing schedule. We look forward to reviewing additional analysis of this study when the OS data has matured later this year to help inform potential further development of the vintafolide/docetaxel combination in NSCLC."

"We are encouraged by the results from the TARGET trial which show activity with vintafolide in these difficult-to-treat patients, and look forward to reviewing still maturing data from TARGET later this year," said Dr. Eric Rubin, vice president, clinical development for oncology, Merck Research Laboratories.

Endocyte's management will host a conference call and webcast today:

Date: March 21, 2014

Time: 9 a.m. EDT

Dial: (877) 845-0711 (US/Canada) or (760) 298-5081 (International)

Webcast information can be accessed under "Events & Presentations" in the Investors & News section of Endocyte's website at [www.endocyte.com](http://www.endocyte.com).

A replay of the call will be available beginning at 12 p.m. EDT on March 21, until midnight EDT, March 28, 2014. To access the replay, please dial (855) 859-2056 (US/Canada) or (404) 537-3406 (International) and reference the conference ID 17729219.

### **About the TARGET trial**

TARGET is an international, multicenter, open-label Phase 2b study designed to evaluate vintafolide in patients with stage IIIb or IV NSCLC with all lesions positive for the folate receptor (FR 100%) as determined by the investigational companion imaging agent etarfolatide (EC20) and who have failed one prior chemotherapy ([ClinicalTrials.gov](http://ClinicalTrials.gov) Identifier: [NCT01577654](https://clinicaltrials.gov/ct2/show/study/NCT01577654)). Secondary endpoints include the comparison of overall response rate, disease control rate, duration of response, duration of disease control, overall survival of the participants between treatment arms, and the incidence of adverse and serious adverse events. TARGET included three investigational arms, vintafolide monotherapy and vintafolide in combination with docetaxel, each of

which was compared to a standard-of-care control arm, docetaxel monotherapy.

### **About Vintafolide, Etarfolatide and IV Folic Acid**

Vintafolide is an investigational conjugate of folic acid (vitamin B9) linked to an anti-cancer agent, the potent vinca alkaloid desacetylvinblastine hydrazide (DAVLBH). Since cancer cells generally consume higher levels of folate than normal cells to fuel their growth, some cancer cell types - including ovarian and NSCLC - have high concentrations of the folate receptor on their surface. Vintafolide is designed to selectively target the folate receptor to deliver the anti-cancer agent to the cancerous tissue. Tumors that have high concentrations of the folate receptor are identified by etarfolatide, a non-invasive imaging diagnostic agent. Intravenous folic acid is used with <sup>99m</sup>Tc-etarfolatide/etarfolatide for the enhancement of image quality.

Vintafolide, etarfolatide and IV folic acid have been granted orphan drug status by the EMA. The U.S. Food and Drug Administration has also granted orphan drug status to vintafolide and etarfolatide. Further evaluation is ongoing in the global PROCEED Phase 3 clinical trial in folate receptor-positive (FR 100%) platinum-resistant ovarian cancer ([ClinicalTrials.gov Identifier: NCT01170650](https://clinicaltrials.gov/ct2/show/study/NCT01170650)). The randomized TARGET Phase 2b study of vintafolide in non-small cell lung cancer has completed enrollment ([ClinicalTrials.gov Identifier: NCT01577654](https://clinicaltrials.gov/ct2/show/study/NCT01577654)), and a Phase 2 study in triple-negative breast cancer is expected to be initiated in Q2 ([ClinicalTrials.gov Identifier: NCT01953536](https://clinicaltrials.gov/ct2/show/study/NCT01953536)).

### **About Endocyte**

Endocyte is a biopharmaceutical company and leader in developing targeted small molecule drug conjugates (SMDCs) and companion imaging agents for personalized therapy in cancer and other serious diseases. Endocyte uses its proprietary technology to create novel SMDCs and companion imaging agents for personalized targeted therapies. The company's SMDCs actively target receptors that are expressed or over-expressed on diseased cells, relative to healthy cells. This targeted approach is designed to enable the treatment of patients with highly potent drugs into these cells. The companion imaging agents are designed to identify patients whose disease expresses the molecular target of the therapy and who therefore may be more likely to benefit from treatment. For more information, visit <http://www.endocyte.com>.

### **Endocyte Forward-Looking Statement**

Certain of the statements made in this press release are forward-looking, such as those, among others, relating to the company's expectations for seeking regulatory approval and commercial launch of its products, including any conditional marketing authorization from the EMA, initiation of future clinical trials, and expectations for the receipt of milestones, royalties or other profits from the company's partnership with Merck. 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, unavailability 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, the goals of its development activities, 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 financial results. 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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