Endocyte, Inc. Logo

Endocyte Announces Enrollment of First Patient in Phase 3 VISION Trial of 177Lu-PSMA-617 in Prostate Cancer

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Additional data from phase 2 investigator-initiated trial of 177Lu-PSMA-617 presented at American Society of Clinical Oncology (ASCO)

WEST LAFAYETTE, Ind., June 05, 2018 (GLOBE NEWSWIRE) -- Endocyte, Inc. (Nasdaq:ECYT), a biopharmaceutical company developing targeted therapeutics for personalized cancer treatment, today announced the enrollment of the first patient in its global phase 3 VISION trial of ^{177}Lu-PSMA-617 in prostate cancer by Dr. Luke Nordquist at Urology Cancer Center in Omaha, NE, a member of Precision Cancer Research. The international, prospective, open-label, multicenter, randomized phase 3 study is evaluating patients with progressive prostate specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC), who have received at least one novel androgen axis drug (abiraterone or enzalutamide) and at least one taxane regimen.

“We are pleased to announce the initiation of this important clinical trial so quickly following our end-of-phase 2 meeting with the FDA. This speed of execution is a result of the enthusiasm of participating physicians and the focus and urgency of our clinical operations team,” said Mike Sherman, president and CEO of Endocyte . “Having collaborated with several of the key opinion leaders in prostate cancer around the world, we are confident in the robustness of the VISION trial design and eager to complete enrollment.”

“In spite of the introduction of new drugs in the last several years, there continues to be a significant need for therapeutic alternatives with new mechanisms of action for men suffering from metastatic castration-resistant prostate cancer,” said Oliver Sartor, M.D., Medical Director of the Tulane Cancer Center. “The data generated with ^{177}Lu-PSMA-617 in early clinical trials have yielded a high level of enthusiasm among physicians. There is a real need to advance this investigational therapy as quickly as possible for these heavily pre-treated patients and begin the work to evaluate it in earlier lines of therapy, particularly in advance of chemotherapy.”

Phase 2 Clinical Data Presented at ASCO

Incremental data from an expansion cohort of 20 patients recently presented at ASCO confirmed and improved upon PSA response to ^{177}Lu-PSMA-617 previously reported in a cohort of 30 patients enrolled in a phase 2 trial at the Peter MacCallum Cancer Centre in Melbourne, Australia.

“Twenty-six of the 50 patients (52%) enrolled in this trial are more heavily pre-treated than the minimum eligibility criteria for the VISION trial, so it is particularly compelling to see a PSA decline of 50% or more in 62% of these advanced patients and a median PSA progression-free survival (PFS) of 7.0 months,” said Alison Armour, chief medical officer of Endocyte. “While the overall survival data are not yet mature for the second cohort of 20 patients, we were pleased to see six-month survival rates similar to the first cohort of 30 patients. Consistent response rates across patient groups with variations in prior therapy is likely a result of a potential differentiated mechanism of action for ^{177}Lu-PSA-617 compared to currently approved therapies.”

^{177}Lu-PSMA-617 was generally well tolerated, with no significant dose-limiting toxicities observed. The most common treatment-related toxicity was Grade 1-2 xerostomia (dry mouth) seen in 68% of patients, but infrequently required any intervention. The occurrence of treatment-related Grade 3-4 hematologic toxicity was low and comparable to the largest retrospective published cohort.

VISION Phase 3 Trial Design

VISION will enroll up to 750 patients worldwide with PSMA-positive scans, randomized in a 2:1 ratio to receive either ^{177}Lu-PSMA-617 plus best supportive/best standard of care versus best supportive/best standard of care alone. Best supportive/best standard of care is palliative in nature and, at the discretion of the investigator, may include enzalutamide or abiraterone. Patients treated with ^{177}Lu-PSMA-617 will receive 7.4 gigabecquerel (GBq) intravenously every six weeks for a maximum of six cycles.

The primary endpoint of the study agreed to by the FDA is overall survival (OS). Secondary endpoints include radiographic progression-free survival (rPFS), response evaluation criteria in solid tumors (RECIST) response, and time to first symptomatic skeletal event. Two interim efficacy analyses of OS will be conducted at 50% and 70% of the first 489 targeted events. Endocyte plans to discuss modifying the first interim analysis endpoint to rPFS to expedite a potential accelerated approval in the U.S. Further information on the global Phase 3 VISION study can be found at www.VISIONClinicalTrial.com.

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 the company’s 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 personalized treatment of cancer. The company's drug conjugation technology targets therapeutics and companion imaging agents specifically to the site of diseased cells. Endocyte's lead program is a prostate specific membrane antigen (PSMA)-targeted radioligand therapy, ^{177}Lu-PSMA-617, entering phase 3 for metastatic castration-resistant prostate cancer (mCRPC). Endocyte also expects to have an Investigational New Drug application submitted in the fourth quarter of 2018 for its adaptor-controlled CAR T-cell therapy which will be initially studied in osteosarcoma. 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 the company's future development plans including those relating to the completion of pre-clinical development in preparation for possible future clinical trials, the initiation of a registration trial, and preparation for potential commercialization. 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 or independent investigators may experience delays in the initiation or completion of 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 prior 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 pre-clinical data may not be indicative of subsequent data when expanded to additional pre-clinical models or to subsequent clinical data; risks that evolving competitive activity and intellectual property landscape may impair the company'sability to capture value for the technology; risks that expectations and estimates turn out to be incorrect, including estimates of the potential global markets for the company’s product candidates, estimates of the availability and 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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