Endocyte, Inc. Logo

Endocyte Announces The Lancet Oncology Publication of Phase 2 Data From Investigator-Initiated Prostate Cancer Trial of (177)Lu-PSMA-617

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-Publication includes analysis of original 30 patients previously presented at 2017 ESMO by Professor Michael Hofman of Peter MacCallum Cancer Centre-

-Relative to previously presented data, publication reflects longer median overall survival, longer median prostate specific antigen (PSA) progression-free survival, and higher RECIST response rates–

–PSA reduction of at least 50% from baseline in 57% of patients as originally reported–

–Response data for an additional 20 patients expected to be presented at ASCO 2018–

WEST LAFAYETTE, Ind., May 09, 2018 (GLOBE NEWSWIRE) -- Endocyte, Inc. (Nasdaq:ECYT), a biopharmaceutical company developing targeted therapeutics for personalized cancer treatment, today announced *The Lancet Oncology* publication of data on 30 patients with PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) treated with ^{177}Lu-PSMA-617. Preliminary results of this open-label phase 2 investigator-initiated trial were previously announced at the 2017 ESMO Congress and presented by Professor Michael Hofman of the Peter MacCallum Cancer Centre (Melbourne, Australia).

"This more detailed publication was consistent with or improved from the summary results presented at ESMO last fall," said Mike Sherman, president and CEO of Endocyte. "The response rates demonstrated to date are encouraging, especially since no agent has been proven to improve survival in this heavily pre-treated patient population. We look forward to beginning enrollment in our global phase 3 VISION trial of ^{177}Lu-PSMA-617 this quarter."

Mr. Sherman continued, "We also look forward to Professor Hofman presenting additional updates at the American Society of Clinical Oncology (ASCO) Annual Meeting in June, with new data from the trial's expansion to 50 patients. Given the expected immaturity of survival data in the additional 20 patients, our focus will be on the PSA and RECIST response rates."

Updated Data Disclosed in *The Lancet Oncology*

The journal article published today in *The Lancet Oncology* reviews the design and results to date of the original 30 patients from this phase 2 trial. This publication provides a more comprehensive summary than previously disclosed of patient characteristics, treatment regimen and more mature outcome data, including updated Kaplan-Meier curves estimating overall survival and PSA progression-free survival (PFS) as well as a swimmer's plot of the 30 patients.

This study evaluated a heavily pre-treated patient population, 87% of which had received > 1 line of prior chemotherapy (80% docetaxel and 47% cabazitaxel) and 83% received prior abiraterone acetate and/or enzalutamide.

Observations in this study include a PSA reduction of at least 50% from baseline (PSA50) in 57% of patients, a PSA reduction of at least 80% from baseline (PSA80) in 43% of patients and a PSA reduction of > 96% in 20% of patients who were identified as 'exceptional responders'. Regarding disease progression and survival, a median PSA PFS of 7.6 months and a median overall survival (OS) of 13.5 months were observed. Both the median PSA PFS and the median OS reflect improved outcomes versus the 6.3 months and 12.7 months for each endpoint, respectively, previously presented at the 2017 ESMO Congress.

Notably, patients with a PSA50 response had median PSA PFS of 9.9 months and median OS of 17.0 months compared to PSA PFS of 4.1 months and median OS of 9.9 months for those who did not achieve a PSA50 response. Additionally, clinically meaningful improvements in quality of life measures were observed.

17 patients (57%) had prostate cancer working group 2 (PCWG2) RECIST 1.1 evaluable nodal or visceral target lesions following CT scan at baseline. Confirmed objective responses were seen in 14 (82%) of these 17 patients, including complete and partial response rates of 29% and 53%, respectively. This response rate is greater than the 71% PCWG2 RECIST 1.1 objective response rate previously reported.

^{177}Lu-PSMA-617 was well tolerated, with no significant dose-limiting toxicities observed. The most common treatment-related toxicity was Grade 1 xerostomia (dry mouth) seen in 87% of patients, which is higher than previously reported (63%), but generally didn't require any intervention. The occurrence of treatment-related Grade 3-4 hematologic toxicity was low and comparable to the largest retrospective published cohort.[1]

The paper is available online at the following link: https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30198-0/supplemental

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 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 future spending, future cash balances, future use of capital, sufficiency of cash, the timing of initiation, interim assessments and completion of clinical trials, the enrollment period for, and availability and reporting of data from, ongoing and future clinical trials, the occurrence and timing of actions by regulatory agencies, estimates of the potential market opportunity for the company's product candidates, and the company's future development plans including those relating to the completion of pre-clinical development in preparation for possible future clinical trials and future sources of supply of product candidates to support clinical and commercial activities. 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 suppliers or other third party contractors may not fulfill their contractual obligations on a timely basis or at all; 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 thetechnology; 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.

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[1] Rahbar K, Ahmadzadehfar J, Kratochwil C, Haberkorn U, Schäfers M, Essler M, Baum RP, Kulkarni HR, Schmidt M, Drzezga A, Bartenstein P, Pfestroff A, Luster M, Lützen U, Marx M, Prasad V, Brenner W, Heinzel A, Mottaghy FM, Ruf J, Meyer PT, Heuschkel M, Eveslage M, Bögemann M, Fendler WP, Krause BJ. German Multicenter Study Investigating ^{177}Lu-PSMA-617 Radioligand Therapy in Advanced Prostate Cancer Patients. J Nucl Med. 2017;58(1):85-90.

Primary Logo

Source: Endocyte, Inc.