Endocyte, Inc. Logo

Endocyte Announces FDA Acceptance of Radiographic Progression Free Survival (rPFS) as an Alternative Primary Endpoint of the VISION Trial in Addition to Overall Survival (OS)

September 10, 2018

Demonstrating benefit in rPFS versus control, with no detriment to OS, sufficient for full approval

A positive assessment on either rPFS or OS is sufficient for full approval

rPFS analysis expected late 2019, approximately one year ahead of final OS analysis

Conference Call Today at 8:30 a.m. EDT

WEST LAFAYETTE, Ind., Sept. 10, 2018 (GLOBE NEWSWIRE) -- Endocyte, Inc. (Nasdaq:ECYT), a biopharmaceutical company developing targeted therapeutics for personalized cancer treatment, today announced that following a meeting with the U.S. Food and Drug Administration (FDA), it was determined that rPFS is an appropriate efficacy endpoint in the ongoing phase 3 VISION trial to support the submission of a New Drug Application (NDA) for full FDA approval of ^{177}Lu-PSMA-617 for the treatment of metastatic castration-resistant prostate cancer (mCRPC).

"We are very pleased with the FDA's support of the rPFS endpoint as the basis for a submission for full approval of ^{177}Lu-PSMA-617. This change provides an opportunity to obtain a full approval sooner than we previously anticipated and highlights the Agency's commitment to addressing the urgent need for a new mechanism of action to treat mCRPC," said Mike Sherman, president and CEO of Endocyte. "Under the updated protocol, we now expect the analysis of rPFS for potential full approval to occur before the end of 2019. We also retained the final, fully powered OS analysis, which is expected to occur near the end of 2020. This provides two potential paths for approval and preserves a robust OS analysis to support a potential label."

Under the updated VISION trial design, the two interim assessments previously planned at 50% and 70% of OS events will be replaced with a single assessment of rPFS. This assessment is expected to occur at approximately the same time that the first interim OS assessment would have occurred under the prior trial design and shortly after the time the trial is fully enrolled. If ^{177}Lu-PSMA-617 meets the primary endpoint in the rPFS assessment, no unexpected safety issues arise, and it demonstrates no detriment in OS relative to the control arm, Endocyte intends to submit an NDA to seek full approval in the United States. The rPFS analysis will include approximately 450 rPFS events. Regardless of the outcome of the rPFS assessment, Endocyte intends to continue to follow patients in the VISION trial in order to assess the final OS alternative primary endpoint. Other aspects of the trial, including patient treatment and assessments, trial size, overall duration, and follow up remain unchanged. The acceptance of rPFS as a primary endpoint for full approval in Europe will be determined in upcoming regulatory interactions.

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 clinical trial investigator, may include a novel anti-androgen drug such as 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 alternative primary endpoints of the trial agreed to by the FDA are radiographic progression-free survival (rPFS) and overall survival (OS). A positive assessment on either is sufficient for full approval. In the case of the rPFS assessment, a corresponding assessment of OS will be made to ensure no detriment in OS has occurred. Secondary endpoints include response evaluation criteria in solid tumors (RECIST) response and time to first symptomatic skeletal event. An efficacy analysis of rPFS and OS will be conducted at approximately 450 and 490 events, respectively. Further information on the global phase 3 VISION trial can be found at https://visionclinicaltrial.com/.

Conference Call

Endocyte management will host a conference call today at 8:30 a.m. EDT.

U.S. and Canadian participants: (877) 845-0711
International participants: (760) 298-5081

A live, listen-only webcast of the conference call may 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 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, in phase 3 for metastatic castration-resistant prostate

cancer (mCRPC) for PSMA-positive patients. 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 studied initially 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, enrollment, and completion of clinical trials, the likelihood of success of clinical trials and of regulatory approval for product candidates, the timing of regulatory submissions for product candidates, estimates of the market opportunity for 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 in support of clinical and commercial activities. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof. 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, availability of data from, or completion of clinical trials and development programs (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 lack of safety and/or 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's ability to capture value for the technology; risks related to the company's inability to maintain, protect and enhance its intellectual property; risks related to costs associated with defending intellectual property infringement and other claims; 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, supply chain issues of any type, including timing of supply, projected cash needs, projected timing of the use of cash, 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 except as required under applicable law.

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Source: Endocyte, Inc.