ENDOCYTE

October 2, 2017

Endocyte Announces Exclusive Worldwide License of Phase 3 Ready PSMA-Targeted Radioligand Therapy for Development in Prostate Cancer

- Transformational Transaction Provides Endocyte with the Most Advanced Targeted Radioligand Therapy in Development for Prostate Cancer, Addressing a Greater than $1 Billion Market Opportunity -

- High Response Rates Demonstrated in Late Stage Prostate Cancer Patients in Clinical Data Presented at Recent European Society for Medical Oncology -

- Endocyte to Focus Resources on Phase 3 Registration Trial Planned to Initiate in First Half 2018 -

- Investigator Initiated Trials Intended to Support Registration and Provide Ongoing Data Assessments -

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

WEST LAFAYETTE, Ind., Oct. 02, 2017 (GLOBE NEWSWIRE) -- Endocyte, Inc. (NASDAQ Global Market:ECYT), a biopharmaceutical company developing targeted therapeutics for personalized cancer treatment, today announced the completion of an exclusive worldwide license of PSMA-617 from ABX GmbH. Endocyte intends to move quickly into Phase 3 development of ^{177}Lu-PSMA-617, a radioligand therapeutic (RLT) that targets the prostate-specific membrane antigen (PSMA), present in approximately 80% of patients with metastatic castration-resistant prostate cancer (mCRPC).

^{177}Lu-PSMA-617 delivers the short-range beta-emitting radioactive isotope lutetium (^{177}Lu) selectively to tumor cells while by-passing non-PSMA-expressing healthy cells with encouraging efficacy and safety results. As highlighted in roughly 20 peer reviewed publications of studies in the post-chemotherapy compassionate use setting, ^{177} Lu-PSMA-617 has consistently demonstrated a PSA response (defined as greater than 50% decline from baseline) in 40% to 60% of patients, and a RECIST response rate in soft tissue disease of between 40% and 50%.

"This transaction is transformational to Endocyte, accelerating our path to commercialization. ^{177}Lu-PSMA-617 has the potential to be the first-in-class RLT to address both bone and soft tissue disease, and it is profoundly important to the many patients suffering from mCRPC," said Mike Sherman, president and CEO of Endocyte. "Our experience with PSMA targeting and companion imaging development, in addition to our relationships with distinguished prostate cancer investigators from around the world, uniquely position Endocyte to lead this therapy to registration. We intend to seek regulatory approval to initiate a Phase 3 registration trial of ^{177}Lu-PSMA-617 in early 2018. By focusing the company's resources on the execution of this program, we project trial completion as early as 2020."

Mr. Sherman continued, "Endocyte remains strongly committed to careful expense management and maintaining a strong balance sheet. With the exception of a very targeted effort to generate proof-of-concept data for our CAR T-cell program, we will focus our resources on the development of ^{177}Lu-PSMA-617. We will explore out-licensing opportunities for all other development programs."

"Despite advances in the last decade that slow the progression of prostate cancer, once metastasized it is nearly always lethal, leading to 300,000 worldwide deaths annually. ^{177}Lu-PSMA-617 has demonstrated the most compelling activity of any drug currently in development for these post-chemotherapy patients," said Alison Armour, chief medical officer.

PSMA-617 was developed at DKFZ (German Cancer Research Center) and University Hospital Heidelberg and exclusively licensed to ABX GmbH in Germany for early clinical development. As a result of the enthusiasm of physician investigators and patients, the investigational therapy has been evaluated in hundreds of patients through both compassionate use studies and prospective trials.

"The data generated thus far have created significant enthusiasm for ^{177}Lu-PSMA-617. PSMA is a promising target in prostate cancer and radioligand therapy may be the best application for this target," said Michael Morris, MD, associate professor, Genitourinary Oncology, Memorial Sloan Kettering Cancer Center. "Particularly where disease has become resistant to current therapies, there is a tremendous need for new approaches and I look forward to working with Endocyte to investigate this innovative, first-in-class therapy for prostate cancer patients."

Clinical Data Presented at European Society for Medical Oncology (ESMO)

Dr. Michael Hofman of the Peter MacCallum Cancer Center in Melbourne, Australia presented the results of an open-label, single-arm, non-randomized pilot study of ^{177} Lu-PSMA-617 in September 2017, at the European Society for Medical Oncology (ESMO) Congress. Thirty mCRPC patients were treated with up to four cycles of 4-8 GBq. Primary endpoints included safety and efficacy as defined by PSA response, quality of life, and imaging response.

The results showed a remarkable 57% PSA response rate (> 50% reduction) and 71% interim response rate in soft tissue lesions (as measured by RECIST criteria) in patients who had previously failed such conventional therapies as docetaxel, cabazitaxel, enzalutamide and abiraterone. Median overall survival was 12.7 months. The drug was well-tolerated, with a low rate of adverse effects and no renal toxicity. Significantly improved quality of life scores and reduction in pain scores were recorded in 37% and 43% of patients, respectively. This trial has subsequently been expanded to 50 subjects from the original 30, with updated results expected to be presented in 2018.

Transaction Terms

Under the terms of the agreement, Endocyte has exclusive worldwide rights to develop and commercialize PSMA-617. Endocyte has made an upfront payment of $12 million to ABX. In addition, Endocyte issued 2 million shares of Endocyte common stock to ABX and issued a warrant for the purchase of up to 4 million additional shares of Endocyte common stock. ABX is eligible for regulatory and commercial milestones of up to $160 million, and tiered royalties beginning in the mid-teens.

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: (760) 298-5081

A live, listen-only webcast of the conference call may also 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 treatment of cancer. Endocyte uses drug conjugation technology to create novel therapeutics and companion imaging agents for personalized targeted therapies. The company's agents actively target receptors that are over-expressed on diseased cells relative to healthy cells, such as prostate specific membrane antigen (PSMA) in prostate cancer. This targeted approach is designed to safely enable the delivery of highly potent drug payloads. The companion imaging agents are designed to identify patients whose disease over-expresses the target of the therapy and who are therefore more likely to benefit from treatment. 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, the timing of initiation and completion of clinical trials, 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. 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 of 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's ability to capture value for the technology; 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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Primary Logo

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