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Merck and Endocyte Announce European CHMP Positive Opinions for VYNFINIT® (vintafolide) and Companion Imaging Agents FOLCEPRI® (etarfolatide) and NEOCEPRI® (Intravenous (IV) folic acid) in Patients with Platinum-Resistant ...

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Merck (NYSE:MRK), known as MSD outside the United States and Canada, and Endocyte, Inc. (NASDAQ:ECYT), today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued positive opinions for the Conditional Marketing Authorisations of VYNFINIT® (vintafolide) and companion imaging components, imaging agent FOLCEPRI® (etarfolatide), and NEOCEPRI® (intravenous (IV) folic acid), for the treatment of adult patients with folate receptor-positive, platinum-resistant, ovarian cancer, in combination with pegylated liposomal doxorubicin (PLD).

"These positive CHMP opinions bring Merck and Endocyte one step closer to providing a personalized approach to address a significant unmet medical need in platinum-resistant ovarian cancer," said Dr. Eric Rubin, vice president, Clinical Development for Oncology, Merck Research Laboratories. "We want to acknowledge our colleagues at Endocyte for their pioneering work in this field, and look forward to the European Commission completing their review of the applications."

"Vintafolide is a folate receptor targeted agent, and if approved, would be the first oncology therapeutic to employ an imaging agent as a companion diagnostic for patient selection," said Ron Ellis, Endocyte's president and CEO. "Today's positive CHMP opinions are an important step toward personalizing ovarian cancer management for appropriate patients, and validate our Company's focus on the development of targeted medicines and companion imaging agents designed to improve patient outcomes."

Vintafolide is proposed for use in combination with PLD for the treatment of adult patients with platinum-resistant ovarian cancer who express the folate receptor on all target lesions. Folate receptor status should be assessed by a diagnostic medicinal product approved for the selection of adult patients for treatment with vintafolide, using Single Photon Emission Computed Tomography (SPECT) imaging, in combination with Computed Tomography (CT) or Magnetic Resonance Imaging (MRI).

Etarfolatide and IV folic acid are medicinal products proposed for diagnostic use only. Etarfolatide, following radiolabelling with sodium pertechnetate (^{99m}Tc) solution, is proposed for SPECT imaging in combination with CT or MRI, for the selection of adult patients for treatment with vintafolide. Intravenous folic acid would be administrated prior to ^{99m}Tc-etarfolatide for the enhancement of SPECT image quality.

The applications for Conditional Marketing Authorisation for vintafolide, etarfolatide and IV folic acid were submitted based on results in platinum-resistant ovarian cancer patients who express the folate receptor on all target lesions as evaluated in the PRECEDENT Phase 2 study (ClinicalTrials.gov Identifier: NCT00722592).

The CHMP positive opinions will be reviewed by the European Commission (EC). If approved, the EC grants a centralized marketing authorization with unified labeling that is valid in the 28 countries that are members of the European Union, as well as European Economic Area members Iceland, Liechtenstein and Norway. The EC usually issues a final legally binding decision within three months of a CHMP opinion.

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 - 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 ^{99m}Tc-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). The randomized TARGET Phase 2b study of vintafolide in non-small cell lung cancer has completed enrollment (ClinicalTrials.gov Identifier: NCT01577654), and a Phase 2 study in triple-negative breast cancer is expected to be initiated in Q2 (ClinicalTrials.gov Identifier: NCT01953536).

About Folate Receptor-Positive Platinum-Resistant Ovarian Cancer

In 2012, it was estimated that there would be over 40,000 new cases of ovarian cancer in the European Union. Ovarian cancer is one of the most lethal cancers of the female reproductive system. Overall, approximately 80 percent of patients relapse after first-line, platinum-based, chemotherapy. Platinum-resistant ovarian cancer, also known as PROC, is a challenging disease with a high unmet need for new treatments. This type of cancer recurs within six months of completion of a platinum-containing regimen, the standard of care for ovarian cancer. An estimated 80 percent of platinum-resistant ovarian cancer patients have been found to have folate receptor-positive disease, and approximately 40 percent express the receptor, as detected by etarfolatide, in all of their target tumor lesions (FR 100%). Compared to patients who do not express folate receptors on their tumors, folate receptor-positive patients have been shown to have a poorer overall prognosis.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook and YouTube.

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.

Merck Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2013 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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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