



NEWS RELEASE

# Merck and Endocyte Announce Acceptance for Review of European Marketing Authorization Applications for Vintafolide and Companion Diagnostic Etarfolatide for Folate-Receptor Positive Platinum-Resistant Ovarian Cancer

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Novel personalized treatment approach targets folate receptors on cancer cells

Merck, known as MSD outside the United States and Canada (NYSE: MRK), and Endocyte Inc. (NASDAQ: ECYT), today announced that the European Medicines Agency (EMA) has accepted for review the marketing authorization application (MAA) filings for the novel investigational cancer candidate vintafolide (MK-8109/EC145) and investigational companion diagnostic imaging agent etarfolatide (EC20), for the targeted treatment of patients with folate-receptor positive platinum-resistant ovarian cancer in combination with pegylated liposomal doxorubicin (PLD). Both vintafolide and etarfolatide have been granted orphan drug status by the European Commission.

Vintafolide is a proprietary, injectable, conjugate consisting of folate (vitamin B9) linked to a potent vinca alkaloid anti-cancer agent, desacetylvinblastine hydrazide (DAVLBH). Folate is essential for cell division, and cancer cells generally consume higher levels of folate than normal cells to fuel their rapid rate of growth and division. In order to satisfy the demand for folate, some cancer cell types – including ovarian – express high concentrations of folate receptors on their surface. Vintafolide is designed to exploit this characteristic by selectively targeting the folate receptor to deliver the anti-cancer agent DAVLBH intracellular to the tumor.

"The acceptance of the EMA filing for vintafolide is an important milestone for Merck and Endocyte," said Gary

Gilliland, M.D., Ph.D., senior vice president and oncology franchise head, Merck Research Laboratories. "Vintafolide is designed to preferentially target cancer cells that actively take up folate via the folate receptor."

The MAA filings are supported by four clinical studies: a Phase I study in solid tumors, two single-agent, single-arm Phase II studies in ovarian cancer and non-small cell lung cancer, and the PRECEDENT trial, a randomized Phase IIb study in patients with platinum-resistant ovarian cancer. The application is being submitted for conditional approval on the basis that the results from the Phase II studies fulfill an unmet medical need.

Vintafolide is currently being evaluated in a Phase III randomized, double-blind clinical trial for platinum-resistant ovarian cancer (PROCEED trial). The PROCEED trial is evaluating vintafolide in combination with PLD compared to PLD plus placebo for the treatment of folate-receptor positive platinum-resistant ovarian cancer. This trial also employs the companion diagnostic imaging agent etarfolatide, which is a molecular imaging agent that is being developed as a non-invasive method to identify tumors that over-express folate receptors. The primary endpoint of the trial is progression-free survival as measured by RECIST v 1.1 (Response Evaluation Criteria In Solid Tumor) criteria in patients with all target tumor lesions positive as assessed by etarfolatide imaging. Overall survival is a secondary endpoint. The trial anticipates recruiting patients at approximately 150 sites in the United States, Canada, Europe and Asia. For further information regarding these trials, please visit <http://www.clinicaltrials.gov>.

"We are pleased with the acceptance of the applications in Europe as an important milestone towards providing a new treatment option targeted for folate-receptor positive platinum-resistant ovarian cancer patients," said Ron Ellis, Endocyte's president and CEO. "The use of etarfolatide as a companion diagnostic imaging agent to guide patient selection for vintafolide is a key element in implementing a personalized medicine approach to treating ovarian cancer."

As part of an exclusive license agreement with Endocyte, Merck, through an MSD affiliate, is responsible for the development and worldwide commercialization of vintafolide in oncology. Endocyte intends to co-promote vintafolide in the United States, and is responsible for the development, manufacture and commercialization of etarfolatide worldwide. Merck will pay Endocyte a \$5 million milestone payment for the EMA filing acceptance.

## About Folate-Receptor Positive Platinum-Resistant Ovarian Cancer

In 2012, it is estimated that there will be 22,280 new cases of ovarian cancer in the United States and over 40,000 new cases in the European Union. Ovarian cancer causes more deaths than any other cancer of the female reproductive system. Overall, approximately 80 percent of patients relapse after first-line platinum-based chemotherapy. Platinum-resistant ovarian cancer is a challenging disease with a high unmet need. This type of cancer recurs within six months of completion with 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 40 percent express the receptor in all of their target tumor lesions. 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](http://www.merck.com).

## About Endocyte

Endocyte is a biopharmaceutical company developing targeted therapies for the treatment of cancer and other serious diseases. Endocyte uses its proprietary technology to create novel Small Molecule Drug Conjugates (SMDCs) and companion imaging diagnostics for personalized targeted therapies. The company's SMDCs actively target receptors that are over-expressed on diseased cells, relative to healthy cells, and deliver highly potent drugs into these cells. Patients can be identified prior to the treatment with the corresponding companion imaging diagnostic. For more information, visit [www.endocyte.com](http://www.endocyte.com).

## 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. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that all of the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to 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 2011 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](http://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 partnership. 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 PLD, 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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