

## Endocyte Announces Interim Results from Randomized Phase II Ovarian Cancer Trial at ASCO

- **Investigational drug combination doubled progression-free survival from 3 to 6 months in women with platinum-resistant ovarian cancer**
- **Phase III clinical trial to begin later this year**

**WEST LAFAYETTE, Ind.** - June 5, 2010 - Endocyte, Inc., a company developing targeted small-molecule drug conjugates, will present results of an interim analysis from a randomized phase II clinical trial in women with platinum-resistant ovarian cancer Sunday (June 6) during the 46<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Ill.<sup>1</sup>

The results of the interim analysis indicate that the investigational agent EC145 plus Doxil<sup>®2</sup> doubled the median progression-free survival compared to Doxil alone, increasing from approximately 3 months to 6 months (hazard ratio of 0.497; p-value<sup>3</sup> of 0.014). The preliminary overall survival analysis also indicates a trend toward benefit in the EC145 plus Doxil arm (hazard ratio of 0.425; p-value<sup>3</sup> of 0.064). The interim analysis was based on data from 91 women.

“The combination of EC145 and Doxil is the first treatment in a randomized study to show such a magnitude of improvement in progression-free survival for these women,” said Wendel Naumann, M.D., gynecologic oncologist at Carolinas Healthcare System. “These results are important, because the disease rapidly progresses in women who are highly resistant to standard chemotherapy.”

### Clinical Trial Design

The international, multi-center randomized trial has enrolled approximately 150 women who had received two or fewer prior systemic cytotoxic regimens and had disease that was resistant to platinum therapy. Patients were randomized to receive EC145 (2.5 mg 3 times a week intravenously weeks 1 and 3) plus Doxil (50 mg/m<sup>2</sup> intravenously every 28 days) or Doxil alone at the same dose until disease progression or death. Interim analysis results also indicated that the combination of EC145 plus Doxil was very well tolerated, with no statistical difference between treatment arms with regard to total adverse events or serious adverse events.

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<sup>1</sup> Naumann, et al. “A randomized phase II trial comparing EC145 and pegylated liposomal doxorubicin (PLD) in combination, versus PLD alone, in subjects with platinum-resistant ovarian cancer.” Presented at 2010 American Society of Clinical Oncology Annual Meeting, June 6, 2010.

<sup>2</sup> Doxil is a registered trademark and the property of its owner.

<sup>3</sup> One-sided logrank test.

“We are particularly pleased with the results of the interim analysis,” said Richard Messmann, M.D., vice president of medical affairs at Endocyte. “Enrollment in this phase II trial is now complete and we look forward to reporting the final results of the study in early 2011 and beginning the phase III study later this year.”

More information about enrollment in the phase III study will be available in early fall at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About Platinum-Resistant Ovarian Cancer**

Ovarian cancer is the fifth leading cause of cancer death among women in the United States<sup>4</sup>. Women with ovarian cancer who respond to initial or secondary platinum-containing systemic therapy but experience disease progression after a treatment-free interval of less than six months are considered to have platinum-resistant disease. These women have a limited number of therapeutic options and often receive topotecan or Doxil. These agents provide patients with a median progression-free survival of approximately 3 months<sup>5</sup>.

### **About EC145**

EC145 is a conjugate of the vitamin folate and a very potent vinca alkaloid. Folate is required for cell division, and rapidly dividing cancer cells over-express folate receptors in order to capture enough folate to support cell division. By attaching a chemotherapy drug to folate through proprietary chemistry, EC145 targets cancer cells while avoiding most normal cells. This targeted approach is designed to provide treatment with potent drugs while lowering toxicity over standard chemotherapy.

### **About Endocyte**

Endocyte is a privately held clinical-stage company headquartered in the Purdue Research Park in West Lafayette, Ind. Based on the applications of Endocyte’s advanced small-molecule drug conjugate technology, the company is working to develop new drugs and diagnostic agents to treat many types of cancer and other serious diseases. The small-molecule drug targeted platform makes it possible to use highly potent drugs on extended and frequent dosing schedules and in combination with other drugs to maximize efficacy. The technology is designed to improve drug targeting and reduce the risk of side effects by combining drugs with ligands that are able to identify and attach to receptors found on tumor and other disease cells. For more information, visit [www.endocyte.com](http://www.endocyte.com).

*This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve significant risks and uncertainties that may cause results to differ materially from those set forth in the statements. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.*

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<sup>4</sup> American Cancer Society. Available at [http://www.cancer.org/docroot/CRI/content/CRI\\_2\\_2\\_1X\\_How\\_many\\_women\\_get\\_ovarian\\_cancer\\_33.asp?sitearea=](http://www.cancer.org/docroot/CRI/content/CRI_2_2_1X_How_many_women_get_ovarian_cancer_33.asp?sitearea=). Accessed May 28, 2010.

<sup>5</sup> Gordon et al, Recurrent Epithelial Ovarian Carcinoma: A Randomized Phase III Study of Pegylated Liposomal Doxorubicin Versus Topotecan. *Journal of Clinical Oncology* 2001(19): 3312-3322.