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THE OVARIAN CANCER NATIONAL ALLIANCE EXPRESSES CONCERN OVER TODAY'S ANNOUNCEMENT REGARDING AVASTIN

Washington DC – *December 16, 2010*. The Ovarian Cancer National Alliance expresses concern over the Food and Drug Administration's (FDA) announcement today to pull the metastatic breast cancer indication from the Avastin (bevacizumab) label. This decision comes six months after an Oncology Drug Advisory Committee recommended the label change, and was expected, but not welcomed, by advocates in the ovarian cancer community.

Avastin is commonly used off-label to treat ovarian cancer, based on the results of numerous published articles including two Phase III studies. The treatment does not work for everyone, but for some women with ovarian cancer, it has been incredibly helpful. Many women with ovarian cancer already face obstacles to receiving insurance coverage for Avastin, although it is contained in government-recognized compendia. Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research, with a nod to personalized medicine, admitted that the drug did work well for some people. Nonetheless, the Ovarian Cancer National Alliance remains concerned that this decision will have a chilling effect on prescribing and coverage for ovarian cancer patients.

Further, the FDA decision calls into question the use of Progression Free Survival (PFS) as an endpoint for cancer clinical trials. Previously, the FDA has approved treatments when they have been shown to increase PFS – the time that a patient's tumor does not grow. This intermediate measure has been acceptable in the past. The FDA release stated that the increase in PFS for metastatic breast cancer reflected "a small, temporary effect in slowing tumor growth." Dr. Woodcock continued that while the FDA does evaluate length of life and quality of life, but that in this case the risks outweigh the benefits. The European Committee for Medicinal Products confirmed that the benefits outweigh the risks; the National Comprehensive Cancer Networks recently reviewed its compendia for breast cancer and its panel of experts kept Avastin on the compendia to treat the disease.

Dr. Woodcock stated that "there will be no disruption in treatment" for women with breast cancer who are being treated with Avastin. Dr. Woodcock said that the Centers for Medicare and Medicaid Services have not yet reviewed its reimbursement policy for the use of Avastin for breast cancer in light of the FDA's decision. The manufacturer of the drug stated that it would request a hearing to maintain the drug as an option for women with breast cancer.

Avastin was approved for breast cancer through an accelerated approval process. The FDA's approval for brain cancer was also conducted under an accelerated approval based on overall response rate – reducing in size or disappearance of the tumor. Dr. Woodcock stated that the label with respect to brain, lung and colon cancers is not affected by today's announcement.

Dr. Richard Pazdur, MD director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research, stated that the "findings are disappointing for patients with breast cancer"and "for FDA as well", who had positive expectations for the drug.

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The Ovarian Cancer National Alliance is the foremost advocate for women with ovarian cancer in the United States. To advance the interests of women with ovarian cancer, the organization advocates at a national level for increases in research funding for the development of an early detection test, improved health care practices, and life-saving treatment protocols. The Ovarian Cancer National Alliance educates health care professionals and raises public awareness of the signs and symptoms of ovarian cancer. The Ovarian Cancer National Alliance is a 501 (c) (3) organization established in 1997. For more information, visit www.ovariancancer.org.