

AVEO and Astellas Announce Initiation of Patient Enrollment in Phase 2 Trial of Tivozanib in Combination with Paclitaxel in Patients with Advanced Triple Negative Breast Cancer

BATON-BC Trial Initiation Marks Entry into Third Tumor Type for Tivozanib Clinical Development Program

CAMBRIDGE, Mass. and TOKYO, Japan, December 3, 2012 - AVEO Oncology (NASDAQ: AVEO) and Astellas Pharma Inc. (TSE: 4503) today announced the initiation of patient enrollment in a randomized, double-blind, multicenter Phase 2 clinical trial, called BATON-BC, evaluating the efficacy of tivozanib, an investigational drug, in combination with paclitaxel compared to placebo in combination with paclitaxel in patients with locally recurrent or metastatic triple negative breast cancer who have received no prior systemic therapy for advanced or metastatic breast cancer (mBC). Triple negative breast cancer was selected for tivozanib clinical evaluation because of high unmet need and insights gained from AVEO's Human Response Platform™ indicating that these tumors are enriched for a signature of VEGF pathway deregulation similar to that seen in renal cell carcinoma (RCC). BATON-BC is the third trial to be initiated as part of the BATON (Biomarker Assessment of Tivozanib in ONcology) clinical development program, which includes ongoing trials in advanced metastatic colorectal cancer (CRC) and advanced RCC.

“While currently available chemotherapy and hormonal therapies have significantly enhanced the survival of women diagnosed with breast cancer, there remains an unmet treatment need for those fighting advanced triple negative breast cancer.” said Erica Mayer, M.D., M.P.H., director of Clinical Research, Dana-Farber/Brigham and Women's Cancer Center at Faulkner Hospital, assistant professor in medicine, Harvard Medical School, and BATON-BC primary investigator. “The BATON-BC trial is designed to evaluate progression free survival as well as improve our understanding of triple negative breast cancer by providing us with the opportunity to identify the patients who are most likely to be responsive or resistant to tivozanib therapy.”

BATON-BC, which is being led by AVEO, is a double-blind, placebo-controlled, randomized (2:1 tivozanib/placebo), multicenter study that will enroll approximately 147 patients at 50 sites worldwide. The primary endpoint of BATON-BC is progression-free survival (PFS). Secondary objectives include evaluation of objective response rate, overall survival and safety. An additional component of BATON-BC is the evaluation of biomarker relationships that may be predictive of clinical response to tivozanib in patients with triple negative breast cancer.

“While tivozanib is currently under review with FDA for advanced RCC, we're committed to investigating the development of tivozanib beyond advanced RCC,” said Stephen Eck, M.D., Ph.D., Vice President of Medical Oncology, Astellas Pharma Global Development. “At Astellas, we are committed to discover and develop molecularly targeted therapies and precision medicines that have the potential to revolutionize the methods used to treat cancer patients.”

Data from a Phase 1b clinical trial of tivozanib (0.5 mg - 1.5 mg per day for three weeks, followed by one week off, repeating at a cycle of 28 days) in combination with weekly paclitaxel (three weeks on, followed by one week off) in patients with metastatic breast cancer demonstrated that the combination was considered tolerable at the full dose and schedule of both agents (tivozanib 1.5 mg and paclitaxel 90

mg/m²), and resulted in an objective response rate of 38% (5/13 patients). In the study, 54% (7/13) of patients had stable disease (SD), with a median duration of SD of 8.5 months (range: 4.2–10.7).¹

“Currently there are no approved targeted therapies for the treatment of triple negative breast cancer. Biomarkers derived from AVEO’s Human Response Platform will be evaluated for potential use in identifying breast cancer patients who will be most likely to benefit from treatment with tivozanib,” said William Slichenmyer, M.D., Sc.M., chief medical officer at AVEO. “Following the recent submission of a New Drug Application to the FDA seeking approval for tivozanib in advanced RCC, we remain committed to expanding the development of tivozanib in additional solid tumor types, and look forward to further evaluating tivozanib as a potential new treatment option for patients living with triple negative breast cancer.”

About Triple Negative Breast Cancer

Globally, breast cancer is diagnosed in about 1.4 million women annually and about 230,000 women annually in the United States.² About 1 in 8 women will develop invasive breast cancer during their lifetime.³

Triple negative breast cancer is comprised of tumors that do not express the estrogen receptor (ER), progesterone receptor (PR) or the human epidermal growth factor receptor-2 (HER2) and accounts for approximately 12-20% of breast cancers.^{2,3} Receptor expression is typically confirmed at the time of a breast cancer diagnosis. There are currently no approved targeted therapies for triple negative breast cancer.

About Tivozanib

Tivozanib is a potent, selective and long half-life inhibitor of all three vascular endothelial growth factor (VEGF) receptors that is designed to optimize VEGF blockade while minimizing off-target toxicities. Tivozanib is an oral, once-daily, investigational tyrosine kinase inhibitor for which positive results from a Phase 3 clinical study in advanced RCC have been reported, and is being evaluated in other tumors.

About BATON-BC

BATON-BC is a double-blind, placebo-controlled, randomized (2:1 tivozanib/placebo), multicenter study that will enroll approximately 147 patients at 50 sites worldwide. The trial is comparing progression-free survival (PFS) of triple negative breast cancer patients treated with tivozanib in combination with paclitaxel versus placebo in combination with paclitaxel. Secondary objectives include evaluation of objective response rate, overall survival and safety. Additional exploratory objectives include the evaluation of potential tumor biomarkers predictive of tumor sensitivity and/or resistance to tivozanib in combination with paclitaxel and effectiveness of tivozanib in combination with paclitaxel in defined intrinsic molecular breast cancer subtypes.

About the AVEO/Astellas Collaboration

In February 2011, AVEO and Astellas entered into a worldwide agreement to develop and commercialize tivozanib outside of Asia for the treatment of a broad range of cancers. Tivozanib, AVEO’s lead investigational drug, is a potent, selective, long half-life inhibitor of all three vascular endothelial growth factor (VEGF) receptors that is designed to optimize VEGF blockade while minimizing off-target toxicities. Subject to regulatory approval, AVEO will lead commercialization of tivozanib in North America and Astellas will lead commercialization of tivozanib in the European Union (EU).

About Astellas

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious Diseases, Oncology, Neuroscience and DM Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit the company website at www.astellas.com/en.

About AVEO

AVEO Oncology (NASDAQ: AVEO) is a cancer therapeutics company committed to discovering, developing and commercializing targeted therapies to impact patients' lives. AVEO's proprietary Human Response Platform™ provides the company unique insights into cancer biology and is being leveraged in the discovery and clinical development of its cancer therapeutics. For more information, please visit the company's website at www.aveooncology.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “target,” “potential,” “could,” “should,” “seek,” or the negative of these terms or other similar expressions, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: tivozanib’s potential role in treating patients with triple negative breast cancer; the BATON-BC trial improving AVEO’s understanding of triple negative breast cancer; assessing biomarkers to predict clinical response to tivozanib in patients with triple negative breast cancer and identify a targeted treatment regimen for such patients; developing medicines that revolutionize the methods used to treat cancer patients; plans by AVEO and Astellas to commercialize tivozanib in North America and the EU, respectively; and AVEO’s plans to leverage its Human Response Platform™. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that AVEO makes due to a number of important factors, including risks relating to: whether the results of AVEO’s Phase 3 TIVO-1 trial (Tivozanib Versus sQrafenib in 1st line advanced RCC) are sufficient to obtain marketing approval for tivozanib, which turns on the ability of AVEO to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities the safety and efficacy of tivozanib based upon the findings of TIVO-1, including its data with respect to PFS, the rate of adverse events, overall survival and other information that the FDA may determine to be relevant to approvability; AVEO’s ability to demonstrate in subsequent trials any safety and efficacy it demonstrated in earlier trials of tivozanib; ongoing regulatory requirements with respect to the approval of tivozanib, including the risk that the FDA or any comparable foreign regulatory agency could require additional positive clinical trials as the basis for product approval; AVEO’s ability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates and technologies; unplanned operating expenses; AVEO’s ability to raise the substantial additional funds required to achieve its goals; adverse general economic and industry conditions; competitive factors; AVEO’s ability to maintain its collaboration with Astellas; AVEO’s and Astellas’ ability to successfully launch and commercialize tivozanib if and when it may be approved for commercialization; and those risks discussed in the section titled “Risk Factors” and elsewhere in AVEO’s most recent Quarterly Report on Form 10-Q and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent AVEO’s views as of the date of this press release. AVEO anticipates that subsequent events and developments will cause its views to change. However, while AVEO may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You

should, therefore, not rely on these forward-looking statements as representing AVEO's views as of any date subsequent to the date of this press release.

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¹ Mayer, EL et al. Combination of tivozanib (AV-951) with weekly paclitaxel for metastatic breast cancer: Results of a phase I study. *J Clin Oncol* 29: 2011 (suppl; abstr 1092).

² Carey LA, Perou CM, Livasy CA et al. Race, breast cancer subtypes, and survival in Carolina Breast Study. *JAMA* 2006; 295:2492-2502.

³ Dent R, Trudeau M, Pritchard KI et al. Triple-negative breast cancer: clinical features and patterns of recurrence. *Clin. Canc. Res.* 2007; 13:4429-4434.