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AVEO and Astellas Announce Tivozanib Successfully Demonstrated Progression-Free Survival Superiority over Sorafenib in Patients with Advanced Renal Cell Cancer in Phase 3 TIVO-1 Trial

TIVO-1 is the First Registration Trial to Compare an Investigational Agent to an Approved VEGF Therapy in First-line RCC; AVEO Conference Call Today at 8:30 a.m. ET

CAMBRIDGE, MASS. and TOKYO, JAPAN, January 3, 2012 – AVEO Pharmaceuticals, Inc. (NASDAQ: AVEO) and Astellas Pharma Inc. (TSE: 4503) today announced that tivozanib demonstrated superiority over sorafenib in the primary endpoint of progression-free survival (PFS) in TIVO-1, a global, randomized Phase 3 clinical trial evaluating the efficacy and safety of investigational drug tivozanib compared to sorafenib in 517 patients with advanced renal cell carcinoma (RCC). TIVO-1 is the first registration study in first-line RCC that is comparing an investigational agent against an approved VEGF therapy.

All patients in TIVO-1 had clear cell RCC, had undergone a prior nephrectomy, and had not previously been treated with either a VEGF or mTOR therapy. Based on the top-line analysis of events in TIVO-1, determined by a blinded, independent review committee, key top-line findings include:

- tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 11.9 months compared to a median PFS of 9.1 months for sorafenib in the overall study population
- tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 12.7 months compared to a median PFS of 9.1 months for sorafenib in the pre-specified subpopulation of patients who were treatment naïve (no prior systemic anti-cancer therapy); this subpopulation was approximately 70% of the total study population
- tivozanib demonstrated a well-tolerated safety profile consistent with the Phase 2 experience; the most commonly reported side effect was hypertension, a well established on-target and manageable effect of VEGFR inhibitors

Based on these data, AVEO and Astellas currently plan to submit for marketing approval of tivozanib in the United States and Europe in 2012, subject to final collection and analyses of all available data from the trial.

“We are very pleased by these results, especially the PFS benefit demonstrated in the treatment naïve population, which represents the most significant market opportunity for tivozanib,” said Tuan Ha-Ngoc, president and chief executive officer, AVEO. “In addition, we were delighted with the favorable safety profile observed in TIVO-1. We would like to acknowledge the investigators and patients who participated in TIVO-1 for their important contributions and commitment to the treatment of patients with RCC.”

The study participants continue to be observed to gather additional data for further analyses. AVEO and Astellas plan to submit detailed findings from TIVO-1 for presentation at the 2012 Annual Meeting of the American Society of Clinical Oncology (ASCO) being held June 1-5, 2012 in Chicago.

“We are delighted with the outcome of TIVO-1 and to be collaborating with AVEO on tivozanib at this critical juncture,” said Steven Ryder, M.D., president, Astellas Pharma Global Development. “Tivozanib is an important asset to our strategy of becoming a global category leader in oncology. We look forward to working closely with our global partner AVEO on next steps for regulatory filings for RCC and advancing clinical development of tivozanib in colorectal cancer and other solid tumors.”

AVEO Conference Call Information
AVEO will hold a conference call to discuss the top-line results of the TIVO-1 trial today at 8:30 a.m. ET. The call can be accessed by dialing 1-866-825-3354 (domestic) or 1-617-213-8063 (international) five minutes prior to the start of the call and providing the passcode 17542026. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing 1-888-286-8010 (domestic) or 1-617-801-6888 (international), providing the passcode 21404848. The replay of the call will be available for two weeks from the date of the live call.

A live, listen-only webcast of the conference call can also be accessed by visiting the investors section of the AVEO website at investor.aveopharma.com. A replay of the webcast will be archived on the company's website for two weeks following the call.

About Renal Cell Carcinoma
Advanced RCC, or kidney cancer, is the ninth most commonly diagnosed cancer in men and women in the U.S.[i] Worldwide it is estimated that more than 250,000 people are diagnosed and more than 100,000 people die from the disease each year.[ii] RCC accounts for 90 percent of all malignant kidney tumors.[iii] Despite advances in RCC therapies, significant unmet need persists.

About Tivozanib
Tivozanib is a potent, selective and continuous 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 top-line results from a Phase 3 clinical study in advanced renal cell carcinoma have been reported, and is being evaluated in other tumors.

About the AVEO/Astellas Collaboration
In February 2011, AVEO and Astellas entered into a worldwide agreement outside of Asia to develop and commercialize tivozanib for the treatment of a broad range of cancers. Tivozanib, AVEO's lead investigational drug, is a potent, selective and continuous 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). AVEO and Astellas are evaluating tivozanib in clinical trials in multiple solid tumors; updates on the progress of those trials are expected to be available in the coming months.

About AVEO
AVEO Pharmaceuticals (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.aveopharma.com.

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 16,800 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 Metabolic Diseases. For more information on Astellas Pharma Inc., please visit the company website at www.astellas.com/en.

AVEO Cautionary Note Regarding Forward-Looking Statements
Any statements in this press release about AVEO's future expectations, plans and prospects, including statements about: the potential efficacy and safety of tivozanib; the anticipated regulatory filings related to tivozanib; making tivozanib available to patients in the future; advancement of the tivozanib clinical development plan in tumors other than RCC, tivozanib's therapeutic potential, as both a single agent and in combination with other anti-cancer therapies; the potential of AVEO's cancer biology platform to offer a unique advantage in oncology drug development; and other statements containing the words "believes," "anticipates," "plans," "expects," "potential," "will" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: AVEO's ability to successfully research, develop and obtain and maintain regulatory approvals for tivozanib and its other product candidates, including risks relating to its ability to successfully advance regulatory filings both domestically and abroad relating to the use of tivozanib for the treatment of RCC; the possibility that favorable historical preclinical and clinical trial results may not be

predictive of the results in future preclinical and clinical trials; AVEO's ability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates and technologies; AVEO's ability to successfully maintain its strategic collaborations, including its collaboration with Astellas for the development and commercialization of tivozanib; unplanned operating expenses; AVEO's ability to raise substantial additional funds to achieve its goals, including with respect to the further development of tivozanib; competition; general economic and industry conditions; and other factors discussed in the "Risk Factors" section of AVEO's Annual Report on Form 10-K filed with the Securities and Exchange Commission, and in other filings that AVEO periodically makes with the SEC. In addition, the forward-looking statements included 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, AVEO specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing AVEO's views as of any date subsequent to the date of this press release.

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[i] U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999–2007 Incidence and Mortality Web-based Report. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2010. Available at: www.cdc.gov/uscs.

[ii] Cancer Research UK http://info.cancerresearchuk.org/cancerstats/world/the-global-picture/#Common; http://publications.cancerresearchuk.org/downloads/Product/cs_pdf_worldwide_2011.pdf

[iii] Motzer RJ, et al. JCO 2009- Sutent.