



## **AVEO and Astellas Announce FDA Acceptance of NDA Filing for Tivozanib for the Treatment of Advanced Renal Cell Carcinoma**

**CAMBRIDGE, Mass. and TOKYO, Japan, November 28, 2012** -- AVEO Oncology (NASDAQ: AVEO) and Astellas Pharma Inc. (TSE: 4503) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for tivozanib with the proposed indication for the treatment of patients with advanced renal cell carcinoma (RCC). Tivozanib is an investigational medicine and is not currently approved in any country. According to the timelines established by the Prescription Drug User Fee Act (PDUFA), the review of the NDA is expected to be complete by July 28, 2013.

The NDA includes results of the global Phase 3 TIVO-1 ([Tivozanib Versus SOrafenib in 1st line Advanced RCC](#)) trial, a randomized superiority-designed pivotal trial evaluating the efficacy and safety of tivozanib compared to sorafenib, an approved targeted agent, in 517 patients with advanced RCC, as well as data from 16 additional AVEO-sponsored studies involving over 1,000 subjects who received tivozanib. [Results of TIVO-1](#) were presented at the 2012 Annual Meeting of the American Society for Clinical Oncology (ASCO).

The proposed brand name for tivozanib is TIVOPATH™, which is a trademark of AVEO Pharmaceuticals, Inc. This name has received conditional acceptance from the FDA and the European Medicines Agency (EMA), but final approval by the FDA and EMA is pending. Tivozanib is an investigational compound. Its safety and efficacy have not yet been fully established.

The FDA's acceptance of the NDA triggers a \$15 million milestone payment to AVEO under its development and commercialization agreement with Astellas.

### **About Kidney Cancer**

Advanced RCC, or kidney cancer, is the ninth most commonly diagnosed cancer in men and women in the U.S.<sup>1</sup> Worldwide it is estimated that more than 250,000 people are diagnosed and more than 100,000 people die from the disease each year.<sup>2</sup> RCC accounts for more than 90 percent of all kidney cancers.<sup>3</sup> Currently available therapies provide less than one year of median PFS in treatment naive patients and are associated with significant toxicities.<sup>4</sup> These toxicities not only lead to high rates of dose reductions and interruptions (potentially compromising efficacy), but also can impact a patient's quality of daily living.<sup>5</sup>

### **About Tivozanib**

Tivozanib 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. Tivozanib is an oral, once-daily, investigational tyrosine kinase inhibitor for which positive results from a Phase 3 clinical study in advanced renal cell carcinoma have been reported. Tivozanib is also under evaluation across a broad range of solid tumors, including metastatic colorectal cancer and metastatic breast cancer.

### **About Astellas**

Astellas Pharma Inc., headquartered 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 Oncology, Urology, Immunology (including Transplantation) and Infectious Diseases, Neuroscience and DM Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit the company's website at [www.astellas.com/en](http://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](http://www.aveooncology.com).

### **Cautionary Note Regarding Forward-Looking Statements**

*This press release contains forward-looking statements of AVEO within the meaning of The Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements. 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: the targeted date for the completion of the FDA's review of the NDA; tivozanib's potential in treating patients with kidney cancer, 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 TIVO-1 are sufficient to obtain marketing approval for tivozanib in the U.S. and abroad, 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 progression-free survival, 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 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.*

Monique Allaire, AVEO Oncology  
(617) 299-5810

**Investor Contact:**

**Media Contacts:**

**AVEO**

Rob Kloppenburg, AVEO Oncology  
(617) 930-5595

**Astellas Pharma Inc.**

Jenny Kite, Astellas US LLC  
(224) 205-5405

###

<sup>1</sup>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](http://www.cdc.gov/uscs).

<sup>2</sup>Cancer Research UK. Available at: [http://info.cancerresearchuk.org/cancerstats/world/the-global-picture/#Common;http://publications.cancerresearchuk.org/downloads/Product/cs\\_pdf\\_worldwide\\_2011.pdf](http://info.cancerresearchuk.org/cancerstats/world/the-global-picture/#Common;http://publications.cancerresearchuk.org/downloads/Product/cs_pdf_worldwide_2011.pdf)

<sup>3</sup>American Cancer Society. Available at: <http://www.cancer.org/Cancer/KidneyCancer/OverviewGuide/kidney-cancer--adult--renal-cell-carcinoma-overview-what-is-kidney-cancer>.

<sup>4</sup>Bhargava, P., Robinson, M. Curr Oncol Rep (2011) 13:103–111

<sup>5</sup>Ravaud, A. Annals of Oncology 20 (Supplement 1): i7–i12, 2009