

**FOR IMMEDIATE RELEASE**

**AVEO and Astellas Report FDA Oncologic Drug Advisory Committee Votes Tivozanib Application Did Not Demonstrate Favorable Benefit-to-Risk Evaluation in Treatment of Advanced Renal Cell Carcinoma**

**CAMBRIDGE, Mass. and TOKYO, Japan, May 2, 2013** - AVEO Oncology (NASDAQ: AVEO) and Astellas Pharma Inc. (TSE: 4503) today reported that the U.S. Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee (ODAC) voted that the application for investigational agent tivozanib did not demonstrate a favorable benefit-to-risk evaluation for the treatment of advanced renal cell carcinoma (RCC) in an adequate and well-controlled trial (13 to 1, 0 abstentions).

“While we are disappointed with the outcome of the ODAC vote, we remain confident in the efficacy, safety and tolerability of tivozanib in RCC patients,” said Tuan Ha-Ngoc, president and chief executive officer of AVEO. “We are committed to the RCC patient community and will work closely with the FDA to address the issues discussed by the panel today as the Agency continues its ongoing review of the New Drug Application for tivozanib.”

The ODAC provides the FDA with independent expert advice and recommendations. The FDA is not bound by the Committee's guidance, but its input will be considered by the Agency in its review of the tivozanib New Drug Application (NDA), which was submitted by AVEO on September 28, 2012. 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 ODAC reviewed findings from a total of 17 trials involving more than 1,000 patients, including 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. In TIVO-1, tivozanib demonstrated a statistically significant improvement in progression-free survival, the primary endpoint of the study, and a favorable tolerability profile when compared to sorafenib.

**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>

**About Tivozanib**

Tivozanib is an oral, once-daily, investigational vascular endothelial growth factor (VEGF) 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 the AVEO/Astellas Collaboration**

In February 2011, AVEO and Astellas entered into an agreement to develop and commercialize tivozanib outside of Asia for the treatment of a broad range of cancers. 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](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 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 planned launch and commercialization of tivozanib; the potential approval by the FDA of tivozanib in advanced RCC; the targeted date for the completion of the FDA’s review of the tivozanib 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 AVEO’s Phase 3 TIVO-1 trial 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 the TIVO-1 trial, 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 the safety and efficacy levels 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's 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 annual report on Form 10-K 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.*

**Investor Contact:**

Caton Morris, Pure Communications  
(910) 232-7166

**Media Contacts:**

Rob Kloppenburg, AVEO Oncology  
(617) 930-5595

Maribeth Landwehr, Astellas US LLC  
(847) 962-6507

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<sup>1</sup> U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999–2009 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; 2013. 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://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>.