

**FOR IMMEDIATE RELEASE**

**AVEO and Astellas Announce FDA Advisory Committee To Review Tivozanib for the Treatment of Advanced Renal Cell Carcinoma**

*- Oncologic Drugs Advisory Committee Meeting Scheduled for May 2, 2013 -*

**CAMBRIDGE, Mass. and NORTHBROOK, Ill., February 27, 2013** - AVEO Oncology (NASDAQ: AVEO) and Astellas Pharma Global Development, Inc., a U.S. subsidiary of Tokyo-based Astellas Pharma Inc. (Tokyo: 4503), today announced that the U.S. Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee (ODAC) will review the company's New Drug Application (NDA) for tivozanib for the treatment of patients with advanced renal cell carcinoma (RCC) during the morning session of its meeting on May 2, 2013. ODAC reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and makes recommendations to the Commissioner of Food and Drugs. 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.

In November 2012, AVEO and Astellas announced that the FDA accepted for filing the NDA for tivozanib with the proposed indication for the treatment of patients with advanced RCC. The NDA includes results of the global Phase 3 TIVO-1 (Tivozanib Versus sOrafenib in 1<sup>st</sup> 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. Tivozanib is an investigational medicine and is not currently approved in any country.

**About Tivozanib**

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 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 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. 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 Global Development, Inc., located in Northbrook, Illinois, is a U.S. affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global category leader in oncology, and has several oncology products on the market and compounds in development. Astellas is proud to be an award recipient of the CEO Gold Standard Accreditation from the CEO Roundtable on Cancer. For more information on Astellas Pharma Inc., please visit our website at [www.astellas.us](http://www.astellas.us).

### **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 dates for the FDA’s ODAC meeting to review the NDA and the completion of the FDA’s review of the NDA; tivozanib’s safety and efficacy profile and its 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 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 current report on Form 8-K filed with the SEC on January 16, 2013 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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<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>.