



**FOR IMMEDIATE RELEASE**

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**Astellas and AVEO Pharmaceuticals Enter into Worldwide Agreement to Develop and Commercialize Tivozanib Outside of Asia**

*-- AVEO to Receive \$125 Million Upfront and \$1.3 Billion in Potential Milestones --*

*-- Global 50/50 Profit Share with AVEO to Lead Commercialization in North America and Astellas to Lead Commercialization in Europe --*

*-- Agreement Accelerates Development of Tivozanib in Multiple Additional Cancer Indications --*

**TOKYO, JAPAN and CAMBRIDGE, MASS., February 16, 2011** – Astellas Pharma Inc. (TSE: 4503, “Astellas”), a global pharmaceutical company, and AVEO Pharmaceuticals, Inc. (NASDAQ: AVEO, “AVEO”) today announced that they have entered into a worldwide agreement outside of Asia to develop and commercialize tivozanib, AVEO’s lead product candidate designed to optimally block the VEGF pathway by inhibiting all three VEGF receptors, for the treatment of a broad range of cancers. Tivozanib is currently being investigated in a pivotal, global Phase 3 clinical trial called TIVO-1 comparing the efficacy and safety of tivozanib to sorafenib (Nexavar<sup>®</sup>) in patients with advanced renal cell carcinoma (RCC), as well as in

additional clinical studies in other solid tumor types as a single agent and in combination with other anti-cancer agents.

Under the terms of the agreement, AVEO will receive an initial cash payment of \$125 million, composed of a \$75 million license fee and \$50 million in research and development funding. AVEO is also eligible to receive approximately \$1.3 billion in potential milestones comprised of \$575 million in clinical and regulatory milestones, including \$90 million in connection with the regulatory filings and market approval of tivozanib in RCC, as well as more than \$780 million in commercial milestones. 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). The companies will share equally all North American and EU development and commercialization costs and profits for tivozanib. Outside of North America and EU, Astellas will be responsible for the development and commercialization costs of tivozanib and will be obligated to pay AVEO a tiered, double-digit royalty on sales in those territories. Pursuant to the terms of a licensing agreement between Kyowa Hakko Kirin and AVEO, Kyowa Hakko Kirin retains the rights to develop and commercialize tivozanib in Asia. AVEO will be responsible for the manufacturing of tivozanib. The upfront cash payment of \$125 million is not included in Astellas' current fiscal year (from April 1, 2010 to March 31, 2011) financial forecast.

“We are very pleased to initiate this collaboration to co-develop and commercialize tivozanib with AVEO as it further supports our stated growth strategy of becoming a Global Category Leader in Oncology,” said Masafumi Nogimori, president and chief executive officer of Astellas. “Oncology is a high-priority therapeutic area for Astellas. We share AVEO’s vision for oncology drug development and confidence that the TIVO-1 trial is positioned for success. We also strongly believe tivozanib has significant potential in multiple cancers beyond RCC and we look forward to working together to maximize the market opportunities for tivozanib and improving the treatment of cancer patients.”

“This collaboration accomplishes the key strategic objectives we were seeking from a partnership for tivozanib which we believe positions us well to realize the full potential value of tivozanib in North America and Europe,” stated Tuan Ha-Ngoc, president and chief executive officer of AVEO. “In particular, the agreement enables us to build out our North American commercial infrastructure to not only launch tivozanib, but also to support future products emerging from our growing oncology pipeline. We are excited to work with Astellas in our efforts to bring tivozanib to market and, based upon our mutual expectation of a favorable outcome in the TIVO-1 trial, we will be moving forward to accelerate and expand the clinical development of tivozanib beyond RCC prior to top-line TIVO-1 data.”

In 2010, AVEO both initiated and completed patient enrollment in TIVO-1, a global, randomized Phase 3 superiority trial evaluating the efficacy and safety of tivozanib compared to sorafenib in patients with clear cell RCC who had a prior nephrectomy. The primary endpoint of the trial is to compare the PFS of patients treated with tivozanib vs. sorafenib. AVEO expects to announce top-line data from TIVO-1 in mid-2011. In addition, tivozanib has demonstrated the ability to be combined with targeted therapies and chemotherapies in multiple indications in Phase 1b clinical trials. In conjunction with the ongoing TIVO-1 trial and combination studies, AVEO and Astellas

will jointly conduct and fund the expansion of tivozanib clinical development into additional solid tumor types.

RCC, or kidney cancer, is the eighth most commonly diagnosed cancer in men and women in the U.S.<sup>1</sup>. Worldwide during 2010, it was estimated that more than 200,000 people would be diagnosed and more than 100,000 people would die from the disease<sup>2</sup>. RCC, which accounts for 90 percent of all malignant kidney tumors, is highly resistant to chemotherapy<sup>3</sup>. Despite advances in RCC therapies, significant unmet need persists. Currently available therapies provide patients less than one year of survival without disease progression and are associated with significant toxicities<sup>4</sup>.

### **Conference Call Information**

AVEO will discuss this corporate development during its fourth quarter 2010 financial results conference call which is scheduled for today at 5:00 p.m. (EST). The call can be accessed by dialing 1-866-356-4441 (domestic) or 1-617-597-5396 (international) five minutes prior to the start of the call and providing the passcode 88594394. 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 36100132. 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](http://investor.aveopharma.com). A replay of the webcast will be archived on the company's website for two weeks following the call.

### **About Tivozanib**

Tivozanib, an investigational new drug, is designed to optimally block the VEGF pathway by inhibiting all three VEGF receptors. Each of the three receptors of the VEGF pathway play an important role in angiogenesis (the formation of new blood vessels), which is critical in cancer cell growth. Tivozanib's high level of potency across VEGF receptors 1, 2 and 3 is designed to potently block the VEGF pathway. Tivozanib's high level of selectivity for VEGF receptors 1, 2 and 3 is designed to minimize off-target toxicities, and its oral, one capsule, once-daily administration may enhance convenience for patients.

In a large, multi-center, randomized Phase 2 clinical trial, the subset of patients with clear cell renal cell carcinoma (RCC) who had a prior nephrectomy receiving tivozanib therapy achieved 14.8 months progression free survival (PFS), the longest PFS reported for a single-agent therapy in this population<sup>5</sup>. The safety profile of tivozanib observed in the Phase 2 trial was notable for the minimal off-target toxicities often associated with VEGF, multi-targeted therapies. There was a low incidence of diarrhea, fatigue, stomatitis and hand-foot syndrome. Hypertension and dysphonia (hoarseness of voice), which are mechanism-related side effects associated with angiogenesis inhibitors, were the most commonly reported drug-related side effects, and both were manageable and reversible<sup>5</sup>. AVEO has completed patient enrollment in TIVO-1, a global, randomized, controlled Phase 3 clinical trial evaluating the efficacy of tivozanib compared to sorafenib (Nexavar<sup>®</sup>) in this same patient population. The primary endpoint of the trial is to

compare the PFS of patients treated with tivozanib vs. sorafenib. AVEO expects to announce top-line data from TIVO-1 in mid-2011.

Tivozanib has also demonstrated the ability to be combined with both targeted therapies and chemotherapies at the full dose and schedule<sup>6-8</sup>. In Phase 1b clinical trials to date, tivozanib has demonstrated safety in combination with temsirolimus (Torisel<sup>®</sup>) in patients with RCC<sup>6</sup>, FOLFOX6 chemotherapy regimen in patients with colorectal cancer<sup>7</sup>, and paclitaxel (Taxol<sup>®</sup>) in patients with metastatic breast cancer<sup>8</sup>. Tivozanib is also being evaluated in a Phase 1b trial in combination with oral capecitabine (Xeloda<sup>®</sup>) in patients with metastatic breast and colorectal cancers.

### **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 pharmaceutical products. Astellas has approximately 16,000 employees worldwide. The organization is committed to becoming a global category leader in urology, immunology & infectious diseases, neuroscience, DM complications & metabolic diseases and oncology. Astellas acquired OSI Pharmaceuticals, Inc. in June 2010 to add oncology infrastructure; OSI and AVEO have been collaborating on drug discovery and translational research related to OSI's novel epithelial-mesenchymal transition (EMT) agents and proprietary patient selection biomarkers since 2007. For more information on Astellas Pharma Inc., please visit our website at <http://www.astellas.com/en>.

### **About AVEO**

AVEO Pharmaceuticals (NASDAQ: AVEO) is a cancer therapeutics company committed to discovering, developing and commercializing targeted therapies to impact patients' lives. The company's lead product candidate, tivozanib, is currently being investigated in a global, randomized Phase 3 clinical trial called TIVO-1 comparing tivozanib to sorafenib in patients with advanced renal cell carcinoma, as well as additional clinical studies in other solid tumor types. AVEO's second most advanced product candidate, ficlatuzumab (AV-299), is a potent, functional anti-HGF/c-MET pathway antibody that is currently in Phase 2 clinical development. AVEO's proprietary Human Response Platform<sup>™</sup> is designed to offer the company a unique advantage in cancer drug development and has provided a discovery engine for multiple therapeutic targets. This approach has resulted in a promising pipeline of monoclonal antibodies against novel targets including HGF, ErbB3, RON, Notch and FGFR. For more information, please visit the company's website at [www.aveopharma.com](http://www.aveopharma.com).

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

*This press release contains forward-looking statements of AVEO 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," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate," 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 expected strategic, operational and financial benefits of AVEO's collaboration with Astellas; AVEO's expectations about the receipt of license fees, milestones and other payments under the agreement with Astellas; tivozanib's therapeutic and commercial potential; AVEO's expectation regarding a favorable outcome in the TIVO-1 trial; AVEO's plans to accelerate the development of tivozanib in other indications and combinations; the potential therapeutic advantages and benefits of ficlatuzumab; plans and timelines for AVEO's ongoing and planned preclinical studies and clinical trials and the development of our commercial infrastructure; 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: the potential inability of Astellas and AVEO to fully realize the benefits contemplated by their collaboration agreement; difficulties, delays and failures in AVEO's ability to successfully research, develop and obtain and maintain regulatory approvals for tivozanib and AVEO's other product candidates; the possibility that AVEO will not obtain positive results in its Phase 3 clinical trial of tivozanib and/or that tivozanib will not achieve the regulatory approvals required for its successful commercialization either in the U.S. or abroad; potential delays in data availability from TIVO-1; AVEO's inability to obtain and maintain adequate protection for intellectual property rights relating to AVEO's product candidates and technologies; unplanned operating expenses; AVEO's inability to raise substantial additional funds to achieve AVEO's goals; adverse general economic and industry conditions; and those risks discussed in "Risk Factors" and elsewhere in AVEO's Quarterly Report on Form 10-Q for the period ended September 30, 2010 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. The Company anticipates that subsequent events and development will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it has no current intention of doing so except to the extent required by applicable law. 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.*

1. [www.cancer.org/cancer/kidneycancer](http://www.cancer.org/cancer/kidneycancer); <http://seer.cancer.gov/statfacts/html/kidrp.html>
2. Jemal A, Murray T, Ward E, et al. Cancer statistics, 2005. CA Cancer J Clin. 2005;55(1):10-30.
3. Parkin DM, Bray F, Ferlay J, et al. Global cancer statistics, 2002. CA Cancer J Clin. 2005;55(2):74-108.
4. Franklin JR, Figlin R, Belldegrun A. Renal cell carcinoma: basic biology and clinical behavior. Semin Urol Oncol. 1996; 14:208.
5. Decision Resources December 2010 All Rights Reserved
6. Package inserts
7. Rini B, et al. J Clin Oncol. 2009;27(27):4462-4468
8. Motzer RJ, et al. 2009
9. Esclier B, et al. 2009
10. Bhargava P, et al. Poster presented at the ASCO Annual Meeting; June 4-8, 2010; Chicago, IL. Abstract 4599. In the tivozanib Phase 2 trial, the intent to treat patient population (n=272) achieved 11.8 months median PFS.
11. Kabbavar FF, et al. Presented at the International Kidney Cancer Symposium; October 1-2, 2010; Chicago, IL.
12. Eskens FALM, et al. Poster presented at the EORTC-NCI-AACR International Symposium on Molecular Targets and Cancer Therapeutics; November 16-19, 2010; Berlin, Germany
13. Mayer EL, et al. Poster presented at the SABCS Annual Meeting; December 8-12, 2010; San Antonio, TX.

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