AVEO Announces Clinical and Regulatory Updates for Tivozanib

- Pivotal TIVO-3 Trial Enrollment Proceeding Substantially Ahead of Schedule; Enrollment Completion Expected in June -

- Phase 1/2 TiNivo Trial Sites Scheduled to Open for Enrollment in Early March -

- Partner EUSA Pharma Receives Day 180 List of Outstanding Issues from EMA, Oral Explanation Expected in 2Q 2017 -

CAMBRIDGE, Mass. – February 9, 2017 – AVEO Oncology (NASDAQ: AVEO) today announced clinical and regulatory updates for its lead drug candidate, tivozanib, an oral, once-daily, vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI).

The Company announced today that its pivotal, Phase 3 TIVO-3 trial, a randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in subjects with refractory advanced renal cell carcinoma (RCC), is enrolling substantially ahead of schedule. The Company now expects TIVO-3 to complete enrollment in June 2017, ahead of its prior guidance of August 2017. Because the study is event driven the Company is not revising the anticipated time to topline data at this time, which is currently expected in the first quarter of 2018. TIVO-3 is expected to undergo a pre-planned futility analysis around midyear. The TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of RCC, is designed to support first and third line indications for tivozanib in the U.S.

The Company also announced today that the Phase 1/2 AVEO-sponsored TiNivo trial evaluating tivozanib in combination with Bristol-Myers Squibb's anti-PD-1 therapy, Opdivo® (nivolumab), in advanced RCC, is scheduled to open sites for enrollment in early March, with dosing of the first patient expected in the same timeframe. The company received approval by the French National Agency for Medicines and Health Products Safety (ANSM) to initiate the study and is currently labelling the nivolumab supply provided by Bristol-Myers Squibb for use in the trial. The study, which will be led by the Institut Gustave Roussy in Paris, is under the direction of Professor Bernard Escudier, MD, Chairman of the Genitourinary Oncology Committee. The Phase 1 trial will evaluate the safety of tivozanib in combination with nivolumab at escalating doses of tivozanib and, assuming favorable results, is expected to be followed by an expansion Phase 2 cohort at the established combination dose.

AVEO also announced today that its European licensee for tivozanib, EUSA Pharma, a specialty pharmaceutical company with a focus on oncology and oncology supportive care, has received the Day 180 List of Outstanding Issues (LOI) from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The Day 180 LOI signifies that the Marketing Authorization Application is not approvable at the present time, and outlines outstanding deficiencies, which are then required to be satisfactorily addressed in an oral explanation and/or in writing prior to a final application decision. EUSA has informed AVEO that

it expects to submit written responses to the Day 180 LOI in April 2017, and the EMA has tentatively scheduled EUSA to provide an oral explanation to the CHMP at its May 2017 meeting.

"We continue to execute on the TIVO-3 and TiNivo studies in our effort to complete our U.S. pivotal clinical strategy, as well as support EUSA Pharma in its response to European regulators," said Michael Bailey, president and chief executive officer of AVEO. "The rapid pace of enrollment in our TIVO-3 study is a testament to the broad level of support and enthusiasm for tivozanib among investigators. Fundamental to this drug candidate's unique profile would be its potential to be safely combined with PD-1 immunotherapies, and we look forward to initial results from the Opdivo® combination TiNivo study in RCC in the first half of 2017."

About Tivozanib

Tivozanib is an oral, once-daily, vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI). It is a potent, selective and long half-life inhibitor of all three VEGF receptors and is designed to optimize VEGF blockade while minimizing off-target toxicities, potentially resulting in improved efficacy and minimal dose modifications. Tivozanib has been investigated in several tumors types, including renal cell, colorectal and breast cancers.

About the TIVO-3 Trial

The Phase 3 TIVO-3 trial is a pivotal, randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in subjects with refractory advanced renal cell carcinoma (RCC). The trial is expected to enroll approximately 322 patients with recurrent RCC who have failed at least two prior regimens, including VEGFR-TKI therapy (other than sorafenib). Eligible patients may also have received checkpoint inhibitor therapy in earlier lines of treatment. Patients will be randomized 1:1 to receive either tivozanib or sorafenib, with no crossover between arms. The primary endpoint of the study is progression free survival. Secondary endpoints include overall survival, overall response rate, and safety and tolerability. The TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of RCC, is designed to support a first and third line indication for tivozanib in the U.S.

About AVEO

AVEO Oncology (AVEO) is a biopharmaceutical company dedicated to advancing a broad portfolio of targeted therapeutics for oncology and other areas of unmet medical need. The company is focused on developing and commercializing its lead candidate tivozanib, a potent, selective, long half-life inhibitor of vascular endothelial growth factor 1, 2 and 3 receptors, in North America as a treatment for Renal Cell Carcinoma and other cancers. AVEO is leveraging multiple partnerships to develop and commercialize tivozanib in non-oncologic indications worldwide and oncology indications outside of North America, as well as to progress its pipeline of novel therapeutic candidates in cancer and cachexia (wasting syndrome). For more information, please visit the company's website at www.aveooncology.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 fact, contained in this press release are forward-looking statements. The words "anticipate," "believe," "expect," "intend," "may,"

"plan," "potential", "could," "should," “would,” "seek," “look forward,” “advance,” “goal,” “strategy,” 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: the expected timelines for completing enrollment, undergoing a futility analysis and receiving top-line data readouts in TIVO-3; the potential for the design of the TIVO-3 and TIVO-1 trials to support first and third line indications in the U.S.; AVEO’s plans to open clinical trial sites and begin dosing patients in the TiNIVO trial in March 2017, and the potential advancement of such trial; AVEO's expectations regarding a registration decision in the EU for tivozanib; plans and strategies of AVEO and its partners and the potential achievement by AVEO and its partners of clinical, regulatory, commercial, manufacturing and other development goals and milestones; the commercial opportunity for tivozanib in the first line RCC market in Europe; and the potential safety, efficacy, tolerability and other benefits of tivozanib in the treatment of renal cell carcinoma as a single agent or in combination with other therapies;. 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 AVEO's ability to enter into and maintain its third party collaboration agreements, and its ability, and the ability of its licensees and other partners, to achieve development and commercialization objectives under these arrangements; AVEO's ability, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies the safety, efficacy and clinically meaningful benefit of AVEO's product candidates; AVEO's ability to successfully enroll and complete clinical trials, including the TIVO-3 and TiNivo studies; AVEO's ability to achieve and maintain compliance with all regulatory requirements applicable to its product candidates; AVEO's ability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates and technologies; developments, expenses and outcomes related to AVEO's ongoing shareholder litigation; AVEO's ability to successfully implement its strategic plans; AVEO's ability to raise the substantial additional funds required to achieve its goals; unplanned capital requirements; adverse general economic and industry conditions; competitive factors; and those risks discussed in the section titled "Risk Factors" in AVEO's most recent Annual Report on Form 10-K, its quarterly reports on Form 10-Q and its other filings with the SEC. 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 may cause its views to change. 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 other than the date of this press release.

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