AVEO Oncology Announces Completion of TIVO-3 Study Futility Analysis with No Changes to Study Protocol

CAMBRIDGE, Mass.– October 5, 2017 – AVEO Oncology (NASDAQ: AVEO) today announced the completion of a pre-planned futility analysis of the Phase 3 TIVO-3 trial, the Company's randomized, controlled, multi-center, open-label study to compare FOTIVDA® (tivozanib) to sorafenib in subjects with refractory advanced renal cell carcinoma (RCC). Based on the results of the futility analysis, which was reviewed by an independent statistician, the study will continue as planned without modification. This analysis did not allow for early stopping due to efficacy to assure adequate follow-up for the key secondary endpoint of overall survival. The pre-planned futility analysis was triggered by the reporting of 128 progression events in early August. Additional events were recorded as part of the data management process leading into the futility analysis, resulting in a revised data cut-off date for the analysis of May 29. The Company continues to expect the TIVO-3 to read out in the first quarter of 2018.

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 regulatory approval of tivozanib in the U.S. as a first and third line treatment for RCC.

"The treatment of advanced renal cell cancer is undergoing rapid change, with immunotherapy and combination regimens delivering improved outcomes for patients and shaping a new treatment paradigm," said Michael Bailey, president and chief executive officer of AVEO. "We believe our tivozanib clinical strategy positions us well in this evolving landscape, with the TIVO-3 study on track to provide the first post-immunotherapy pivotal datasets for a VEGF-TKI, and the TiNivo study providing early and encouraging combination data. We look forward to readout of the TIVO-3 trial in the first quarter of 2018. We also look forward to presenting Phase 1 results from the Phase 1/2 TiNivo study of tivozanib in combination with OPDIVO® at a medical conference this fall, and to leveraging tivozanib's unique safety and efficacy profile in future potential therapy combinations."

The TIVO-3 trial was designed to enroll 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 are 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 TiNivo trial is a Phase 1/2 study of tivozanib in combination with Bristol-Myers Squibb's OPDIVO® (nivolumab), an immune checkpoint, or PD-1, inhibitor, for the treatment of RCC. The TiNivo trial is being led by the Institut Gustave Roussy in Paris under the direction of Bernard Escudier, MD, Chairman of the Genitourinary Oncology Committee. The trial advanced into the Phase 2 expansion portion following successful completion of the Phase 1 dose escalation portion.

The combination was well tolerated to the full dose and schedule of single agent tivozanib, with no dose limiting toxicities. The expansion portion of the trial is expected to enroll an additional 20 subjects. Phase 1 results from the ongoing study have been submitted for presentation at a scientific meeting taking place in the fourth quarter.

About Tivozanib (FOTIVDA®)

Tivozanib (FOTIVDA®) is an oral, once-daily, vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) discovered by Kyowa Hakko Kirin and approved for the treatment of adult patients with advanced renal cell carcinoma in the European Union plus Norway and Iceland. 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 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 seeking to develop and commercialize 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 aimed at developing and commercializing tivozanib in oncology indications outside of North America, and at progressing its pipeline of novel therapeutic candidates in cancer and cachexia (wasting syndrome). Tivozanib (FOTIVDA®) is approved by the European Commission for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union plus Norway and Iceland. 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, statements about: clinical, regulatory and commercial plans of AVEO and its partner EUSA Pharma to progress the development of FOTIVDA® (tivozanib); the expected timeline for reporting data from TIVO-3; the role and expected benefits of tivozanib and other TKIs on a stand-alone basis, or in combination with or following immunotherapy; the expected enrollment of the TiNivo trial and presentation of TiNivo results; expectations about the potential for additional payments by EUSA Pharma; the value of AVEO's partnerships in advancing its pipeline; and AVEO's strategy, prospects, plans and objectives, including as they pertain specifically to tivozanib. AVEO has based its expectations and estimates on assumptions that may prove to be incorrect. As a result, readers are cautioned not

to place undue reliance on these expectations and estimates. 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, including tivozanib. AVEO faces other risks relating to its business as well, including risks relating to its 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, including those goals pertaining to the development and commercialization of tivozanib; unplanned capital requirements; adverse general economic and industry conditions; competitive factors; and those risks discussed in the section titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" included in AVEO's Annual Report on Form 10-K for the year ended December 31, 2016, its quarterly reports on Form 10-Q and in other filings that AVEO may make with the SEC in the future. 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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