AVEO Oncology Announces Initiation of Topline Analysis of Phase 3 TIVO-3 Trial

- Analysis Initiated on the Unanimous Recommendation of the TIVO-3 Study Independent Steering Committee -

- Company Expects to Report Topline Results in Approximately 6 Weeks -

CAMBRIDGE, Mass. – October 1, 2018 – AVEO Oncology (NASDAQ: AVEO) today announced that it has initiated topline analysis of the phase 3 TIVO-3 clinical trial on the unanimous recommendation of the independent TIVO-3 Study Steering Committee, and after notice to the FDA. The TIVO-3 trial is 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). The Company expects to complete data analysis and report topline results from the study in approximately 6 weeks.

The Steering Committee recommendation was preceded by a slowing in the rate of progression free survival (PFS) events in the trial over the last 4-6 months. The reasons given by the Steering Committee for the unanimous recommendation were that current patients have been on study for at least one year and may not progress for some time, and that the small reduction in events at the time of final analysis was unlikely to materially affect the clinical interpretation of the results. As of September 26, 2018, the last review of events, a total of 242 PFS events had occurred in the trial. The Company plans to set the data cutoff date for the primary analysis at October 4, 2018. Performing the primary analysis at 242 events reduces the power of the study from 90% (based on the prior target of 255 PFS events) to 88%.

Following the last review of events, 42 patients remain on treatment in the TIVO-3 study with 28 of the remaining patients yet to have a PFS event as determined by the independent radiology committee. All patients still enrolled in the study will continue to receive treatment per study protocol. The Company will remain blinded to study data until data analysis is complete.

"Initiation of the topline analysis of the TIVO-3 trial brings us one step closer to potentially realizing the strategy we laid out in 2015, which included commercialization of tivozanib in the United States and Europe, and exploration of tivozanib's clinical potential in immunotherapy combinations," said Michael Bailey, president and chief executive officer of AVEO. "With the introduction of immunotherapy as a treatment for earlier-line RCC, survival among patients is extending well beyond disease progression on first- and second-line treatment, which we believe may substantially increase the third-plus-line opportunity for tivozanib. TIVO-3 has the potential to serve as the first prospective Phase 3 randomized dataset in this setting, creating an evidence-based guidepost for sequencing therapies in refractory disease. We look forward to announcing the topline results of TIVO-3 in the coming weeks."

The TIVO-3 trial was designed to enroll patients with RCC who have failed at least two prior regimens, including VEGFR-TKI therapy. 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 PFS. Secondary endpoints include overall survival (OS), overall response rate, and safety and tolerability. TIVO-3, together with the previously completed TIVO-1 trial of tivozanib in the first-line treatment of RCC, is designed to support a regulatory submission of tivozanib in the U.S. as a treatment for RCC, if the data are positive. TIVO-3 patients were exclusively enrolled in North America, Western Europe, and Central Europe.

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 (RCC) 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.[1,2] Tivozanib has been shown to significantly reduce regulatory T-cell production in preclinical models, enabling potentially enhanced activity when used in combination with immune modulating therapy.[3] As part of a North American registration plan, tivozanib is currently being studied in the Phase 3 TIVO-3 trial, a randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in subjects with refractory RCC. Tivozanib has been investigated in several tumors types, including renal cell, hepatocellular, colorectal and breast cancers.

About AVEO

AVEO Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company dedicated to advancing a broad portfolio of targeted medicines for oncology and other areas of unmet medical need. The Company's strategy is to retain North American rights to its oncology portfolio while securing partners in development and commercialization outside of North America. The Company is seeking to develop and commercialize its lead candidate tivozanib in North America as a treatment for advanced renal cell carcinoma ("RCC"). The Company has outlicensed tivozanib (FOTIVDA®) for oncology in Europe and other territories outside of North America. Tivozanib is approved in the European Union, as well as Norway and Iceland, for the first-line treatment of adult patients with RCC and for adult patients who are vascular endothelial growth factor receptor and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for RCC. The Company has entered into partnerships for the development and commercialization of AV-203 (CAN017) and ficlatuzumab, both clinical stage assets in oncology. The Company is currently seeking a partner to develop the AV-353 platform, a preclinical asset, worldwide for the potential treatment of pulmonary arterial hypertension. The Company has recently regained the rights to its AV-380 program for the potential treatment of cachexia and is considering a variety of options to advance the program's development.

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: the Company's expected timeline to complete data analysis and report topline results from the TIVO-3 study; the expectation of the Steering Committee for the TIVO-3 trial that the outcome of the primary study analysis is unlikely to change with additional patient follow-up; the Company's plans and strategies for commercialization of tivozanib in the United States and Europe; the potential for tivozanib to have clinical potential in immunotherapy combinations; the potential for TIVO-3 to serve as the first prospective Phase 3 randomized dataset in the setting of immunotherapy, creating an evidence-based guidepost for sequencing therapies in refractory disease; the Company's plan to seek a partner to develop the AV-353 platform,; the Company's plans regarding AV-380and AVEO's strategy, prospects, plans and objectives. 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 and license agreements, and its ability, and the ability of its collaborators, licensees and other strategic partners, to achieve development and commercialization objectives under these arrangements; and AVEO's ability, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies such as the FDA 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 and its collaborators' 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; 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 quarterly and annual reports on file with the Securities and Exchange Commission (SEC) 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. Any reference to AVEO's website

address in this press release is intended to be an inactive textual reference only and not an active hyperlink.

References

[1]. Fotivda (Tivozanib) SmPC August 2017
[2]. Motzer RJ, Nosov D, Eisen T, et al. J Clin Oncol 2013; 31(30): 3791-9.
[3]. Pawlowski N et al. AACR 2013. Poster 3971.

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