AVEO Oncology Announces Updated Overall Survival Hazard Ratio of 0.99 in Phase 3 TIVO-3 Trial of Tivozanib in Renal Cell Carcinoma

- 20 Patients Remain Progression Free on Tivozanib Arm vs. 2 on Sorafenib Arm -

- Company Plans to Discuss Updated Results with FDA -

- AVEO to Host Conference Call Today at 8:00 am Eastern Time -

CAMBRIDGE, Mass. – September 10, 2019 – AVEO Oncology (NASDAQ: AVEO) today announced results from the second prespecified analysis of overall survival (OS) in the TIVO-3 trial. TIVO-3 is the Company's Phase 3 randomized, controlled, multi-center, open-label study to compare tivozanib (FOTIVDA®) to sorafenib in 350 subjects with highly refractory metastatic renal cell carcinoma (RCC). These results include an OS hazard ratio (HR) below 1.00, favoring tivozanib (HR=0.99; 95% CI: 0.76-1.29; p=0.95). An OS hazard ratio assesses the relative risk of death for the entirety of the data set. TIVO-3 is the first and only positive Phase 3 study in 3rd and 4th line RCC, and the first Phase 3 study in RCC to investigate a predefined subpopulation of patients who received prior immunotherapy, an emerging standard of care for earlier lines of therapy.

The data cutoff date for the second prespecified analysis was August 15, 2019, two years from the last patient enrolled and approximately ten months from the data cut-off date for the first prespecified analysis. Between the two data cut-off dates, 16 additional OS events were reported on the tivozanib arm and 28 on the sorafenib arm, resulting in a total of 114 OS events on the tivozanib arm and 113 on the sorafenib arm. Median OS, a point in time value separating the earlier half of events from the latter half within each arm, was 16.4 months for tivozanib (95% CI: 13.4-22.2) and 19.7 months for sorafenib (95% CI: 15.0-24.2). Twenty patients remain progression free on the tivozanib arm and two on the sorafenib arm, with a median duration on study of 32.5 months.

In November 2018, the Company announced positive final results for the primary endpoint of progression-free survival (PFS) and the secondary endpoint of overall response rate (ORR). Statistically significant improvements favoring tivozanib were reported for PFS (HR=0.73; p=0.0165) and ORR (18% vs. 8%; p=0.02). The Company also announced that tivozanib was found to be generally well-tolerated, with grade 3 or higher adverse events consistent with those observed in previous tivozanib trials. Infrequent but severe adverse events reported in greater number in the tivozanib arm were thrombotic events similar to those observed in previous tivozanib studies. The most common adverse event in patients receiving tivozanib was hypertension, an adverse event known to reflect effective VEGF pathway inhibition.

The Company plans to discuss the updated OS results with the U.S. Food and Drug Administration to identify the appropriate path forward for tivozanib in RCC in the fourth quarter, and to provide an update regarding the potential submission of a New Drug Application for tivozanib in RCC following these discussions.

"These are the first data to demonstrate durable improvements in this highly refractory advanced kidney cancer population, including the post-immunotherapy setting, a predefined subset of the

TIVO-3 trial," said Brian Rini, MD, Professor of Medicine, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Director, Cleveland Clinic Genitourinary Cancer Program, and principal investigator of the TIVO-3 trial. "The TIVO-3 study suggests the potential for tivozanib to serve as an important new treatment option for patients with advanced RCC. I look forward to seeing tivozanib studied further in the immunotherapy combination setting, and to continuing to explore its full potential in the evolving RCC treatment landscape."

"We are pleased to see that the positive PFS and ORR outcomes from TIVO-3 have translated into an improved OS hazard ratio," said Michael Bailey, president and chief executive officer of AVEO. "On behalf of the entire AVEO team, we once again offer our sincerest thanks to the patients, caregivers and investigators for participating in this study. AVEO remains committed to improving outcomes for patients with RCC, and we look forward to discussing these results with the FDA."

Conference Call and Webcast

In connection with this announcement, AVEO will host a conference call and audio webcast today, September 10, 2019, at 8:00 am Eastern Time. The call can be accessed by dialing (844) 882-7841 (U.S. and Canada) or (574) 990-9828 (international). The passcode for the conference call is 3275406. To access the live audio webcast, or the subsequent archived recording, please visit the Investors section of the AVEO website at www.aveooncology.com. The webcast will be recorded and available for replay on AVEO's website for two weeks.

About TIVO-3

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 were randomized 1:1 to receive either tivozanib or sorafenib, with no crossover between arms. The primary endpoint of the study is progression free survival (PFS). Secondary endpoints include overall survival (OS), overall response rate (ORR), 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 in multiple lines of therapy. 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 Kirin and approved for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union plus Norway, New Zealand 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[3] and has demonstrated synergy in combination with nivolumab (anti PD-1) in a Phase 2 study in RCC[4]. Tivozanib has been investigated in several tumor types, including renal cell, hepatocellular, colorectal, ovarian and breast cancers.

About AVEO

AVEO Pharmaceuticals is a biopharmaceutical company seeking to advance targeted medicines for oncology and other unmet medical needs. The Company's lead candidate is tivozanib, a potent, selective, long half-life inhibitor of vascular endothelial growth factor 1, 2 and 3 receptors, which AVEO is working to develop and commercialize in North America as a treatment for renal cell carcinoma (RCC), hepatocellular carcinoma (HCC) and other cancers. Tivozanib (FOTIVDA®) is approved by the European Commission for the treatment of adult patients with advanced RCC in the European Union plus Norway, New Zealand and Iceland. AVEO is leveraging or seeks to leverage partnerships to develop and commercialize its pipeline of products and product candidates, including tivozanib in oncology and other indications in various geographies, and ficlatuzumab (HGF MAb) in head and neck cancer, pancreatic cancer and acute myeloid leukemia. AVEO's earlier-stage pipeline includes AV-203 (anti-ErbB3 MAb), AV-380 (GDF15 MAb) and AV-353 (Notch 3 MAb), drug candidates being developed for various oncology indications.

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 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 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 potential for tivozanib as a treatment option for patients with advanced RCC; AVEO's plans to discuss the updated OS results from TIVO-3 with the FDA to identify the path forward for tivozanib in RCC and to provide an update regarding a potential NDA submission; the potential efficacy, safety, and tolerability of tivozanib, as a single agent and in combination with other therapies in several indications, such as RCC and HCC; and AVEO's strategy, prospects, plans and objectives for its product candidates and for the Company generally. 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, 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, in particular, tivozanib; AVEO's ability to successfully file an NDA for tivozanib; and AVEO's ability to enter into and maintain its third party collaboration and license agreements, and its ability, and the ability of its strategic partners, to achieve development and commercialization objectives under these arrangements. AVEO faces other risks relating to its business as well, including risks relating to the timing and costs of seeking and obtaining regulatory approval; AVEO's and its collaborators' ability to successfully enroll and complete clinical trials; AVEO's ability to maintain compliance with 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; 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 sections 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 makes with the SEC. The forward-looking statements in this press release represent AVEO's views as of the date of this press release, and 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.
4. Barthelemy et al. ESMO 2018. Poster 878P.

AVEO Contact:
David Pitts, Argot Partners
(212) 600-1902
aveo@argotpartners.com