AVEO Oncology Announces Presentation of Key Subgroup and Quality of Life Analyses from the Phase 3 TIVO-3 Study of Tivozanib in Renal Cell Carcinoma

February 11, 2021

– Data Presented at the ASCO 2021 GU Cancers Symposium –

–Sequencing Data Support Tivozanib is a Differentiated Selective VEGF TKI; Q-TWiST Quality of Life Measure Shows Significant Improvement for Tivozanib over Sorafenib –

BOSTON, Mass.--(BUSINESS WIRE)--Feb. 11, 2021-- AVEO Oncology (Nasdaq: AVEO) today announced the presentation of two analyses of the Company's pivotal TIVO-3 study, its Phase 3 trial comparing tivozanib, AVEO's next-generation vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor (TKI) drug candidate, to sorafenib in third- and fourth-line renal cell carcinoma (RCC). The data are being presented in a poster discussion session at the American Society of Clinical Oncology (ASCO) 2021 Genitourinary (GU) Cancers Symposium being held virtually.

"Data reported today continue to support tivozanib's differentiation among TKIs and its potential to serve as a meaningful option for RCC patients who have relapsed or become refractory to multiple lines of therapy," said Brian Rini, MD, Chief of Clinical Trials at Vanderbilt Ingram Cancer Center. "Of note, sequencing data suggest differential activity between tivozanib and axitinib, despite both being potent and selective VEGF TKIs. With no existing evidence-based standard of care for this historically difficult-to-treat population, tivozanib could potentially play a key role in the evolving relapsed or refractory RCC treatment landscape."

"These findings enhance our understanding of tivozanib in a clinically relevant patient population and add to the body of data from TIVO-3, which, as the first positive superiority study in patients who have relapsed or become refractory to two or more systemic therapies, could potentially serve as an important guide for treatment decisions in this setting," said Michael Bailey, president and chief executive officer of AVEO. "As we await the U.S. Food and Drug Administration's decision on our New Drug Application submission for tivozanib as a treatment for relapsed or refractory RCC, we remain focused on commercial preparations to support a robust potential U.S. launch. We are committed to our mission of improving both outcomes and patient experience, and to ensuring that tivozanib becomes available to as many appropriate patients as possible."

ASCO GU Data

- **Q-TWiST Analysis.** A poster titled, "Q-TWiST analysis of tivozanib versus sorafenib in patients with advanced renal cell carcinoma (RCC) in the TIVO-3 study" (abstract 298) highlighted findings from a quality-adjusted time without symptoms or toxicity analysis (Q-TWiST) used to assess health-related quality of life. Findings showed that tivozanib significantly increased Q-TWiST relative to sorafenib in patients treated in the TIVO-3 study (15.04 months vs. 12.78 months; p=0.0493), and tivozanib nearly doubled Q-TWiST compared to sorafenib (10.30 months vs. 5.35 months.) These data suggest that tivozanib may convey tolerability advantages as measured by a patient-centered health-related patient quality of life. Q-TWiST analyses have previously been used to assess other TKIs for the treatment of RCC.

- **Prior Axitinib Therapy.** A presentation titled, "Tivozanib in Patients with Advanced Renal Cell Carcinoma (aRCC) who have Progressed After Prior Treatment with Axitinib: Results from TIVO-3" (abstract 278) highlighted outcomes of TIVO-3 patients who received prior axitinib therapy, now commonly part of front-line advanced RCC treatment. Of this group, patients treated with tivozanib (n=83) demonstrated a median progression free survival (PFS) of 5.5 months compared to 3.7 months for those treated with sorafenib (n=89) (Hazard Ratio of 0.68), with an overall response rate of 13% and 8%, respectively. In addition, prior axitinib therapy did not appear to influence tivozanib tolerability, with adverse events, including dose reductions, interruptions, and discontinuations, similar in patients treated with and without prior axitinib therapy. These results suggest that tivozanib, a selective VEGF TKI, is active following prior axitinib therapy and can potentially provide superior PFS benefit compared to sorafenib, a multi-targeted VEGF TKI.

A copy of each presentation will be available in the Scientific Publications & Presentations section of AVEO's website.

About Tivozanib (FOTIVDA®)

Tivozanib is an oral, once-daily, next-generation VEGF TKI discovered by Kyowa Kirin Co. and approved as FOTIVDA® for the treatment of adult patients with advanced RCC in the European Union and other countries in the territory of the Company's partner, EUSA Pharma (UK) Limited (EUSA territory). 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 is being studied in the TIVO-3 trial, which is supporting a regulatory submission of tivozanib in the U.S. seeking marketing approval as a treatment for adult patients with relapsed or refractory advanced RCC. 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. Tivozanib is also being studied by partner Kyowa Kirin Co. in non-oncology indications.

About AVEO Pharmaceuticals, Inc.

AVEO is an oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for cancer patients. AVEO's strategy is to focus its resources toward development and commercialization of its product candidates in North America, while leveraging partnerships to support development and commercialization in other geographies. AVEO's lead candidate, tivozanib, is approved as FOTIVDA ® in the European Union and other countries in the EUSA territory for the treatment of adult patients with advanced RCC. Tivozanib is being studied in the TIVO-3 trial, which is supporting a regulatory submission of tivozanib in the U.S. seeking marketing approval as a treatment for relapsed or refractory RCC. AVEO has previously reported promising early clinical data on ficlatuzumab (anti-HGF mAb) in head and neck cancer, acute myeloid leukemia and pancreatic cancer and is conducting a randomized Phase 2 confirmatory clinical trial of ficlatuzumab in head and neck cancer. AVEO's earlier-stage pipeline includes several monoclonal antibodies in oncology development, including AV-203 (anti-ErbB3 mAb), AV-380 (anti-GDF15 mAb) and AV-353 (anti-Notch 3 mAb). AVEO is committed to creating an environment of diversity and inclusion as a foundation for innovation.

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," "design," "expect," "hope," "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 HCC or relapsed/refractory or advanced RCC; the potential efficacy, safety, and tolerability of tivozanib, both as a stand-alone drug candidate and in combination with other therapies in several indications; AVEO's execution of its clinical and regulatory strategy for tivozanib; AVEO's plans and strategies for current and future clinical trials of tivozanib and for commercialization of tivozanib in the United States; the advancement of AVEO's pipeline, including the advancement of ficlatuzumab in multiple clinical studies; 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: whether the results of TIVO-3 are sufficient to obtain marketing approval for tivozanib in the U.S., which turns on the ability of AVEO to demonstrate to the satisfaction of the FDA the safety and efficacy of tivozanib based upon the findings of TIVO-3, including its data with respect to progression-free survival, the rate of adverse events, overall survival and other information that the FDA may consider to be relevant to an approval determination; AVEO's ability to successfully implement its strategic plans, including its ability to successfully launch and commercialize tivozanib if it may be approved for commercialization by the FDA and to obtain and maintain market and third party payor acceptance of tivozanib if it may be approved for commercialization by the FDA; AVEO's ability to raise the substantial additional funds required to achieve its goals, including those goals pertaining to the launch and commercialization of tivozanib; 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, and risks relating to the timing and costs of seeking and obtaining regulatory approvals; 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'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; unplanned capital requirements; uncertainties related to AVEO's ability to access future borrowings under the Hercules loan facility, which turns on the achievement of milestones related to the approval and commercialization of tivozanib in the U.S., which milestones may not be achieved; adverse general economic and industry conditions; the potential adverse effects of the COVID-19 pandemic on AVEO's business continuity, financial condition, results of operations, liquidity and ability to successfully and timely enroll, complete and read-out data from its clinical trials; 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

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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

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