AVEO Oncology Highlights Recent Progress and 2021 Outlook

January 7, 2021

– Commercial Readiness Nearing Completion in Support of Potential Tivozanib U.S. Launch –

– Updated IP Strategy Offers Potential for Tivozanib Patent Term Extension to November 2028 –

– Corinne D. Epperly, MD, MPH, Appointed to Board of Directors –

– Phase 2 Open Label Randomized Study of Ficlatuzumab in HNSCC Enrollment Complete; Plans to Announce Results and Phase 3 Decision on Track for Mid-2021 –

– AV-380 Phase 1 Clinical Study Initiated Following FDA's IND Acceptance –

BOSTON--(BUSINESS WIRE)--Jan. 7, 2021-- AVEO Oncology (Nasdaq: AVEO) today highlighted its recent progress and outlined its 2021 outlook.

"We remain keenly focused on building out our commercial team ahead of the potential U.S. launch of tivozanib as a treatment for relapsed or refractory renal cell carcinoma (RCC), including the addition of Dr. Corinne Epperly to our Board of Directors," said Michael Bailey, president and chief executive officer of AVEO. "If approved, we believe tivozanib has the potential to serve as a new treatment for the rapidly growing population of patients with relapsed or refractory RCC. In support of the further clinical and commercial development of tivozanib, we have identified opportunities to potentially extend its patent exclusivity period."

Mr. Bailey added: "In addition to our launch preparation, we continue to make great progress advancing our clinical pipeline, with each asset expected to reach an important milestone this year. These include progress in our immunotherapy combination programs for tivozanib, a decision on whether to initiate a pivotal study of ficlatuzumab in head and neck squamous cell carcinoma (HNSCC), and the execution of our Phase 1 study of AV-380. We believe 2021 will be a transformational year for AVEO, and we look forward to delivering on a number of milestones designed to enhance our long-term value."

Key Recent Program Updates and Anticipated 2021 Milestones

Tivozanib U.S. Regulatory and Commercial Updates

- **Commercial Readiness Nearing Completion in Support of Potential Tivozanib U.S. Launch.** Commercial preparations are well underway to support the potential U.S. launch of tivozanib, AVEO's vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) drug candidate, as a treatment for relapsed or refractory RCC. U.S. sales leadership, sales training, marketing, market access and medical affairs teams as well as distribution capabilities are now in place. Hiring, training, and deployment of the Company's field sales organization is on track for completion ahead of the U.S. Food and Drug Administration's (FDA) New Drug Application Prescription Drug User Fee Act target action date for tivozanib of March 31, 2021.
- **Relapsed/Refractory RCC Disease Awareness Website Launched for U.S. Healthcare Professionals.** The Company today announced the recent launch of www.ReimagineRCC.com, a relapsed/refractory RCC disease awareness resource for U.S. healthcare professionals highlighted by the headline: "After multiple prior treatments in renal cell carcinoma (RCC), the journey can quickly become a challenge". The website highlights the need for more robust data and better tolerated treatment options to support the roughly half of patients who receive second line therapy yet do not continue therapy beyond progression.

Corporate Updates

- **Updated IP Strategy Offers Potential for Tivozanib Patent Term Extension to November 2028.** AVEO holds an exclusive license to two issued U.S. patents for tivozanib, one pertaining to the tivozanib composition of matter, which expires in April 2022, and the other pertaining to a crystalline form of tivozanib, which expires in November 2023. A patent term extension of up to five years may be available under the Hatch-Waxman Act, although only one patent can be extended under the Act. The Company currently intends to file applications for patent term extension on both patents in parallel to provide optionality in its exclusivity strategy. Depending upon which patent the Company ultimately chooses to extend, if a full five year extension is granted for such patent, tivozanib's exclusivity period could reach either April 2027 or November 2028.
- **Corinne D. Epperly, MD, MPH Appointed to Board of Directors.** AVEO today announced the appointment of Corinne D.

Epperly, MD, MPH, to its Board of Directors. Dr. Epperly brings over 15 years of experience in oncology as a physician and scientist, blending medicine and business with a proven track record in oncology drug development and launches, commercial and medical strategy, marketing, M&A, and operations gained at Iovance Biotherapeutics, VBL Therapeutics, Bristol Myers Squibb, Goldman Sachs, and the National Cancer Institute of the NIH.

Tivozanib Immuno-Oncology Updates

- **Results from Phase 1b/2 TiNivo Study of Tivozanib in Combination with OPDIVO® (nivolumab) in RCC Published in Annals of Oncology.** In November 2020, AVEO announced that previously reported results from the Phase 1b/2 TiNivo study of oral (PO) tivozanib (FOTIVDA®) in combination with intravenous (IV) nivolumab (OPDIVO®, Bristol-Myers Squibb), an immune checkpoint, or PD-1, inhibitor, for the treatment of advanced RCC, were published in *Annals of Oncology*. The article, titled "TiNivo: Safety and Efficacy of Tivozanib-Nivolumab Combination Therapy in Patients with Metastatic Renal Cell Carcinoma", is available online first via this link. AVEO plans to detail next steps in its investigations of the tivozanib-nivolumab combination following potential FDA approval of tivozanib.
- **Results from the Phase 1b Portion of DEDUCTIVE Study to Be Presented Friday, January 15, 2021, at ASCO GI Cancer Symposium.** AVEO is also studying tivozanib in combination with IMFINZI® (durvalumab), AstraZeneca's human monoclonal antibody directed against programmed death-ligand 1 (PD-L1), in patients with first line metastatic hepatocellular carcinoma in the Phase 1b/2 DEDUCTIVE clinical trial, which is currently in Phase 2, with enrollment expected to complete this year. Results from the Phase 1b portion of the DEDUCTIVE study are expected to be presented at on Friday, January 15, 2021, at 8:00 am ET, at the American Society of Clinical Oncology Gastrointestinal Cancer Symposium.

Ficlatuzumab Update

- **Enrollment Complete in Phase 2 Open Label Randomized Study of Ficlatuzumab in HNSCC; Results Expected to Be Presented at a Medical Meeting in Mid-2021; Phase 3 Decision on Track for Mid-2021.** The Company announced today that enrollment is now complete in its randomized confirmatory Phase 2 study of ficlatuzumab as a single agent or in combination with cetuximab, an EGFR-targeted antibody, in metastatic HNSCC patients who have failed prior immunotherapy, chemotherapy and cetuximab (ERBITUX®). Ficlatuzumab is AVEO's potent hepatocyte growth factor (HGF) inhibitor antibody which binds to the HGF ligand with high affinity and specificity to inhibit HGF/c-Met biological activities. The study was designed to confirm findings from a Phase 1/2 study of ficlatuzumab and cetuximab where the combination was well tolerated and resulted in a disease control rate of 67%, as well as prolonged progression-free survival (PFS) and overall survival (OS) compared to historical controls.

  Results from the Phase 2 study are expected to be presented at a medical meeting in mid-2021. In that timeframe, the Company plans to announce a Phase 3 decision for ficlatuzumab. In September 2020, AVEO regained full global rights to ficlatuzumab and has initiated clinical manufacture of ficlatuzumab to supply a potential Phase 3 clinical trial in HNSCC, as well as additional potential Phase 2 studies in pancreatic cancer and acute myeloid leukemia.

AV-380 Update

- **Phase 1 Clinical Study Initiated Following U.S. FDA Acceptance of IND Filing.** The Company announced today that its investigational New Drug Application (IND) application for AV-380, its first-in-class, potent, humanized inhibitory antibody targeting GDF15, for the treatment of cancer cachexia, has been accepted by the FDA. Cachexia, a common complication in patients with advanced cancer and other chronic diseases, is a complex metabolic syndrome characterized by malnutrition and severe involuntary weight loss due to the loss of muscle and fat tissue, as well as the clinical manifestation of anemia, inflammation and suppression of immune functions. A Phase 1 study in healthy subjects has been initiated.

About Tivozanib (FOTIVDA®)

Tivozanib is an oral, once-daily, next-generation VEGFR 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: AVEO's planned timing for making tivozanib available to patients in the U.S.; 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, ficlatuzumab and AV-380 and for commercialization of tivozanib in the United States; the advancement of AVEO's pipeline, including the advancement of ficlatuzumab in multiple clinical studies; the potential efficacy, safety and tolerability of ficlatuzumab, both as a stand-alone drug candidate and in combination with other therapies; the potential outcomes from studies of ficlatuzumab to provide AVEO with opportunities to pursue regulatory strategies; the potential clinical utility of ficlatuzumab in areas of unmet need; the potential to extend U.S. patent exclusivity for tivozanib and the timing of such potential extension; 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 PFS, the rate of adverse events, OS 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 "Cautionary Note Regarding Forward-Looking Statements" in AVEO's September 2020 press release regarding ficlatuzumab, and 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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AVEO:
David Pitts, Argot Partners
(212) 600-1902
aveo@argotpartners.com

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