AVEO Oncology Announces Clinical Updates to Tivozanib and Ficlatuzumab Programs

- Enrollment complete in Phase 2 portion of Phase 1/2 TiNivo trial;
Next data presentation expected at 2018 Genitourinary Cancers Symposium in February 2018-

- Investigator-sponsored studies of ficlatuzumab initiated in HNSCC and Pancreatic Cancer -

CAMBRIDGE, Mass.–December 7, 2017 – AVEO Oncology (NASDAQ: AVEO) today announced clinical updates for two of its oncology programs: FOTIVDA® (tivozanib), the Company's potent, selective, long half-life inhibitor of all three vascular endothelial growth factor (VEGF) receptors, and ficlatuzumab, the Company's humanized IgG1 antibody that binds to the hepatocyte growth factor (HGF) ligand with high affinity and specificity to inhibit the biological activities of the HGF/c-Met pathway.

"We continue to build strong momentum in our oncology programs, including progress with our lead program, tivozanib, and the advancement of our other oncology programs, including ficlatuzumab and AV-203," said Michael Bailey, president and chief executive officer of AVEO. "With approval of tivozanib and commercial sales underway in Europe, we are squarely focused on the next two pillars of our tivozanib strategy: the potential for U.S. registration and additional immunotherapy combination studies. As these strategies unfold, 2018 is expected to be another transformative year, with anticipated top-line results in the TIVO-3 study of tivozanib in third line advanced renal cell carcinoma (RCC), as well as development of our earlier-stage programs, including the TiNivo study of tivozanib in combination with Opdivo®, and the initiation of two ficlatuzumab investigator-sponsored studies."

Tivozanib Updates

- **Enrollment Complete in Phase 2 Portion of Phase 1/2 TiNivo Trial in Advanced RCC.** AVEO announced today that enrollment of 21 patients is now complete, with one patient remaining in screening, in the Phase 2 portion of the TiNivo study, a Phase 1/2 multicenter trial of tivozanib in combination with Bristol-Myers Squibb's OPDIVO® (nivolumab), an immune checkpoint, or PD-1, inhibitor, for the treatment of advanced RCC. In the Phase 1 dose escalation portion of the trial, tivozanib was administered in two escalating dose cohorts, 1.0 and 1.5 mg daily, in combination with nivolumab at 240 mg every 2 weeks (n=6).

  Phase 1 data from the study, which were presented at the 16th International Kidney Cancer Symposium, demonstrated that the combination of Opdivo and tivozanib was well tolerated up to the full dose and schedule of single agent tivozanib (1.5 mg daily), with no dose limiting toxicities. The most common adverse events (any grade) were hypertension, asthenia and decreased appetite. No grade 4 adverse events were reported. Two grade 3 events were reported beyond cycle 1 (stomatitis and increased ALT), which did not lead to study discontinuation and were managed concurrently. Best response at the time of presentation included a 67% (4/6) partial response (PR) rate and a 100% disease control rate (4 confirmed PR + 2 stable disease, 1 of which was unconfirmed). Additional results from the Phase 1 portion of the trial and initial results from the Phase 2 portion are expected to be presented at scientific meetings in the first half of 2018, including at the 2018 Genitourinary Cancers Symposium taking place February 8-10, 2018, and co-sponsored by the American Society of Clinical Oncology.

Ficlatuzumab Updates

- **Phase 2 Study of Ficlatuzumab in Combination with Cetuximab in HNSCC Initiated**. The Company announced today the initiation of an investigator-sponsored randomized, multicenter Phase 2 trial of ficlatuzumab and cetuximab (ERBITUX®), an EGFR-targeted antibody, in patients with cetuximab-resistant, metastatic head and neck squamous cell carcinoma (HNSCC). AVEO is partnered with Biodesix, Inc. on the developments of ficlatuzumab. The study will seek to confirm findings from a Phase 1 study where the addition of ficlatuzumab to cetuximab resulted in a disease control rate of 67%, and prolonged progression free and overall survival compared to historical controls, in addition to being well tolerated. This Phase 2 multi-center study, which is being conducted under the direction of Julie E. Bauman, MD, MPH, Professor of Medicine, Chief, Division of Hematology/Oncology, Associate Director of Translational Research, University of Arizona Cancer Center, is expected to enroll approximately 60 patients randomized to receive either ficlatuzumab alone or ficlatuzumab and cetuximab.

- **Phase 1b Study of Ficlatuzumab in Combination with Gemcitabine and Nab-paclitaxel in Pancreatic Cancer Initiated**. The Company announced today the initiation of an investigator-sponsored Phase 1b study to test the safety and tolerability of ficlatuzumab when combined with Nab-paclitaxel and Gemcitabine in previously untreated metastatic pancreatic ductal cancer (PDAC). The goal of the study, which is based on preclinical findings demonstrating a synergistic effect of these drugs in a preclinical model of PDAC, is designed to determine maximum tolerated dose of ficlatuzumab when combined with gemcitabine and nab-paclitaxel. Secondary outcome measures include response rate and progression free survival. The study, which is being conducted under the direction of Kimberly Perez, M.D. at the Dana-Farber Cancer Institute, is expected to enroll approximately 30 patients.

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 Ficlatuzumab

Ficlatuzumab (formerly known as AV-299) is a potent hepatocyte growth factor (HGF) inhibitory antibody that binds to the HGF ligand with high affinity and specificity to inhibit HGF/c-Met biological activities. AVEO and Biodesix, Inc. currently divide all worldwide development costs for ficlatuzumab and are seeking a commercialization partner. Ficlatuzumab is currently being evaluated in investigator-sponsored trials in squamous cell carcinoma of the head and neck (HNSCC) and acute myeloid leukemia (AML).

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 with respect to tivozanib (FOTIVDA®); the expected timeline for reporting data from TIVO-3 and TiNivo; the role and expected benefits of tivozanib and other TKIs on a stand-alone basis, or in combination with or following immunotherapy; the expected benefits of ficlatuzumab alone or in combination; 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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