AVEO Oncology and EUSA Pharma Announce Updated Interim Results from Phase 2 Portion of the TiNivo Study in Renal Cell Carcinoma

Tivozanib-Nivolumab Combination Continues to Demonstrate Favorable Efficacy and Safety

Data Presented at the European Society of Medical Oncology (ESMO) 2018 Annual Congress

CAMBRIDGE, Mass., USA and HEMEL HEMPSTEAD, England – October 22, 2018 – AVEO Oncology (NASDAQ: AVEO) and EUSA Pharma today announced the presentation of updated interim results from the Phase 2 portion of the TiNivo study, a Phase 1b/2 multicenter trial 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 or metastatic renal cell carcinoma. The results were presented today at European Society of Medical Oncology (ESMO) 2018 Annual Congress, in a poster presentation titled "TiNivo: Tivozanib Combined with Nivolumab: Safety and Efficacy in Patients with Metastatic Renal Cell Carcinoma (mRCC)" (Presentation 878P). A copy of the presentation is available at www.aveooncology.com or further information can be obtained via EUSA Pharma Medical Information.

The Phase 1b/2 study has enrolled a total of 28 patients. The Phase 2 portion of the study (n=22) was designed to assess the safety, tolerability, and anti-tumor activity of the full dose and schedule of PO tivozanib (1.5 mg/QD for 21 days followed by a 7-day rest period), as established in the Phase 1b portion of the study (n=6), in combination with IV nivolumab (240 mg every 2 weeks). The combination was generally well tolerated. Treatment-related Grade 3/4 adverse events occurred in 60% of patients, the most common of which was hypertension.

Interim efficacy was assessed in all 25 patients treated with the full dose and schedule of PO tivozanib in combination with IV nivolumab and enrolled at least 4 months prior to the data cutoff date. Of these, 13 (52%) had received at least one prior systemic therapy. An objective response rate was observed in 56% of patients (complete responses + partial responses), including 4% of patients (n=1) achieving a complete response, and a disease control rate (complete response + partial response + stable disease) was observed in 96% of patients. At the time of data collection 52% (n=13), of patients remained on study. To date, a total of 72% of patients (n=18) had tumor shrinkage of ≥25%, with a majority of patients having disease control for ≥48 weeks.

"With high and durable tumor shrinkage rates for the combination of tivozanib and nivolumab, including a complete response, coupled with a favorable tolerability profile and nearly all patients having disease control, the TiNivo study continues to underscore a compelling rationale for using a high-specificity VEGF inhibitor as the TKI of choice in immuno-oncology combinations," Doctor Bernard Escudier, MD, ex-Chairman of the Genitourinary Oncology Committee, Gustave Roussy, and lead investigator of the study. "The ability to give a VEGF inhibitor and immuno-oncology agent both at full dose and strength could serve to deliver both improved outcomes and an improved patient experience. I look forward to better understanding tivozanib's potential in

immunotherapy combinations through a larger randomized study, which is currently being planned."

"There are multiple cancers where IO-TKI combinations have demonstrated potential, and the favorable tolerability and efficacy outcomes seen in the TiNivo study make further exploration of these indications a priority for AVEO," said Michael Bailey, president and chief executive officer of AVEO. "We continue to build out a clinical strategy for studying such combinations, and look forward to outlining our plans following reporting of topline data from our Phase 3 TIVO-3 study, which is expected in the mid-fourth quarter."

"The data arising from combination studies with checkpoint inhibitors demonstrate the considerable potential for tivozanib in metastatic RCC," said Lee Morley, Chief Executive Officer of EUSA Pharma. "EUSA continues to launch tivozanib across the EU in line with its EMA approval as monotherapy in the first line setting where its efficacy and favorable tolerability profile continue to provide benefits to patients, and we are excited by the prospect of further development of tivozanib as part of a future IO-TKI treatment option."

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 or metastatic 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.

About EUSA Pharma

Founded in March 2015, EUSA Pharma is a world-class biopharmaceutical company focused on oncology and rare disease. The company has commercial operations in the United States and Europe, and a wider distribution network in approximately 40 countries around the world. EUSA Pharma is led by an experienced management team with a strong record of building successful pharmaceutical companies, and is supported by significant funding raised from leading life science investor EW Healthcare Partners. For more information, please visit www.eusapharma.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 expected benefits of combining TKIs and checkpoint inhibitors; the expected timeline for reporting topline data from TIVO-3; 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 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; AVEO's ability, and the ability of its collaborators and 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 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; developments, expenses and outcomes related to AVEO's 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 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.

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.

AVEO:

Argot Partners
David Pitts, 212-600-1902
aveo@argotpartners.com

or

EUSA:

EUSA Pharma
Lee Morley, +44 (0)330 5001140
Chief Executive