AVEO Reports Full Year 2018 Financial Results and Provides Business Update

CAMBRIDGE, Mass. – March 14, 2019 – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the full year ended December 31, 2018 and provided a business update.

"The results of TIVO-3, presented in February at the 2019 ASCO GU Symposium, underscore a unique activity and tolerability profile among VEGF TKIs in the treatment of kidney cancer," said Michael Bailey, president and chief executive officer of AVEO. "We continue to believe that there is a significant potential commercial opportunity for an active and well tolerated therapy within the third plus line of therapy, particularly one that demonstrated activity in a highly refractory patient population that has received prior PD-1 treatment. We are hopeful that the positive PFS outcomes from TIVO-3 translate into an improved overall survival hazard ratio and look forward to reporting a more mature interim OS outcome in the fourth quarter of 2019."

Recent Highlights

- **Presented Topline Results from TIVO-3 During an Oral Presentation at the 2019 ASCO Genitourinary Cancers Symposium.** In February 2019, AVEO presented topline results from the TIVO-3 trial, AVEO's Phase 3 randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in 350 subjects with refractory advanced or metastatic renal cell carcinoma (RCC) at the 2019 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium held February 14-16, 2019 in San Francisco. The results were presented during an oral presentation titled "TIVO-3: A Phase 3, Randomized, Controlled, Multi-Center, Open-Label Study to Compare Tivozanib to Sorafenib in Subjects with Refractory Advanced Renal Cell Carcinoma (RCC)." A copy of the presentation is currently available in the Publications & Presentation section of AVEO's website.

  The presentation noted that the TIVO-3 trial met its primary endpoint of demonstrating a statistically significant benefit in median progression-free survival (PFS). Median PFS for tivozanib was also longer than sorafenib both in patients who received prior PD-1 therapy and those who received two prior VEGF TKI therapies. The secondary endpoint of overall response rate also demonstrated a statistically significant improvement for patients receiving tivozanib compared to sorafenib.

  The analysis of the secondary endpoint of overall survival (OS) was not mature at the time of the final PFS analysis. As presented, the preliminary OS analysis conducted at an October 4, 2018 data cutoff date, which included additional patients previously lost to follow-up, showed a non-statistically significant difference in OS favoring sorafenib (hazard ratio: 1.12, p-value: 0.44).

Tivozanib was generally well-tolerated relative to sorafenib, with reported grade 3 or higher adverse events consistent with those observed in previous tivozanib trials. The improved tolerability of tivozanib was evident in the lower rates of dose reductions and interruptions for toxicity in patients receiving tivozanib compared to those receiving sorafenib. The most common adverse event in patients receiving tivozanib was hypertension, an adverse event known to reflect effective VEGF pathway inhibition.

- **Announced NDA Timing Update**. In January 2019, the U.S. Food and Drug Administration (FDA) recommended that AVEO not submit a New Drug Application (NDA) for tivozanib at this time using the preliminary OS results from the TIVO-3 trial. The FDA indicated that these preliminary OS results do not allay their concerns about the potential detriment in OS outlined in the Complete Response Letter dated June 6, 2013. AVEO now plans to make an NDA filing decision following the availability of more mature OS results. AVEO intends to conduct an additional interim OS analysis in August 2019, the results of which are expected to be reported in the fourth quarter of 2019.

- **Data from Phase 1b Expansion Cohort of Ficlatuzumab and Cytarabine in Relapsed and Refractory AML to be Presented at 2019 AACR Annual Meeting.** Data from the investigator-sponsored Phase 1b expansion cohort evaluating the safety and tolerability of ficlatuzumab, AVEO's potent hepatocyte growth factor (HGF) inhibitory antibody, in combination with cytarabine in patients with relapsed and refractory acute myeloid leukemia (AML) will be presented during a poster session at the 2019 American Association for Cancer Research (AACR) Annual Meeting. The presentation, titled, "Cyfi: Results from a Phase 1b expansion cohort of anti-hepatocyte growth factor and cytarabine in relapsed and refractory AML" (abstract CT078 / 2) will be featured during a poster session (Session PO.CT03) on Monday, April 1, 2019 from 1:00-5:00pm Eastern Time.

- **Entered Immuno-Oncology Clinical Supply Agreement with AstraZeneca.** In December 2018, AVEO entered into a clinical supply agreement with AstraZeneca to evaluate the safety and efficacy of AstraZeneca's IMFINZI® (durvalumab), a human monoclonal antibody directed against programmed death-ligand 1 (PD-L1), in combination with tivozanib in first-line hepatocellular carcinoma, or liver cancer, in a Phase 1/2 study. AVEO will serve as the study sponsor; each party will contribute the clinical supply of its study drug and study costs will be otherwise shared equally. The Phase 1 portion of the study is expected to commence this year.

- **Earned $2 Million Milestone Payment from EUSA Pharma.** In November 2018, AVEO announced the triggering of a $2 million milestone payment from EUSA Pharma related to the reimbursement in Germany for FOTIVDA® as a first line treatment of adult patients with advanced RCC.

- **Extended Debt Facility Interest-Only Period.** In December 2018, AVEO announced a six-month extension to the interest-only period under its existing amended and restated loan and security agreement with Hercules Capital, Inc. The extension was granted as a

result of achieving certain predefined requirements under the agreement, including successfully meeting the primary endpoint of the TIVO-3 trial.

- **Raised $7.5 Million Under the Sales Agreement with SVB Leerink, Extending Financial Runway.** In February 2019, AVEO raised $7.5 million through its sales agreement with SVB Leerink. Approximately $32 million of shares remain available for future issuance and sale pursuant to the sales agreement, which was originally entered into in February 2018. AVEO believes that the proceeds generated in February 2019 through the sales agreement, together with its available cash, cash equivalents, and marketable securities at December 31, 2018, and together with the extension of the interest-only period under the Hercules loan agreement, which results in deferment of principal payments, will allow it to fund planned operations into the first quarter of 2020.

Full Year 2018 Financial Highlights

- AVEO ended 2018 with $24.4 million in cash, cash equivalents and marketable securities as compared with $33.5 million at December 31, 2017.
- Total revenue for 2018 was approximately $5.4 million compared with $7.6 million for 2017.
- Research and development expense for 2018 was $20.7 million compared with $25.2 million for 2017.
- General and administrative expense for 2018 was $10.8 million compared with $9.1 million for 2017.
- Net loss for 2018 was $5.3 million, or a loss of $0.04 and $0.19 per basic and diluted share, respectively, compared with a net loss of $65.0 million for 2017, or a loss of $0.61 per basic and diluted share.
    - The 2018 net loss was partially offset by an approximate $19.9 million non-cash gain attributable to the decrease in the fair value of the 2016 private placement warrant liability that principally resulted from the decrease in the stock price that occurred within the fiscal year. In 2017, the non-cash loss attributable to the increase in the fair value of such warrant liability was $33.7 million.

Financial Guidance

AVEO believes that its $24.4 million in cash, cash equivalents, and marketable securities at the end of 2018, together with the additional $7.5 million raised from sales under its sales agreement with SVB Leerink in February 2019 and together with the extension of the interest-only period under the Hercules loan agreement, which results in deferment of principal payments, would allow it to fund planned operations into the first quarter of 2020. This estimate assumes no receipt of additional milestones from AVEO's partners, no additional funding from new partnership agreements, no additional equity or debt financings, and no sales of equity through the exercise of

outstanding warrants issued in connection with the 2016 private placement or outstanding warrants issued in connection with the recent settlement of the securities class action litigation.

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[3] and has demonstrated synergy in combination with nivolumab (anti PD-1) in a Phase 2 study in RCC. Tivozanib has been investigated in several tumor types, including renal cell, hepatocellular, colorectal and breast cancers. In addition, a new formulation of tivozanib is in pre-clinical development for the treatment of age-related macular degeneration.

About AVEO

AVEO Pharmaceuticals, Inc. (the "Company" or "AVEO") is a biopharmaceutical company seeking to advance targeted medicines for oncology and other unmet medical needs. The Company is working to develop and commercialize its lead candidate tivozanib in North America as a treatment for RCC. The Company has sublicensed tivozanib (FOTIVDA®) for oncological indications 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 also has clinical collaborations to study tivozanib in combination with immune checkpoint inhibitors in RCC and in hepatocellular carcinoma. In addition, a new formulation of tivozanib is in pre-clinical development for the treatment of age-related macular degeneration. As part of the Company's strategy, the Company has also entered into partnerships to help fund the development and commercialization of its other product candidates. Ficlatuzumab, a hepatocyte growth factor inhibitory antibody, is currently being tested in several investigator sponsored studies jointly funded by the Company and one of its development partners for the potential treatment of squamous cell carcinoma of the head and neck, AML, and pancreatic cancer. The Company's partner for AV-203, an anti-ErbB3 monoclonal antibody, is planning to initiate clinical studies in China in 2019 in esophageal squamous cell carcinoma and has committed to funding the development of AV-203 through proof-of-concept. The Company has recently regained the rights to AV-380, a humanized IgG1 inhibitory monoclonal antibody targeting growth differentiation factor 15, a divergent member of the TGF-ß family, for the potential treatment of cancer cachexia, and is working to initiate preclinical toxicology studies mid-2019 to support the potential filing of an investigational new drug application with the FDA. The Company is evaluating options for the development of its preclinical AV-353 platform which targets the Notch 3 pathway.

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: the potential commercial opportunity of tivozanib; AVEO's plans to make a NDA filing decision following the availability of more mature OS results; AVEO's plans to complete an interim OS analysis for the TIVO-3 trial in August 2019 and to report the results of this analysis in the fourth quarter; AVEO's expectation that the OS outcome will be more mature by August 2019; 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 liver cancer; timing for the commencement of the Phase 1 portion of the IMFINZI and tivozanib combination study; AVEO's cash runway; AVEO's plans and strategies for commercialization of tivozanib in the United States and Europe; AVEO's plan to develop the AV-353 platform; AVEO's plans regarding AV-380 and AVEO's other 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.

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AVEO PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Collaboration and licensing revenue	$ 1,296	$ 63	$ 4,947	$ 7,560
Partnership royalties	187	19	462	19
	1,483	82	5,409	7,579
Operating expenses:				
Research and development	5,201	5,676	20,652	25,179
General and administrative	2,625	2,404	10,781	9,138
Settlement costs	—	2,073	(667)	2,073
	7,826	10,153	30,766	36,390
Loss from operations	(6,343)	(10,071)	(25,357)	(28,811)
Other income (expense), net:				
Interest expense, net	(570)	(637)	(2,191)	(2,373)
Change in fair value of PIPE Warrant liability	26,431	14,207	19,919	(33,740)
Other income (expense), net	2,300	—	2,300	—
Other income (expense), net	28,161	13,570	20,028	(36,113)
Net income (loss) before provision for income taxes	21,818	3,499	(5,329)	(64,924)
Provision for income taxes	—	—	—	(101)
Net income (loss)	$ 21,818	$ 3,499	$ (5,329)	$ (65,025)
Basic net income (loss) per share				
Net income (loss) per share	$ 0.18	$ 0.03	$ (0.04)	$ (0.61)
Weighted average number of common shares outstanding	124,395	118,323	120,592	105,930
Diluted net income (loss) per share				
Net income (loss) per share	$ (0.03)	$ (0.08)	$ (0.19)	$ (0.61)
Weighted average number of common shares and dilutive common share equivalents outstanding	133,580	130,108	130,731	105,930

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	December 31, 2018	December 31, 2017
Assets		
Cash, cash equivalents and marketable securities	$ 24,427	$ 33,525
Accounts receivable	3,026	402
Prepaid expenses and other current assets	482	1,256
Insurance recovery	—	15,000
Other assets	—	15
Total assets	$ 27,935	$ 50,198
Liabilities and stockholders' deficit		
Accounts payable and accrued expenses	$ 12,451	$ 13,215
Loans payable	19,033	18,477
Deferred revenue and research and development reimbursements	5,914	2,820
PIPE Warrant liability	16,674	37,746
Estimated settlement liability	—	17,073
Other liabilities	1,090	1,630
Stockholder's deficit	(27,227)	(40,763)
Total liabilities and stockholders' deficit	$ 27,935	$ 50,198