AVEO Reports First Quarter 2019 Financial Results and Provides Business Update

CAMBRIDGE, Mass. – May 9, 2019 – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the first quarter ended March 31, 2019 and provided a business update.

"With a successful recent equity offering, together with the triggering of a FOTIVDA® (tivozanib) milestone from EUSA, AVEO's strengthened balance sheet provides us with a cash runway that we expect will take us into the fourth quarter of 2020," said Michael Bailey, president and chief executive officer of AVEO. "We remain committed to our goal of improving outcomes and patient experience in renal cell carcinoma (RCC), and look forward to reporting more mature interim OS results from our TIVO-3 study in advanced or metastatic RCC, which we expect will occur in the fourth quarter of 2019, as well as the subsequent decision regarding a potential NDA filing in the U.S. We also continue to make progress with the balance of our programs and pipeline, most notably the ongoing clinical collaborations combining FOTIVDA® with Bristol Myers Squibb's OPDIVO® (nivolumab) for the TiNivo study in RCC and with AstraZeneca's IMFINZI® (durvalumab) in first-line hepatocellular carcinoma, ongoing studies of ficlatuzumab in multiple oncology indications, and the emerging potential of a new ocular formulation of tivozanib for the treatment of age-related macular degeneration."

Recent Highlights

- **$2 Million Milestone Payment from EUSA Pharma Triggered.** In April 2019, AVEO announced the triggering of a $2 million milestone payment from EUSA Pharma related to the February 2019 reimbursement approval and subsequent commercial launch of FOTIVDA® (tivozanib) in Spain as a first-line treatment of adult patients with RCC.

- **Closing of Public Offering of Common Stock and Warrants.** In April 2019, AVEO completed an underwritten public offering of 21,739,131 shares of common stock and 25,000,000 warrants to purchase common stock at the public offering price of $1.14 per share and $0.01 per warrant. The warrants have a two-year term and a strike price of $1.25 per share. Gross proceeds of the offering were approximately $25.0 million and are expected to be used for ongoing clinical and preclinical development of AVEO's product candidates, as well as for working capital and other general corporate purposes.

- **Announced Positive Results from Phase 1b Ficlatuzumab-Cytarabine Trial (CyFi) in Patients with Relapsed and Refractory AML.** In April 2019, AVEO announced the presentation of positive data from an investigator-sponsored Phase 1b expansion cohort 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), at the American Association for Cancer Research (AACR) Annual Meeting, held March 29 - Apr 3, 2019 in Atlanta. Of 18 AML patients enrolled in the study, all had disease that was refractory to initial treatment, 17 were evaluable and 9 achieved a complete response. The most frequent grade 3/4 treatment emergent adverse

events observed were febrile neutropenia, LFT abnormalities, and electrolyte disturbance. There was one death from sepsis and multi-organ failure that was determined to be disease related, and one patient withdrew from the study due to grade 4 gastrointestinal bleed, determined to be likely ficlatuzumab related. A copy of the presentation is currently available in the Publications & Presentation section of AVEO's website.

Based on these results, the Company is evaluating potential next steps for this program in collaboration with its ficlatuzumab development and commercialization partner, Biodesix, Inc.

- **Appointed Gregory T. Mayes to Board of Directors.** In February 2019, the Company announced the appointment of Gregory T. Mayes to its Board of Directors. Mr. Mayes brings to the AVEO Board over 20 years of experience as a biopharmaceutical executive with deep expertise in public company governance, business strategy and the commercialization of life sciences products.

- **Presented Topline Results from TIVO-3 in an Oral Presentation at the 2019 ASCO Genitourinary Cancers Symposium and Announced Updated NDA Timing**. 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 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 progression-free survival (PFS) versus sorafenib. There was also a significant PFS improvement demonstrated for tivozanib both in the subgroups of patients who received prior PD-1 therapy and those who received two prior VEGF TKI therapies. The secondary endpoint of overall response rate 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, but the hazard ratio at the time of the analysis favored sorafenib. Tivozanib was generally well-tolerated, with grade 3 or higher adverse events consistent with those observed in previous tivozanib trials. Infrequent but severe adverse events reported in greater number in the tivozanib arm were thrombotic events similar to those observed in previous tivozanib studies. The most common adverse event in patients receiving tivozanib was hypertension, an adverse event known to reflect effective VEGF pathway inhibition.

  AVEO intends to initiate an additional interim OS analysis in August 2019, the results of which are expected to be reported in the fourth quarter of 2019 and would be the first planned update since the prior OS analysis was initiated in the fourth quarter of 2018. At

the recommendation of the U.S. Food and Drug Administration, AVEO plans to make a New Drug Application (NDA) filing decision following the availability of more mature OS results.

First Quarter 2019 Financial Results

- AVEO ended Q1 2019 with $23.5 million in cash, cash equivalents and marketable securities as compared with $24.4 million at December 31, 2018.
- Total revenue for Q1 2019 was approximately $1.6 million compared with $1.0 million for Q1 2018.
- Research and development expense for Q1 2019 was $6.9 million compared with $5.4 million for Q1 2018.
- General and administrative expense for Q1 2019 was $2.5 million compared with $2.6 million for Q1 2018.
- Net income for Q1 2019 was $0.6 million, or net income of $0.01 and net loss of $0.06 per basic and diluted share, respectively, compared with a net loss of $9.0 million for Q1 2018, or net loss of $0.08 per basic and diluted share.
    - The Q1 2019 net income was driven by an approximate $8.8 million non-cash gain attributable to the decrease in the fair value of the 2016 PIPE warrant liability that principally resulted from the decrease in the stock price that occurred during the fiscal quarter. In Q1 2018, the non-cash loss attributable to the increase in the fair value of such warrant liability was $1.5 million.

Financial Guidance

AVEO believes that our approximate $23.5 million in cash, cash equivalents and marketable securities at March 31, 2019, along with approximately $24.2 million in additional net funding received in the second quarter of 2019 to-date, as described above, would allow us to fund our planned operations into the fourth quarter of 2020. This estimate excludes possible additional clinical trials we may sponsor and, subject to our decision whether to submit an NDA for tivozanib to the FDA following the availability of more mature OS results, remaining costs to prepare and filing fees in connection with a possible NDA submission, any related drug manufacturing and drug supply distribution, and pre-commercialization activities that we may undertake. This estimate also assumes no receipt of additional milestone payments from our partners, no funding from new partnership agreements, no additional equity financings, no debt financings, no additional sales of equity under our Leerink Sales Agreement and no additional sales of equity through the exercise of our outstanding warrants. Accordingly, the timing and nature of activities contemplated for the remainder of 2019 and thereafter will be conducted subject to the availability of sufficient financial resources.

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 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. have a worldwide agreement to develop and commercialize ficlatuzumab. Ficlatuzumab is currently being evaluated in investigator-sponsored trials in squamous cell carcinoma of the head and neck (HNSCC), metastatic pancreatic ductal cancer (PDAC), and acute myeloid leukemia (AML).

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 HNSCC, AML, and PDAC. 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 in 2019 to support the potential filing of an investigational new drug application with the FDA. The Company is evaluating options for the development of AV-353, a preclinical asset 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 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," "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 initiate an interim OS analysis for the TIVO-3 trial in August 2019 and to report the results of this analysis in the fourth quarter and make a NDA filing decision following such analysis; 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 March 31,	
	2019	**2018**
Revenues:		
Collaboration and licensing revenue	$ 1,454	$ 980
Partnership royalties	157	46
	1,611	1,026
Operating expenses:		
Research and development	6,852	5,404
General and administrative	2,455	2,610
Settlement costs	—	42
	9,307	8,056
Loss from operations	(7,696)	(7,030)
Other income (expense), net:		
Interest expense, net	(564)	(493)
Change in fair value of PIPE Warrant liability	8,815	(1,465)
Other income (expense), net	8,251	(1,958)
Net income (loss)	$ 555	$ (8,988)
Basic net income (loss) per share		
Net income (loss) per share	$ 0.01	$ (0.08)
Weighted average number of common shares outstanding	132,304	118,840
Diluted net income (loss) per share		
Net income (loss) per share	$ (0.06)	$ (0.08)
Weighted average number of common shares and dilutive common share equivalents outstanding	132,831	118,840

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	March 31, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 23,483	$ 24,427
Accounts receivable	2,571	3,026
Prepaid expenses and other current assets	241	482
Other assets	212	—
Total assets	$ 26,507	$ 27,935
Liabilities and stockholders' deficit		
Accounts payable and accrued expenses	$ 10,593	$ 12,451
Loans payable, net of discount	19,199	19,033
Deferred revenue and research and development reimbursements	6,342	5,914
PIPE Warrant liability	7,859	16,674
Other liabilities	1,090	1,090
Stockholder's deficit	(18,576)	(27,227)
Total liabilities and stockholders' deficit	$ 26,507	$ 27,935