AVEO Reports First Quarter 2018 Financial Results and Provides Business Update

CAMBRIDGE, Mass. – May 8, 2018 – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the first quarter ended March 31, 2018 and provided a business update.

"We continue to work toward reporting topline results from our Phase 3 TIVO-3 Study, which we now anticipate will occur in the third quarter of 2018. We are working closely with our contract research organization (CRO) to shorten the time required to do the data cleaning and analysis upon reaching the requisite number of events. Together with the TIVO-1 study, the TIVO-3 study has been designed to serve as the basis for a potential U.S. approval of tivozanib as a first- and third-line treatment for advanced renal cell carcinoma (aRCC)," said Michael Bailey, president and chief executive officer of AVEO. "This important milestone, if achieved, would add to the continued commercial progress of FOTIVDA® which is approved in Europe, with launches currently underway in Germany, the U.K. and Austria. We finished the quarter with $27 million in cash, cash equivalents and investments as of March 31, 2018. Under our agreement with our partner EUSA, we have double-digit royalty payments due to us on net sales of FOTIVDA® in Europe, potential milestone payments including $8 million related to reimbursement approvals for France, Germany, Italy, and Spain, and $20M in potential R&D reimbursement for access to TIVO-3 data in the event of a positive study."

Mr. Bailey added, "As we work toward our goal of commercialization in the U.S., we also continue to aggressively pursue the third pillar of our tivozanib strategy, combinations with immunotherapy. We were pleased to present results from the ongoing Phase 2 portion of the TiNivo study of tivozanib and nivolumab (OPDIVO®) in aRCC at ASCO GU. These early results demonstrated a combination of a favorable safety profile and activity that we believe hold significant promise for patients with aRCC and potentially other tumor types such as hepatocellular carcinoma (HCC)."

Tivozanib TIVO-3 Study North America Update

Update on Anticipated Timeline to Topline Data from Phase 3 TIVO-3 Study. AVEO today announced that the pre-specified number of progression free survival (PFS) events required to trigger data analysis of the Phase 3 TIVO-3 trial have not been reached at this time and, as such, the Company is amending its guidance for the anticipated topline data readout from the second to the third quarter of 2018. In collaboration with the CRO conducting the TIVO-3 study, AVEO has taken measures to shorten the data cleaning and analysis period following the pre-specified events trigger from 8-10 weeks down to 6-8 weeks. Together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of aRCC, TIVO-3 is designed to support regulatory approval of tivozanib in the U.S. as a first- and third-line treatment for aRCC.

Tivozanib (FOTIVDA®) European Union Updates

- **Tivozanib (FOTIVDA®) Launched in Austria for the Treatment of aRCC.** In April 2018, FOTIVDA® was launched in Austria for the treatment of adult patients with aRCC. This follows the February 2018 publication by the United Kingdom's National Institute for Health and Care Excellence (NICE) of a Final Appraisal Determination recommending FOTIVDA® for the first line treatment of adult patients with aRCC, which triggered the commercial launch in the UK as well as a $2M milestone payment to AVEO from EUSA Pharma, the licensee for tivozanib in Europe. FOTIVDA® is now available in the Germany, the U.K., and Austria.

  FOTIVDA® was granted European Commission (EC) approval in August 2017 for the treatment of adult patients with aRCC in the European Union plus Norway and Iceland.

Additional Tivozanib Updates

- **Long-term Follow-up Results from TIVO-1 Extension Study (Study 902), Published in the *European Journal of Cancer*.** In March 2018, AVEO announced the publication of long-term follow-up results from Study 902, where patients were treated with tivozanib (FOTIVDA®) as second-line treatment for aRCC, in the *European Journal of Cancer*. Findings from the study underscore the activity of tivozanib in the refractory setting, with evidence of encouraging clinical responses, disease control and overall survival outcomes in patients previously treated with a VEGFR TKI and support the rationale for the ongoing Phase 3 TIVO-3 study. The publication, titled "Efficacy of Tivozanib Treatment after Sorafenib in Patients with Advanced Renal Cell Carcinoma: Crossover of a Phase 3 Study," is available on our website at www.aveooncology.com.

- **Results from Phase 2 Portion of the TiNivo Study of Tivozanib and Nivolumab (OPDIVO®) in mRCC Presented at ASCO GU**. In February 2018, Bernard Escudier, M.D., from the Institute Gustav Roussy in Paris, France presented results from the ongoing Phase 2 portion of the TiNivo study at the 2018 American Society of Clinical Oncology's Genitourinary Cancers Symposium (ASCO GU). TiNivo is a Phase 1b/2 multi-center trial of oral tivozanib in combination with intravenous nivolumab (OPDIVO®, Bristol-Myers Squibb), an immune checkpoint, or PD-1, inhibitor, for the treatment of metastatic renal cell carcinoma (mRCC). The presentation noted the favorable safety profile and promising preliminary anti-tumor activity observed to date. These results continue to support the potential advantages of using a high-specificity VEGF inhibitor TKI in building upon the benefit of immune checkpoint therapy in renal cancer. AVEO and EUSA Pharma expect to present further updates to the TiNivo study at upcoming medical meetings in the second half of 2018.

- **Phase 1b/2 Study Results of Tivozanib in Patients with Advanced Hepatocellular Carcinoma Presented at ASCO GI**. In January 2018, AVEO announced the presentation of data from a multi-center, Phase 1b/2 study of tivozanib in previously untreated patients with advanced, unresectable HCC at the 2018 American Society of Clinical Oncology

Gastrointestinal Cancers Symposium (ASCO GI). Findings from the study suggest that tivozanib has the potential to yield comparable PFS and a favorable response rate when compared to current first-line standards of care for HCC patients, and demonstrated a favorable safety profile which may enable therapeutic combinations with immunotherapy. The Phase 1b/2 study was led by Renuka Iyar, M.D., from the Roswell Park Cancer Center and was one of several studies funded by a grant provided to the National Comprehensive Cancer Network by AVEO.

Ficlatuzumab Update

- **Trials in Progress Poster for Phase 1b Study of Ficlatuzumab in Combination with Gemcitabine and Nab-paclitaxel in Pancreatic Cancer to be Presented at the 2018 ASCO Annual Meeting.** An ongoing, 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) will be presented as a trials in progress poster (Poster Board: #330b, Abstract TPS4152) at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL. The study, which is being conducted under the direction of Kimberly Perez, M.D. at the Dana-Farber Cancer Institute, is currently enrolling, with an expected total enrollment of approximately 30 patients.

Corporate Updates

- **Refinanced Debt Facility, Extending Cash Runway into 2019**. In January 2018, AVEO announced that it completed the refinancing of its existing $20.0 million debt facility with Hercules Capital, Inc. and its affiliates, the terms of which enable approximately an additional $12.1 million in cash flow over 2018 and 2019, when compared to the prior loan. The new $20.0 million facility has a 42-month maturity from closing, no financial covenants, a lower interest rate and an interest-only period of no less than 12 months, which could be extended up to a maximum of 24 months, assuming the achievement of specified milestones relating to the development of tivozanib. Extension of the interest-only period is expected to enable the Company to extend its cash runway into the first quarter of 2019. Proceeds of the new facility were used to retire the Company's previous $20.0 million of secured debt with Hercules.

- **Strengthened Board of Directors.** In February 2018, AVEO announced the appointment of John H. Johnson to the Company's Board of Directors. Mr. Johnson brings to AVEO over three decades of experience in the biotechnology and pharmaceuticals industries, having held commercial and executive management roles at leading global corporations that have a focus on oncology.

First Quarter 2018 Financial Highlights

- AVEO ended Q1 2018 with $27.0 million in cash, cash equivalents and marketable securities as compared with $33.5 million at December 31, 2017.

- Total revenue for Q1 2018 was approximately $1.0 million compared with $2.5 million for Q1 2017.
- Research and development expense for Q1 2018 was $5.4 million compared with $8.0 million for Q1 2017.
- General and administrative expense for Q1 2018 was $2.6 million compared with $2.3 million for Q1 2017.
- Net loss for Q1 2018 was $9.0 million, or a loss of $0.08 per basic and diluted share, compared with net loss of $8.8 million for Q1 2017, or a loss of $0.12 per basic and diluted share. Approximately $1.5 million of the Q1 2018 net loss was a non-cash loss attributable to the increase in the fair value of the warrant liability that principally resulted from the increase in the stock price that occurred within the quarter. In Q1 2017, the non-cash loss attributable to the increase in the fair value of the warrant liability was $0.5 million.

Financial Guidance

We believe that our $27.0 million in cash resources would allow us to fund our planned operations into the first quarter of 2019. This estimate assumes no receipt of additional milestones from our partners or related payment of potential licensing milestones to third parties, no additional funding from new partnership agreements, no additional equity or debt financings, and no sales of equity through the exercise of our outstanding warrants issued in connection with our 2016 private placement.

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 other areas of unmet medical need. Tivozanib (FOTIVDA®) is approved by the European Commission for the treatment of adult patients with advanced renal cell carcinoma 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: the Company's plans and prospects for seeking and obtaining FDA approval of tivozanib as a first- and third-line treatment for aRCC; the expected timeline for reporting data from TIVO-3 and TiNivo clinical

trials; advancement of AVEO's pipeline; potential payments under AVEO's license agreement with EUSA; the period in which AVEO anticipates that its existing cash resources will fund its operations; 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; and 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 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.

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

	Three Months Ended March 31,	
	2018	**2017**
Revenues:		
Collaboration and licensing revenue	$ 980	$ 2,532
Partnership royalties	46	—
	1,026	2,532
Operating expenses:		
Research and development	5,404	7,956
General and administrative	2,610	2,331
Settlement costs	42	—
	8,056	10,287
Loss from operations	(7,030)	(7,755)
Other expense, net:		
Interest expense, net	(493)	(551)
Change in fair value of PIPE warrant liability	(1,465)	(484)
Other expense, net	(1,958)	(1,035)
Loss before provision for income taxes	(8,988)	(8,790)
Provision for income taxes	—	(50)
Net loss	$ (8,988)	$ (8,840)
Net loss per share — basic and diluted	$ (0.08)	$ (0.12)
Weighted average number of common shares outstanding	118,840	76,246

Consolidated Balance Sheet Data
(In thousands)

	March 31, 2018	December 31, 2017
Assets		
Cash, cash equivalents and marketable securities	$ 26,995	$ 33,525
Accounts receivable	600	402
Prepaid expenses and other current assets	1,007	1,256
Insurance recovery	15,000	15,000
Other assets	11	15
Total assets	$ 43,613	$ 50,198
Liabilities and stockholders' deficit		
Accounts payable and accrued expenses	$ 12,679	$ 13,215
Loans payable, net of discount	18,588	18,477
Deferred revenue and research and development reimbursements	6,276	2,820
PIPE warrant liability	38,110	37,746
Estimated settlement liability	17,115	17,073
Other liabilities	1,090	1,630
Stockholder's deficit	(50,245)	(40,763)
Total liabilities and stockholders' deficit	$ 43,613	$ 50,198