



AVEO Reports Full Year 2017 Financial Results and Provides Business Update

CAMBRIDGE, Mass. – March 13, 2018 – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the full year ended December 31, 2017 and provided a business update.

“Last year was one of major progress for AVEO, with highlights including the first commercial launch of tivozanib (FOTIVDA[®]); the completion of the enrollment for TIVO-3, our U.S. registration study; the receipt of promising results from the Phase 1b/2 TiNivo combination trial of tivozanib and nivolumab (OPDIVO[®]); and progress across our earlier stage pipeline,” said Michael Bailey, president and chief executive officer of AVEO. “These achievements are only the beginning of our effort to unlock the value of tivozanib through registration and development including combination therapy. We also are excited by the potential of our AVEO-developed pipeline candidates, including ficlatuzumab, AV-203, AV-380 and AV-353. Supporting our multifaceted goals, we have worked to strengthen our executive management team and Board with the appointment of experienced leaders and to reinforce our balance sheet through milestone payments, royalties, the renegotiation of our debt agreement and careful financial stewardship.”

Tivozanib (FOTIVDA[®]) European Union Update

- **Tivozanib (FOTIVDA[®]) Launched in Germany, Granted Positive NICE Final Appraisal Determination for the Treatment of Advanced Renal Cell Carcinoma (aRCC) in the UK.** In November 2017, AVEO and EUSA Pharma, the licensee for tivozanib in Europe, North and South Africa, Latin America and Australasia, announced the first commercial launch of FOTIVDA[®] with the initiation of product sales in Germany. In February 2018, AVEO announced that the United Kingdom’s National Institute for Health and Care Excellence (NICE) published a Final Appraisal Determination recommending FOTIVDA[®] for the first line treatment of adult patients with advanced renal cell carcinoma (aRCC). The positive recommendation was followed by the launch of FOTIVDA[®] in the United Kingdom and triggered a \$2M milestone payment to AVEO from EUSA Pharma. 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.

Tivozanib TIVO-3 Study North America Update

- **Successfully Completed the TIVO-3 Futility Analysis with No Changes to Study Protocol.** In October 2017, AVEO announced the completion of a pre-planned interim futility analysis of the Phase 3 TIVO-3 trial, the Company’s randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib (NEXAVAR[®]) in subjects with aRCC. Based on the results of the futility analysis, which were reviewed by an independent statistician, the study continued as planned without modification. The analysis did not allow for early stopping due to efficacy to assure adequate follow-up for the key secondary endpoint of overall survival. Based on the current rate of progression-free survival (PFS) events, the Company expects the TIVO-3 trial to read out in the second quarter of 2018. The TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the

first line treatment of aRCC, is designed to support a potential regulatory approval of tivozanib in the U.S. as a first- and third-line treatment for aRCC.

TiNivo Combination Study Clinical Update

- **Phase 1b/2 Results from the TiNivo Trial of Tivozanib and Nivolumab (OPDIVO®) in aRCC presented at International KCS and ASCO GU.** In November 2017, the results from the Phase 1b portion of the Phase 1b/2 TiNivo study were presented at the 16th International Kidney Cancer Symposium. In February 2018, Bernard Escudier, M.D, from the Institute Gustav Roussy in Paris, France presented preliminary results from the 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 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 oral 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 intravenous nivolumab (240 mg every 2 weeks). The combination was generally well tolerated. Treatment-related Grade 3/4 adverse events occurred in 44% of patients, the most common of which was hypertension. Preliminary efficacy was assessed in 14 patients treated with the full dose and schedule of oral tivozanib in combination with intravenous nivolumab and enrolled at least 4 months prior to the data cutoff date. Of these, seven patients had received at least one prior systemic therapy and seven were treatment naive. A partial response was observed in 64% of patients, and a disease control rate (partial response + stable disease) was observed in 100% of patients. At the time of data collection, 11 of 14 evaluable patients remained on study. The Company and EUSA Pharma expect to present further updates to the TiNivo study at upcoming medical meetings in the second half of 2018.
- **TiNivo Combination Study Opt-in.** In September 2017, AVEO announced that EUSA Pharma, under its multi-territory licensing agreement with AVEO for tivozanib, opted in to co-develop the Phase 1b/2 TiNivo study and potential future combination studies in exchange for research and development reimbursement payments totaling \$2.0 million. Under terms of the agreement, EUSA will fund up to half of the Phase 1b/2 TiNivo study, not to exceed \$2.0 million, and may utilize the data from the study for regulatory or commercial purposes.

Tivozanib Clinical Development in Hepatocellular Carcinoma

- **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 hepatocellular carcinoma (HCC) at the 2018 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI). The study, designed to evaluate the safety and efficacy of tivozanib in advanced HCC, enrolled a total of 21 patients at three study sites. Tivozanib at 1.0 mg daily was selected in the Phase 1b portion of the study as the dose for the Phase 2 expansion. Of 19 patients

evaluable for efficacy, at a median follow up of 16.9 months, the study's primary endpoint of PFS and PFS at week 24 were 5.5 months and 47%, respectively. A partial response (PR) was seen in 21% (4/19) of patients and stable disease (SD) was observed in 42% (8/19) of patients, for a disease control rate (DCR) of 63%. Overall survival (OS) at 6 and 12 months was 58% and 25%, respectively, with a median OS of 7.5 months. Notably, 4 patients have maintained SD for over two years. There were no significant changes in hepatitis B or hepatitis C viral load during study treatment. Tivozanib was generally well tolerated, with adverse events consistent with those observed in previous tivozanib trials. 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.

Pipeline Updates

- **Phase 2 Study of Ficlaturuzumab in Combination with Cetuximab in HNSCC Initiated.** In December 2017, AVEO announced the initiation of an investigator-sponsored randomized, multi-center 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 has partnered with Biodesix, Inc. on the development of ficlatuzumab, a 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. 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, M.D., M.P.H., Professor of Medicine, Chief, Division of Hematology/Oncology, Associate Director of Translational Research, University of Arizona Cancer Center, is expected to enroll approximately 70 patients randomized to receive either ficlatuzumab alone or ficlatuzumab and cetuximab.
- **Phase 1b Study of Ficlaturuzumab in Combination with Gemcitabine and Nab-paclitaxel in Pancreatic Cancer Initiated.** In December 2017, AVEO announced 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 the 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.
- **IND Application for CAN017 (AV-203) Trial in Esophageal Squamous Cell Cancer (ESCC) Filed by CANbridge In China.** In December 2017, CANbridge Life Sciences,

the licensee for CAN017 (AV-203) outside of North America, announced that it filed an Investigational New Drug application with the China Food and Drug Administration for a Phase 1b/3 clinical study of CAN017 in esophageal squamous cell cancer (ESCC). CAN017 is an ErbB3 (HER3) inhibitory antibody candidate developed by AVEO. CANbridge also announced that it entered into a strategic partnership with Amoy Diagnostics Co., Ltd. to develop a CAN017 biomarker companion diagnostic.

Corporate Updates

- **Strengthened Executive Team and Board of Directors.** In November 2017, AVEO announced the appointment of Nikhil Mehta, Ph.D., as Senior Vice President of Regulatory and Quality Assurance. In this role, Dr. Mehta oversees all aspects of regulatory, quality and technical operations for the Company's portfolio. Dr. Mehta brings to AVEO more than 25 years of experience in the biotechnology and pharmaceutical industries.

AVEO also recently appointed Mike Ferraresso as Vice President, Business Analytics and Commercial Operations. Mr. Ferraresso brings more than 20 years of pharmaceutical industry experience in commercial strategy, sales operations and business analytics. He previously worked at AVEO from 2011 to 2013 as Senior Director of Business Analytics.

AVEO also announced today that Karuna Rubin has been named Senior Vice President and General Counsel, effective February 1, 2018. Ms. Rubin has more than 15 years of experience representing public companies in a variety of industries in securities, finance, mergers and acquisitions, litigation and other matters and has served as AVEO's lead counsel since 2015. She received her J.D. from Columbia Law School and A.B. from Brown University.

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.

- **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.

Full Year 2017 Financial Highlights

- AVEO ended 2017 with \$33.5 million in cash, cash equivalents and marketable securities as compared with \$23.3 million at December 31, 2016.

- Total collaboration revenue for 2017 was approximately \$7.6 million compared with \$2.5 million for 2016.
- Research and development expense for 2017 was \$25.2 million compared with \$23.7 million for 2016.
- General and administrative expense for 2017 was \$9.1 million compared with \$8.2 million for 2016.
- Net loss for 2017 was \$65.0 million, or a loss of \$0.61 per basic and diluted share, compared with net loss of \$26.9 million for 2016, or a loss of \$0.39 per basic and diluted share. Approximately \$33.7 million of the 2017 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 year. In 2016, the non-cash gain attributable to the decrease in the fair value of the warrant liability was \$4.8 million.

Updated Financial Guidance

We believe that our \$33.5 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 RCC; 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.

AVEO Contact:

David Pitts, Argot Partners

(212) 600-1902

aveo@argotpartners.com

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

	Three Months ended		For the Years Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
Collaboration and licensing revenue	\$ 82	\$ 127	\$ 7,579	\$ 2,515
Operating expenses:				
Research and development	5,676	7,683	25,179	23,703
General and administrative	2,404	1,870	9,138	8,205
Settlement costs	2,073	—	2,073	—
	<u>10,153</u>	<u>9,553</u>	<u>36,390</u>	<u>31,908</u>
Loss from operations	(10,071)	(9,426)	(28,811)	(29,393)
Other income (expense), net:				
Change in fair value of PIPE warrant liability	14,207	4,569	(33,740)	4,751
Other expense, net	(637)	(748)	(2,373)	(2,144)
Other income (expense), net	<u>13,570</u>	<u>3,821</u>	<u>(36,113)</u>	<u>2,607</u>
Net loss before provision for income taxes	3,499	(5,605)	(64,924)	(26,786)
Provision for income taxes	—	—	(101)	(101)
Net income (loss)	<u>\$ 3,499</u>	<u>\$ (5,605)</u>	<u>\$ (65,025)</u>	<u>\$ (26,887)</u>
Basic net income (loss) per share				
Net income (loss) per share	\$ 0.03	\$ (0.07)	\$ (0.61)	\$ (0.39)
Weighted average number of common shares outstanding	118,323	75,863	105,930	69,268
Dilutive net income (loss) per share				
Net income (loss) per share	\$ (0.08)	\$ (0.07)	\$ (0.61)	\$ (0.39)
Weighted average number of common shares and dilutive common share equivalents outstanding	130,108	75,863	105,930	69,268

Consolidated Balance Sheet Data
(In thousands)

	December 31, 2017	December 31, 2016
Assets		
Cash, cash equivalents and marketable securities	\$ 33,525	\$ 23,348
Accounts receivable	402	1,027
Prepaid expenses and other current assets	1,256	1,940
Insurance recovery	15,000	—
Other assets	15	970
Total assets	\$ 50,198	\$ 27,285
Liabilities and stockholders' deficit		
Accounts payable and accrued expenses	\$ 13,215	\$ 7,715
Loans payable	18,477	14,003
Deferred revenue and research and development reimbursements	2,820	2,207
PIPE warrant liability	37,746	4,593
Estimated settlement liability	17,073	—
Other liabilities	1,630	690
Stockholder's deficit	(40,763)	(1,923)
Total liabilities and stockholders' deficit	\$ 50,198	\$ 27,285