



## **AVEO Reports Third Quarter 2017 Financial Results and Provides Business Update**

**CAMBRIDGE, Mass.– November 7, 2017** – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the third quarter ended September 30, 2017 and provided a business update.

“The third quarter was a transformative period for AVEO, with the achievement of significant milestones in each of the three pillars of our global strategy for tivozanib. Notably, with the European approval of tivozanib (FOTIVDA<sup>®</sup>) in advanced RCC, we have transitioned from a development stage company to one with a commercially approved product, a watershed achievement for any emerging life sciences company,” said Michael Bailey, president and chief executive officer of AVEO. “In addition, TIVO-3, our U.S. registration study, successfully passed the interim futility analysis with no changes to study protocol. Finally, we presented promising Phase 1 immunotherapy combination data from the Phase 1/2 TiNivo study of tivozanib and nivolumab (OPDIVO<sup>®</sup>), and announced that EUSA Pharma, our European licensee for tivozanib, has opted into our combination development strategy.”

Mr. Bailey continued, “In addition, we expect the imminent launch of tivozanib (FOTIVDA<sup>®</sup>) in Europe, the anticipated readout of TIVO-3 in the first quarter of 2018 and Phase 2 data from TiNivo in the first half of 2018. Supporting these efforts, we have a balance sheet bolstered by recent milestone payments that could be extended by additional potential payments from EUSA related to reimbursement approval in EU5 countries, as well as double-digit royalty payments on net sales for tivozanib in Europe.”

### **Recent Updates**

- **Tivozanib (FOTIVDA<sup>®</sup>) Approved in the European Union for the Treatment of Advanced Renal Cell Carcinoma (RCC).** In August 2017, AVEO announced that the European Commission (EC) approved tivozanib (FOTIVDA<sup>®</sup>) for the treatment of adult patients with RCC in the European Union plus Norway and Iceland. Tivozanib is indicated for the first line treatment of adult patients with advanced RCC and for adult patients who are vascular endothelial growth factor receptor (VEGFR) and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for advanced RCC.
- **Successfully Passed 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 (FOTIVDA<sup>®</sup>) to sorafenib (NEXAVAR<sup>®</sup>) in subjects with advanced RCC. 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. The Company continues to expect the TIVO-3 trial to read out in the first quarter of 2018. The TIVO-3

trial, together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of RCC, is designed to support a potential regulatory approval of tivozanib in the U.S. as a first and third line treatment for RCC.

- **Phase 1 Results from the TiNivo Trial of Tivozanib and Nivolumab (OPDIVO®) in RCC - Oral Presentation at the 16<sup>th</sup> International Kidney Cancer Symposium.** On November 3, 2017 AVEO presented results from the Phase 1 portion of the Phase 1/2 TiNivo study at the 16th International Kidney Cancer Symposium. The oral presentation, titled “TiNivo: A Phase 1b Dose Escalation Trial of Tivozanib and Nivolumab in Renal Cell Carcinoma,” was given by Laurence Albiges, M.D., Ph.D., Head, Genitourinary Unit, Institut Gustave Roussy, and a lead investigator of the study. The TiNivo trial is a Phase 1/2 multicenter trial of tivozanib (FOTIVDA®) in combination with Bristol-Myers Squibb’s nivolumab (OPDIVO®), an immune checkpoint, or PD-1, inhibitor, for the treatment of advanced renal cell carcinoma. The ongoing Phase 1 portion of the trial enrolled six patients, and demonstrated that the combination of tivozanib and nivolumab was well tolerated to the full dose and schedule of single agent tivozanib, with no dose limiting toxicities. The results also demonstrated promising early signs of potential efficacy, with 67% of patients demonstrating a partial response (PR), and a 100% disease control rate (PR + stable disease). Five out of six patients remain on study therapy. Enrollment of approximately 20 patients in the Phase 2 portion is ongoing. The trial is being led by the Institut Gustave Roussy in Paris under the direction of Bernard Escudier, MD, Chairman of the Genitourinary Oncology Committee.
- **TiNivo Combination Study Opt-in.** In September 2017, AVEO announced that EUSA Pharma, under its multi-territory licensing agreement with AVEO for tivozanib (FOTIVDA®), opted in to co-develop the Phase 1/2 TiNivo study and potential future combination studies in exchange for a research and development reimbursement payment totaling \$2.0 million. Under terms of the agreement, EUSA will fund up to half of the Phase 1/2 TiNivo study, not to exceed \$2.0 million, and may utilize data from study for regulatory or commercial purposes.
- **Receipt of Payments from EUSA Pharma and CANbridge.** In September 2017, AVEO announced the receipt of a \$4.0 million research and development reimbursement payment from EUSA Pharma related to the approval of tivozanib (FOTIVDA®) for the treatment of adult patients with advanced RCC in Europe, and a \$0.5 million milestone payment from CANbridge related to manufacturing development activities for AV-203, AVEO’s clinical-stage ErbB3 (HER3) inhibitory antibody candidate.

### **Third Quarter 2017 Financial Highlights**

- AVEO ended Q3 2017 with \$37.4 million in cash, cash equivalents and marketable securities as compared with \$23.3 million at December 31, 2016.
- Total collaboration revenue was approximately \$4.6 million in Q3 2017 compared with \$1.0 million for Q3 2016.

- Research and development expense was \$4.7 million in Q3 2017 compared with \$4.4 million for Q3 2016.
- General and administrative expense was \$2.1 million in Q3 2017 compared with \$2.1 million for Q3 2016.
- Net loss for Q3 2017 was \$26.4 million, or a loss of \$0.22 per basic and diluted share, compared with a net loss of \$5.0 million, or a loss of \$0.07 per basic and diluted share for Q3 2016. Approximately \$23.5 million of the net loss was a non-cash loss attributable to the increase in the fair value of the warrant liability that was recorded in Q3 2017 that principally resulted from the increase in the stock price that occurred within the quarter. In Q3 2016, the non-cash gain attributable to fair value of the warrant liability was \$1.2 million.

### **Updated Financial Guidance**

We believe that our \$37.4 million in cash resources would allow us to fund our planned operations into the fourth quarter of 2018. This estimate assumes no receipt of additional milestone or royalty payments from our partners or related payment of potential licensing milestones to third parties, no additional funding from new partnership agreements, no additional equity financings, no debt financings and no further sales of equity under our Sales Agreement with FBR or through the exercise of our outstanding PIPE Warrants. This estimate also assumes no acceleration in repayment of the term loan by Hercules in the event of non-compliance with the \$10.0 million financial covenant.

### **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 cachexia (wasting syndrome). Tivozanib (FOTIVDA<sup>®</sup>) is approved by the European Commission for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union plus Norway and Iceland. For more information, please visit the company's website at [www.aveooncology.com](http://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: clinical,

regulatory and commercial plans of AVEO and its partner EUSA Pharma with respect to tivozanib (FOTIVDA<sup>®</sup>); the expected timeline for reporting data from TIVO-3 and TiNivo; the role and expected benefits of tivozanib and other TKIs on a stand-alone basis, or in combination with or following immunotherapy; the expected enrollment of the TiNivo trial; expectations about the potential for additional payments by EUSA Pharma; the value of AVEO's partnerships in advancing its pipeline; 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 agreements, and its ability, and the ability of its licensees and other partners, to achieve development and commercialization objectives under these arrangements; AVEO's ability, and the ability of its 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 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 ongoing 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 Annual Report on Form 10-K for the year ended December 31, 2016, its quarterly reports on Form 10-Q 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Collaboration and licensing revenue	\$ 4,614	\$ 992	\$ 7,497	\$ 2,388
Operating expenses:				
Research and development	4,666	4,444	19,503	16,020
General and administrative	2,101	2,141	6,734	6,344
	<u>6,767</u>	<u>6,585</u>	<u>26,237</u>	<u>22,364</u>
Loss from operations	(2,153)	(5,593)	(18,740)	(19,976)
Other expense, net:				
Interest expense, net	(655)	(551)	(1,736)	(1,388)
Change in fair value of warrant liability	(23,538)	1,178	(47,947)	182
Other expense, net	(24,193)	627	(49,683)	(1,206)
Loss before provision for income taxes	(26,346)	(4,966)	(68,423)	(21,182)
Provision for income taxes	(51)	—	(101)	(100)
Net loss	<u>\$ (26,397)</u>	<u>\$ (4,966)</u>	<u>\$ (68,524)</u>	<u>\$ (21,282)</u>
Net loss per share — basic and diluted	\$ (0.22)	\$ (0.07)	\$ (0.67)	\$ (0.32)
Weighted average number of common shares outstanding	<u>118,006</u>	<u>75,861</u>	<u>101,754</u>	<u>67,046</u>

**Consolidated Balance Sheet Data**  
**(In thousands)**  
**(Unaudited)**

	September 30, 2017	December 31, 2016
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 37,409	\$ 23,348
Accounts receivable	2,375	1,027
Prepaid expenses and other current assets	1,744	1,940
Other assets	183	970
Total assets	<u>\$ 41,711</u>	<u>\$ 27,285</u>
<b>Liabilities and stockholders' deficit</b>		
Accounts payable and accrued expenses	\$ 11,058	\$ 7,715
Loans payable	19,244	14,003
Deferred revenue and research and development reimbursements	3,190	2,207
Warrant liability	51,953	4,593
Other liabilities	840	690
Stockholder's deficit	(44,574)	(1,923)
Total liabilities and stockholders' deficit	<u>\$ 41,711</u>	<u>\$ 27,285</u>