AVEO Reports Second Quarter 2017 Financial Results and Provides Business Update

CAMBRIDGE, Mass. – Aug 9, 2017 – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the second quarter ended June 30, 2017, and provided a business update.

"The second quarter was marked by validating events in each of the three pillars of our global tivozanib strategy: a recommendation for approval of tivozanib in advanced renal cell carcinoma (RCC) by the CHMP, reaching our enrollment target for the Phase 3 TIVO-3 trial in RCC, and the successful advancement to Phase 2, at full dose, of the TiNivo trial, our Opdivo® combination trial in RCC," said Michael Bailey, president and chief executive officer of AVEO. "We look forward to several key milestones in the coming quarters, including a final determination from the European Commission (EC) on marketing authorization for tivozanib for RCC, as well as the expected presentation of TiNivo Phase 1 study results this fall and the anticipated readout of TIVO-3 in the first quarter of 2018. We believe that we now have the balance sheet to take AVEO beyond these milestones and into the fourth quarter of 2018. This runway could be extended by additional potential payments of up to $16 million by our European tivozanib partner, EUSA Pharma, related to European regulatory and reimbursement approvals, and double-digit royalty payments on net sales for tivozanib in Europe if the EC grants marketing approval for tivozanib."

Mr. Bailey added: "We also look forward to progress in our earlier pipeline programs, including the initiation of an investigator-sponsored, randomized Phase 2 trial of ficlatuzumab, our potent HGF inhibitory antibody, in combination with cetuximab in patients with cetuximab-resistant, metastatic head and neck squamous cell carcinoma (HNSCC). As presented at the ASCO annual meeting this past quarter, this combination demonstrated prolonged progression free and overall survival compared to historical controls in Phase 1."

Recent Updates

- **Enrollment Target Reached for Pivotal Phase 3 TIVO-3 Study of Tivozanib in RCC.** In June 2017, AVEO announced that the Company's pivotal TIVO-3 trial, a randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in subjects with refractory RCC, reached its enrollment target of 322 patients, more than two months ahead of the Company's initial guidance. A pre-planned futility analysis of the TIVO-3 trial is expected around midyear 2017, with topline data expected 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 an application seeking regulatory approval of tivozanib in the U.S. as a first and third line treatment for RCC.

- **$14M in Aggregate Gross Proceeds Secured from Credit Facility and At-the-Market Stock Offerings.** In June 2017, AVEO announced that it secured gross proceeds of $14 million through two financing facilities: $5 million through a drawdown of its credit facility with Hercules Capital, Inc. and $9 million from the sale of common stock under

its at-the-market issuance sales agreement with FBR & Co, effectively exhausting the balance of that facility.

- **Positive CHMP Opinion for Tivozanib as a Treatment of Advanced RCC.** On June 23, 2017, AVEO announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), recommended tivozanib for approval as a treatment for patients with advanced RCC. The CHMP's recommendation was referred to the EC, which is expected to make its final decision about 67 days from the date of the CHMP's recommendation. If approved by the EC, marketing authorization for tivozanib will be granted in all 28 countries of the European Union, Norway, Iceland and Liechtenstein. Approval would trigger a $4 million research and development reimbursement payment to AVEO from EUSA Pharma, the European licensee for tivozanib, and AVEO would also be eligible for up to $12 million in additional milestones based on reimbursement approvals.

- **Phase 1/2 TiNivo Trial of Tivozanib and Opdivo® (nivolumab) in RCC Successfully Advanced to Phase 2 Portion.** In June 2017, AVEO announced that its Phase 1/2 AVEO-sponsored TiNivo trial evaluating tivozanib in combination with Bristol-Myers Squibb's anti-PD-1 therapy, Opdivo® (nivolumab), in subjects with advanced RCC progressed to the Phase 2 portion of the trial, following completion of the Phase 1 portion, which saw no dose limiting toxicities, a good tolerability profile and promising early signs of activity. The full dose tivozanib regimen of 1.5 mg daily for 21 days, followed by a 7-day rest period, was selected as the recommended Phase 2 dose (RP2D) for the expansion portion of the trial, which is expected to enroll an additional 20 subjects.

- **Results from Two Investigator-Sponsored Phase 1 Studies of HGF Targeted Antibody Ficlatuzumab Presented at the 2017 ASCO Annual Meeting.** In June 2017, AVEO announced the presentation of results from two investigator-sponsored Phase 1 studies of ficlatuzumab, 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, at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. The first was a study of ficlatuzumab in combination with the EGFR inhibitor cetuximab in patients with cetuximab-resistant, metastatic HNSCC, which demonstrated a disease control rate, prolonged progression free and overall survival that compared favorably to historical controls, in addition to being well tolerated. The Company announced that a randomized, Phase 2, multicenter, investigator-initiated trial to confirm these findings is expected to initiate in the second half of 2017. The second, ongoing study explored ficlatuzumab in combination with high-dose cytarabine in patients with high risk relapsed or refractory AML, demonstrating early signs of tolerability and activity, including a 50% complete response rate.

- **Matthew Dallas Appointed Chief Financial Officer.** In June 2017, Matthew Dallas joined AVEO as its chief financial officer. In this role, Mr. Dallas is responsible for the Company's financial strategy and management, and serves on the executive leadership

team that governs corporate strategy at AVEO. Mr. Dallas succeeds Keith Ehrlich, who retired from the Company.

- **Receipt of USPTO Notice of Allowance Related to AV-353.** In May 2017, AVEO announced receipt of a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for U.S. patent application number 14/653,684, entitled "notch binding agents and antagonists and methods of use thereof." Allowed under the application are composition of matter and method of use claims related to the Company's humanized anti-Notch 3 antibodies, including AV-353, a potent inhibitory antibody specific to Notch 3. The Notch 3 pathway is implicated in multiple diseases, including Pulmonary Arterial Hypertension. The U.S. patent scheduled to issue from this application will expire December 19, 2032, with the potential for extension to December 19, 2037.

Second Quarter 2017 Financial Highlights

- AVEO ended Q2 2017 with $40.1 million in cash, cash equivalents and marketable securities as compared with $23.3 million at December 31, 2016.
- Total collaboration revenue was approximately $0.4 million in Q2 2017 compared with $0.2 million for Q2 2016.
- Research and development expense was $6.9 million in Q2 2017 compared with $5.6 million for Q2 2016.
- General and administrative expense was $2.3 million in Q2 2017 compared with $1.7 million for Q2 2016.
- Net loss for Q2 2017 was $33.3 million, or a loss of $0.30 per basic and diluted share, compared with a net loss of $8.6 million, or a loss of $0.13 per basic and diluted share for Q2 2016. An approximate $23.9 million non-cash loss attributable to the increase in the fair value of the warrant liability was recorded in Q2 2017 that principally resulted from the increase in the stock price that occurred within the quarter. In Q2 2016 the non-cash loss attributable to fair value of the warrant liability was $1.0 million.

Updated Financial Guidance

We believe that our $40.1 million in cash resources would allow us to fund our planned operations into the fourth quarter of 2018. This estimate assumes no receipt of milestone 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. 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. 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, cachexia (wasting syndrome) and pulmonary arterial hypertension (PAH). 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 expected decision on tivozanib by the EC; the planned presentation of TiNivo Phase 1 study results in the Fall; the anticipated readout of TIVO-3 in the first quarter of 2018; the period in which the Company expects to have cash to fund its operations; expectations about the potential for additional payments by EUSA Pharma; plans to progress pipeline programs, including the initiation of a Phase 2 trial of ficlatuzumab; and AVEO's strategy, prospects, plans and objectives. 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 without limitation risks relating to the ability of EUSA to successfully obtain approval of tivozanib from the EC. 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.

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 June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Collaboration and licensing revenue	$ 351	$ 193	$ 2,883	$ 1,396
Operating expenses:				
Research and development	6,881	5,604	14,837	11,576
General and administrative	2,302	1,731	4,633	4,203
	9,183	7,335	19,470	15,779
Loss from operations	(8,832)	(7,142)	(16,587)	(14,383)
Other expense, net:				
Interest expense, net	(530)	(468)	(1,081)	(837)
Change in fair value of warrant liability	(23,925)	(996)	(24,409)	(996)
Other expense, net	(24,455)	(1,464)	(25,490)	(1,833)
Loss before provision for income taxes	(33,287)	(8,606)	(42,077)	(16,216)
Provision for income taxes	—	—	(50)	(100)
Net loss per share	$ (33,287)	$ (8,606)	$ (42,127)	$ (16,316)
Net loss per share - basic	$ (0.30)	$ (0.13)	$ (0.45)	$ (0.26)
Weighted average number of common shares outstanding	110,550	66,917	93,493	62,566

Consolidated Balance Sheet Data

(In thousands)
(Unaudited)

	June 30, 2017	December 31, 2016
Assets		
Cash, cash equivalents and marketable securities	$ 40,127	$ 23,348
Accounts receivable	445	1,027
Prepaid expenses and other current assets	1,568	1,940
Other assets	352	970
Total assets	$ 42,492	$ 27,285
Liabilities and stockholders' deficit		
Accounts payable and accrued expenses	$ 10,964	$ 7,715
Loans payable	19,122	14,003
Deferred revenue	1,894	2,207
Warrant liability	29,002	4,593
Other liabilities	840	690
Stockholder's deficit	(19,330)	(1,923)
Total liabilities and stockholders' deficit	$ 42,492	$ 27,285