



AVEO Reports Second Quarter 2018 Financial Results and Provides Business Update

CAMBRIDGE, Mass. – August 7, 2018 – AVEO Oncology (NASDAQ: AVEO) today reported financial results for the second quarter ended June 30, 2018 and provided a business update.

“Our U.S. registration strategy remains a key focus for AVEO, with topline readout of the Phase 3 TIVO-3 study expected in the fourth quarter of this year,” said Michael Bailey, president and chief executive officer of AVEO. “TIVO-3 is the first randomized Phase 3 study in advanced kidney cancer to stratify for prior immunotherapy and, as a result, it has the potential to serve as a benchmark study for the sequencing of therapies in advanced disease.”

Mr. Bailey added: “The next two pillars of our tivozanib strategy also continue to make progress. The recent launch of FOTIVDA[®] in Scotland adds to ongoing commercial efforts in Germany, the U.K., and Austria by our partner EUSA Pharma. We anticipate additional potential reimbursement approvals for France, Germany, Italy, and Spain in the coming months, triggering up to \$8 million in milestone payments due to AVEO in addition to double-digit royalty payments on net sales of FOTIVDA[®] in Europe. EUSA has the option to access TIVO-3 data in the event of a positive outcome in exchange for a \$20 million R&D reimbursement payment to AVEO. Finally, we look forward to presenting additional data at the ESMO meeting in October from the Phase 2 portion of the TiNivo study of tivozanib and nivolumab (OPDIVO[®]) in aRCC, a study which to date has demonstrated promising activity and a favorable safety profile.”

Tivozanib TIVO-3 Study North America Update

- **Topline Data from Phase 3 TIVO-3 Study Anticipated in the Fourth Quarter of 2018.** As previously announced, the Company expects to report topline results from the TIVO-3 study, AVEO’s Phase 3 trial of tivozanib as a third-line treatment for advanced renal cell carcinoma (aRCC), in the fourth quarter of 2018, approximately 6-8 weeks after the trial records 255 progression free survival (PFS) events. AVEO plans to announce when 255 PFS events have occurred and the topline data analysis for the trial has been initiated. Together with the TIVO-1 study, TIVO-3 is designed to serve as the basis for a potential U.S. approval of tivozanib (FOTIVDA[®]) as a first- and third-line treatment for aRCC.

Tivozanib (FOTIVDA[®]) European Union Updates

- **Tivozanib (FOTIVDA[®]) Launched in Scotland for the Treatment of aRCC.** In July 2018, FOTIVDA[®] was launched in Scotland for the first-line treatment of adult patients with aRCC after the Scottish Medicines Consortium approved its use. FOTIVDA[®] is now available in Germany, Scotland, the U.K., and Austria. FOTIVDA[®] was granted European

Medicines Association approval in August 2017 for the treatment of adult patients with aRCC in the European Union plus Norway and Iceland.

- **Tivozanib (FOTIVDA[®]) Expanded Access Program Launched in Italy.** In July 2018, The Program of Therapeutic Use Tivozanib (Expanded Access Program) for renal cell carcinoma (RCC) was initiated, allowing patients in Italy to have access to tivozanib as front-line therapy. In addition, EUSA pharma is effecting the reimbursement procedure with the Italian Drug Agency (AIFA), a process which is expected to be finalized in the coming months.

Additional Tivozanib Updates

- **Updated Phase 2 Results from the TiNivo Trial of Tivozanib and Nivolumab (OPDIVO[®]) in aRCC to be Presented at the 2018 ESMO Annual Meeting.** Updated Phase 2 data from the Phase 1b/2 TiNivo study of tivozanib in combination with nivolumab (OPDIVO[®], Bristol-Myers Squibb), an immune checkpoint, or PD-1, inhibitor, will be presented at the 2018 European Society for Medical Oncology (ESMO) Annual Meeting in Munich. The data will be presented during a poster presentation titled, “TiNivo: Tivozanib combined with nivolumab: safety and efficacy in patients with metastatic renal cell carcinoma (mRCC)” (Presentation Number 878P). Previously presented results support the potential advantages of a combination therapy using a high-specificity VEGF inhibitor TKI in connection with an immune checkpoint therapy in renal cancer.

Ficlatuzumab Update

- **Trials in Progress Poster for Phase 2 Study of Ficlatuzumab in Combination with Cetuximab in HNSCC to be Presented at the 2018 ESMO Annual Meeting.** Data from an ongoing, investigator-sponsored 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) will be presented as a trials in progress poster at the 2018 ESMO Annual Meeting (Presentation Number 1124TiP). This randomized multi-center study, which is being conducted under the direction of Julie E. Bauman, MD, MPH, Professor of Medicine, Chief, Division of Hematology/Oncology, Associate Director of Translational Research, University of Arizona Cancer Center, is expected to enroll approximately 60 patients randomized to receive either ficlatuzumab alone or ficlatuzumab and cetuximab.
- **Trials in Progress Poster for Phase 1b Study of Ficlatuzumab in Combination with Gemcitabine and Nab-paclitaxel in Pancreatic Cancer Presented at the 2018 ASCO Annual Meeting.** Data from 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) was 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 in June 2018. The study, which is being conducted under the direction of Kimberly Perez,

MD at the Dana-Farber Cancer Institute, is currently enrolling, with an expected total enrollment of approximately 30 patients.

Corporate Update

- **Added to the Russell 2000, Russell 3000, and Russell Microcap Indexes.** In June 2018, AVEO announced that it had been added to the Russell 2000[®], Russell 3000[®], and Russell Microcap[®] Indexes as part of FTSE's annual reconstitution. Russell U.S. Indexes are widely used by investment managers and institutional investors as the basis for index funds and as benchmarks for active investment strategies. Approximately \$9 trillion in assets are benchmarked against Russell U.S. Indexes.

Second Quarter 2018 Financial Highlights

- AVEO ended Q2 2018 with \$18.1 million in cash, cash equivalents and marketable securities as compared with \$33.5 million at December 31, 2017.
- Total revenue for Q2 2018 was approximately \$0.4 million compared with \$0.4 million for Q2 2017.
- Research and development expense for Q2 2018 was \$4.9 million compared with \$6.9 million for Q2 2017.
- General and administrative expense for Q2 2018 was \$2.8 million compared with \$2.3 million for Q2 2017.
- Net income for Q2 2018 was \$4.0 million, or income of \$0.03 per basic share and a loss of \$0.06 per diluted share, compared with net loss of \$33.3 million for Q2 2017, or a loss of \$0.30 per basic and diluted share. Approximately \$11.1 million of Q2 2018 net income was a non-cash gain attributable to the decrease in the fair value of the 2016 private placement warrant liability that principally resulted from the decrease in the stock price that occurred within the quarter. In Q2 2017, the non-cash loss attributable to the increase in the fair value of such warrant liability was \$23.9 million.

Financial Guidance

We believe that our \$18.1 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, 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 or outstanding warrants issued in connection with the recent settlement of our securities class action litigation.

About AVEO

AVEO Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company dedicated to advancing a broad portfolio of targeted medicines for oncology and other areas of unmet medical need. The Company's strategy is to retain North American rights to its oncology portfolio while

securing partners in development and commercialization outside of North America. The Company is seeking to develop and commercialize its lead candidate tivozanib in North America as a treatment for renal cell carcinoma (“RCC”). The Company has outlicensed tivozanib (FOTIVDA[®]) for oncology 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 advanced RCC (“aRCC”) 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 aRCC. The Company has entered into partnerships to fund the development and commercialization of AV-203 and ficlatuzumab, both clinical stage assets in oncology. The Company is currently seeking a partner to develop the AV-353 platform, a preclinical asset, worldwide for the potential treatment of pulmonary arterial hypertension. The Company previously partnered with Novartis International Pharmaceutical Ltd. (“Novartis”) to develop the AV-380 program in cachexia and other indications. Effective August 28, 2018 the Company expects to regain the rights to AV-380 and is considering a variety of options to continue the program’s development.

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 advancing its lead development programs, including its expectations regarding the timing for top line results from the Phase 3 TIVO-3 study of tivozanib in aRCC, and for providing an update to the Phase 2 portion of the TiNivo Study of Tivozanib and Nivolumab (OPDIVO[®]) in mRCC; the advancement of AVEO’s pipeline; AVEO’s cash runway; and AVEO’s strategy, prospects, plans and objectives, including as they pertain specifically to tivozanib and leveraging partnerships. 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; 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. 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.

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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,	
	2018	2017	2018	2017
Revenues:				
Collaboration and licensing revenue	\$ 336	\$ 351	\$ 1,316	\$ 2,883
Partnership royalties	97	—	143	—
	<u>433</u>	<u>351</u>	<u>1,459</u>	<u>2,883</u>
Operating expenses:				
Research and development	4,887	6,881	10,291	14,837
General and administrative	2,827	2,302	5,437	4,633
Settlement costs	(709)	—	(667)	—
	<u>7,005</u>	<u>9,183</u>	<u>15,061</u>	<u>19,470</u>
Loss from operations	(6,572)	(8,832)	(13,602)	(16,587)
Other income (expense), net:				
Interest expense, net	(549)	(530)	(1,042)	(1,081)
Change in fair value of PIPE Warrant liability	11,125	(23,925)	9,660	(24,409)
Other income (expense), net	10,576	(24,455)	8,618	(25,490)
Income (loss) before provision for income taxes	4,004	(33,287)	(4,984)	(42,077)
Provision for income taxes	—	—	—	(50)
Net income (loss)	<u>\$ 4,004</u>	<u>\$ (33,287)</u>	<u>\$ (4,984)</u>	<u>\$ (42,127)</u>
Basic net income (loss) per share				
Net income (loss) per share	\$ 0.03	\$ (0.30)	\$ (0.04)	\$ (0.45)
Weighted average number of common shares outstanding	<u>118,940</u>	<u>110,550</u>	<u>118,891</u>	<u>93,493</u>
Diluted net income (loss) per share				
Net income (loss) per share	\$ (0.06)	\$ (0.30)	\$ (0.11)	\$ (0.45)
Weighted average number of common shares and dilutive common share equivalents outstanding	<u>128,692</u>	<u>110,550</u>	<u>129,372</u>	<u>93,493</u>

Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	June 30, 2018	December 31, 2017
Assets		
Cash, cash equivalents and marketable securities	\$ 18,089	\$ 33,525
Accounts receivable	973	402
Prepaid expenses and other current assets	937	1,256
Insurance recovery	—	15,000
Other assets	7	15
Total assets	<u>\$ 20,006</u>	<u>\$ 50,198</u>
Liabilities and stockholders' deficit		
Accounts payable and accrued expenses	\$ 11,497	\$ 13,215
Loans payable, net of discount	18,730	18,477
Deferred revenue and research and development reimbursements	5,743	2,820
PIPE Warrant liability	26,985	37,746
Estimated settlement liability	1,406	17,073
Other liabilities	1,090	1,630
Stockholder's deficit	(45,445)	(40,763)
Total liabilities and stockholders' deficit	<u>\$ 20,006</u>	<u>\$ 50,198</u>