AVEO Oncology Reports Third Quarter 2021 Financial Results and Provides Business Update

November 8, 2021

– Total Q3 2021 Revenue of $15.2 Million Includes FOTIVDA® (tivozanib) U.S. Net Product Revenue of $14.3 Million –
– Enrollment Open for Pivotal Phase 3 TiNivo-2 Clinical Trial of FOTIVDA® (tivozanib) in Combination with OPDIVO® (nivolumab) –
– Ficlatuzumab and ERBITUX® (cetuximab) Granted Fast Track Designation by the U.S. FDA for R/R HNSCC; Potential Registrational Clinical Trial Expected to Commence in 1H 2023 –
– Company to Host Conference Call Today at 4:30 p.m. ET –

BOSTON--(BUSINESS WIRE)--Nov. 8, 2021-- AVEO Oncology (Nasdaq: AVEO), a commercial stage, oncology-focused biopharmaceutical company, today reported financial results for the third quarter ended September 30, 2021 and provided a business update.

"During the third quarter, we continued to see strong commercial uptake for FOTIVDA®, further underscoring the significant unmet medical need that exists in the indicated treatment population. FOTIVDA has been well received by oncologists treating relapsed or refractory (R/R) renal cell carcinoma (RCC), noting both the durable responses and tolerability profile as attractive for their third-line patients. We believe FOTIVDA has the potential to serve as a standard of care for these later line patients," said Michael Bailey, president and chief executive officer of AVEO. "Opening enrollment for our pivotal Phase 3 TiNivo-2 trial of tivozanib and nivolumab marks an important milestone in our efforts to assess tivozanib's potential as an earlier line of therapy and in the immunotherapy combination setting."

Mr. Bailey continued: "Following the recent receipt of Fast Track Designation (FTD) from the U.S. Food and Drug Administration (FDA) for ficlatuzumab and cetuximab in relapsed or recurrent head and neck squamous cell carcinoma (R/R HNSCC), we believe the clinical development of ficlatuzumab is well positioned to advance in this important potential new treatment option. We expect to commence manufacturing of ficlatuzumab clinical supply in the second quarter of 2022, with the initiation of a potential registrational clinical trial in the human papillomavirus negative (HPV-) HNSCC patient population anticipated in the first half of 2023."

Third Quarter 2021 and Recent Highlights

- **Strong Third Quarter Sales Growth for U.S. Commercial Launch of FOTIVDA for the Treatment of Adult Patients with R/R Advanced RCC Following Two or More Prior Systemic Therapies**.
  - U.S. net product revenue for the third quarter of 2021 was $14.3 million, which reflects inventory shipped to distributors and a gross-to-net estimate of 16% during the quarter. As of September 30, 2021, year-to-date U.S. net product revenue since FOTIVDA's commercial launch on March 22, 2021 was $22.1 million.
  - $14.3 million of U.S. net product revenue for the third quarter of 2021, representing a 113% increase from $6.7 million in the second quarter of 2021.
    - 619 commercial prescriptions filled in the third quarter of 2021, representing a 119% increase from 283 commercial prescriptions filled in the second quarter of 2021.
  - Approximately 260 accounts have ordered as of September 30, 2021, representing a 90% increase compared to 137 accounts having ordered as of June 30, 2021.
  - Quarter-end inventory of approximately two weeks for the third quarter of 2021 suggests that the Company's quarterly sales revenue are currently primarily driven by end user demand.
  - As planned, the Company's early launch sampling program has decreased to 75 samples delivered in the third quarter of 2021 compared to 180 samples in the second quarter of 2021.
- **Enrollment Open for Pivotal Phase 3 TiNivo-2 Trial in IO Advanced Refractory RCC.** Patient enrollment opened this quarter for the Phase 3 TiNivo-2 trial evaluating tivozanib in combination with nivolumab, Bristol Myers Squibb's (NYSE: BMY) antibody directed against programmed death-1, in patients with advanced refractory RCC following one or two lines of therapy, one of which is immunotherapy. Per the previously announced March 2021 clinical trial collaboration and supply agreement, BMY will provide nivolumab clinical drug supply for the trial.
- **Ficlatuzumab Well-Positioned to Advance in Clinical Development for Treating R/R HNSCC Following FTD Being Granted by the FDA.** In September 2021, AVEO announced that the FDA granted FTD for the investigation of ficlatuzumab and cetuximab for the treatment of patients with R/R HNSCC. Ficlatuzumab is AVEO's investigational potent humanized immunoglobulin G1 monoclonal antibody that targets hepatocyte growth factor.

  The Company expects to commence manufacturing of ficlatuzumab clinical supply in the second quarter of 2022, subject to availability of key raw materials and manufacturing supplies also used in COVID-19 vaccine manufacturing, with the

initiation of a potential registrational clinical trial in HPV- HNSCC now anticipated in the first half of 2023. The Company expects to continue to discuss potential ficlatuzumab pivotal clinical trial designs with the FDA and to continue to seek a strategic partner.

Third Quarter 2021 Financial Highlights

- AVEO ended Q3 2021 with $94.0 million in cash, cash equivalents and marketable securities, as compared with $102.9 million at the end of June 30, 2021 and $61.8 million at December 31, 2020.
- Total revenue for Q3 2021 was approximately $15.2 million compared with $3.6 million of total revenue for Q3 2020.
- FOTIVDA U.S. net product revenue for Q3 2021 was $14.3 million.
- Research and development expense for Q3 2021 was $7.5 million compared with $5.9 million for Q3 2020.
- Selling, general and administrative expense for Q3 2021 was $15.1 million compared with $5.8 million for Q3 2020.
    - The increase in selling, general and administrative expense for Q3 2021 is primarily due to costs associated with the commercial launch of FOTIVDA.
- Net loss for Q3 2021 was $10.4 million, or net loss of $0.30 per basic and diluted share, compared with a net loss of $8.4 million for Q3 2020, or net loss of $0.33 per basic and diluted share.

Financial Guidance

AVEO believes that its $94.0 million in cash, cash equivalents and marketable securities as of September 30, 2021, along with expected net product revenues from the commercial launch of FOTIVDA in the United States, would enable AVEO to maintain its current operations for a period of at least 12 months following the filing of its Quarterly Report on Form 10-Q for the quarter ended September 30, 2021.

In 2021, AVEO expects commercial spend will be approximately $40 million, research and development expense will be approximately $30 million and general and administrative expense will be approximately $20 million. Gross margins are expected to be in the mid-to-high 80th percentile.

Conference Call and Webcast

In connection with this announcement, AVEO will host a conference call and audio webcast today, November 8, 2021, at 4:30 PM Eastern Time. The call can be accessed by dialing (844) 882-7841 (U.S. and Canada) or (574) 990-9828 (international). The passcode for the conference call is 1647457. To access the live webcast, or the subsequent archived recording, please visit the Calendar of Events sub-section within the Investors section of the AVEO website at www.aveooncology.com.

About FOTIVDA® (tivozanib)

FOTIVDA® (tivozanib) is an oral, next-generation vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI). It is a potent, selective inhibitor of VEGFRs 1, 2, and 3 with a long half-life designed to improve efficacy and tolerability. AVEO received U.S. Food and Drug Administration (FDA) approval for FOTIVDA on March 10, 2021 for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. FOTIVDA was approved in August 2017 in the European Union and other countries in the territory of its partner EUSA Pharma (UK) Limited for the treatment of adult patients with advanced RCC. FOTIVDA has been shown to significantly reduce regulatory T-cell production in preclinical models.[1] FOTIVDA was discovered by Kyowa Kirin.

INDICATIONS

FOTIVDA is indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypertension and Hypertensive Crisis: Control blood pressure prior to initiating FOTIVDA. Monitor for hypertension and treat as needed. For persistent hypertension despite use of anti-hypertensive medications, reduce the FOTIVDA dose.

Cardiac Failure: Monitor for signs or symptoms of cardiac failure throughout treatment with FOTIVDA.

Cardiac Ischemia and Arterial Thromboembolic Events: Closely monitor patients who are at increased risk for these events. Permanently discontinue FOTIVDA for severe arterial thromboembolic events, such as myocardial infarction and stroke.

Venous Thromboembolic Events: Closely monitor patients who are at increased risk for these events. Permanently discontinue FOTIVDA for severe venous thromboembolic events.

Hemorrhagic Events: Closely monitor patients who are at risk for or who have a history of bleeding.

Proteinuria: Monitor throughout treatment with FOTIVDA. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment with FOTIVDA.

Thyroid Dysfunction: Monitor before initiation and throughout treatment with FOTIVDA.

Risk of Impaired Wound Healing: Withhold FOTIVDA for at least 24 days before elective surgery. Do not administer for at least 2 weeks following major surgery and adequate wound healing. The safety of resumption of FOTIVDA after resolution of wound healing complications has not been established.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): Discontinue FOTIVDA if signs or symptoms of RPLS occur.

Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

Allergic Reactions to Tartrazine: The 0.89 mg capsule of FOTIVDA contains FD&C Yellow No.5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible patients.

ADVERSE REACTIONS

The most common (≥20%) adverse reactions were fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis, and the most common Grade 3 or 4 laboratory abnormalities (≥5%) were sodium decreased, lipase increased, and phosphate decreased.

DRUG INTERACTIONS

Strong CYP3A4 Inducers: Avoid coadministration of FOTIVDA with strong CYP3A4 inducers.

USE IN SPECIFIC POPULATIONS

Lactation: Advise not to breastfeed.
Females and Males of Reproductive Potential: Can impair fertility.
Hepatic Impairment: Adjust dosage in patients with moderate hepatic impairment. Avoid use in patients with severe hepatic impairment.

To report SUSPECTED ADVERSE REACTIONS, contact AVEO Pharmaceuticals, Inc. at 1-833-FOTIVDA (1-833-368-4832) or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

Please see FOTIVDA Full Prescribing Information which is available at www.FOTIVDA.com.

About Advanced Renal Cell Carcinoma

According to the American Cancer Society's 2021 statistics, renal cell carcinoma (RCC) is the most common type of kidney cancer, which is among the ten most common cancers in both men and women. Approximately 73,750 new cases of kidney cancer will be diagnosed annually and about 14,830 people will die from this disease. In patients with late-stage disease, the five-year survival rate is 13%. Agents that target the vascular endothelial growth factor (VEGF) pathway have shown significant antitumor activity in RCC.[2] According to a 2019 publication, 50% of the approximately 10,000 patients who progress following two or more lines of therapy choose not to receive further treatment,[3] which may be attributable to tolerability concerns and a lack of data to support evidence-based treatment decisions in this highly relapsed or refractory patient population.

About AVEO Pharmaceuticals, Inc.

AVEO is a commercial-stage, oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for patients with cancer. AVEO currently markets FOTIVDA® (tivozanib) in the U.S. for the treatment of adult patients with relapsed or refractory renal cell carcinoma (RCC) following two or more prior systemic therapies. AVEO continues to develop FOTIVDA in immuno-oncology combinations in RCC and other indications, and has several other investigational programs in clinical development. AVEO is committed to creating an environment of diversity, equity and inclusion to diversify representation within the Company.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of AVEO within the meaning of the Private Securities Litigation Reform Act of 1995 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," "design," "expect," "hope," "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: AVEO's ability to successfully sell and distribute FOTIVDA to patients in the United States; the potential for FOTIVDA as a treatment option for patients with relapsed or refractory advanced RCC; the potential efficacy, safety, and tolerability of tivozanib, both as a stand-alone drug candidate and in combination with other therapies in several indications; the potential registrational clinical trial of ficlatuzumab in HPV- patients with R/R HNSCC; AVEO's plans, strategies and execution for current and future clinical trials of tivozanib, ficlatuzumab and AV-380 and for commercialization of FOTIVDA in the United States; the advancement of AVEO's pipeline, including the advancement of tivozanib (in additional indications), ficlatuzumab and AV-380 in multiple clinical studies; the timing of delivery and availability of clinical supplies of ficlatuzumab; the potential efficacy, safety and tolerability of ficlatuzumab, both as a stand-alone drug candidate and in combination with other therapies in HPV- R/R HNSCC and other indications; the potential outcomes from studies of its product candidates to provide AVEO with opportunities to pursue regulatory strategies; the potential clinical utility of ficlatuzumab and AV-380 in areas of unmet need; the period in which AVEO expects to have cash to fund its operations; AVEO's strategy, prospects, plans and objectives for FOTIVDA and its product candidates and for AVEO generally; the potential commercial opportunity of FOTIVDA and AVEO's other product candidates; and AVEO's estimates for its cash runway and the contingencies on which such runway is dependent. 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 successfully implement its strategic plans, including its ability to successfully commercialize FOTIVDA and to obtain and maintain market and third party payor acceptance of FOTIVDA; 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, and risks relating to the timing and costs of seeking and obtaining regulatory approvals; AVEO's dependence on third-party vendors for the development, manufacture, supply, storage and distribution of FOTIVDA, ficlatuzumab and its other product candidates; AVEO's ability to enter into and maintain its third party collaboration and license agreements, and its ability, and the ability of its strategic partners, to achieve development and commercialization objectives under these arrangements; AVEO's and its collaborators' ability to successfully enroll and complete clinical trials; AVEO's ability to maintain compliance with regulatory requirements applicable to FOTIVDA and its product candidates; AVEO's ability to obtain sufficient clinical supplies of its product candidates; AVEO's ability to obtain and maintain adequate protection for intellectual property rights relating to FOTIVDA and its other product candidates; unplanned capital

requirements; uncertainties related to AVEO's ability to access future borrowings under the Hercules loan agreement, which turns on the achievement of milestones related to sales of FOTIVDA in the U.S., which milestones may not be achieved; adverse general economic, political and industry conditions; the potential adverse effects of the COVID-19 pandemic on AVEO's business continuity, financial condition, results of operations, liquidity and ability to commercialize FOTIVDA, manufacture clinical and commercial product and timely initiate new clinical trials or complete its ongoing clinical trials; competitive factors; and those risks discussed in the sections titled "Risk Factor Summary," "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 makes with the SEC. The forward-looking statements in this press release represent AVEO's views as of the date of this press release, and 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.

References

1. Pawlowski N et al. AACR 2013. Poster 3971
2. J Angulo and O Shapiro, Cancers (Basel) 2019 Sep; 11(9): 1227. [10.3390/cancers11091227]
3. Decision Resources. RCC landscape and forecast. December 12, 2019.

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,	
	2021	**2020**	**2021**	**2020**
Revenues:				
FOTIVDA U.S. product revenue, net	$ 14,318	$ —	$ 22,119	$ —
Partnership licensing and royalty revenue	855	3,600	2,530	5,133
	15,173	3,600	24,649	5,133
Operating expenses:				
Cost of products sold	1,744	—	2,704	—
Research and development	7,502	5,860	20,177	18,105
Selling, general and administrative	15,142	5,800	45,162	13,209
	24,388	11,660	68,043	31,314
Loss from operations	(9,215)	(8,060)	(43,394)	(26,181)
Other income (expense), net:				
Interest expense, net	(1,153)	(419)	(2,892)	(1,083)
Change in fair value of PIPE Warrant liability	—	86	199	3,184
	(1,153)	(333)	(2,693)	2,101
Net loss	$ (10,368)	$ (8,393)	$(46,087)	$(24,080)
Net loss per share - basic and diluted	$ (0.30)	$ (0.33)	$ (1.44)	$ (1.22)
Weighted average number of common shares outstanding	34,374	25,808	32,081	19,773

AVEO PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets
(In thousands)
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 94,016	$ 61,761
Trade receivables, net and partnership receivables	9,508	1,197
Inventory	1,252	-
Prepaid expenses and other current assets	3,201	2,550
Property and equipment, net	292	343
Operating lease right-of-use asset	560	903
Other assets	258	158
Total assets	$ 109,087	$ 66,912
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	$ 20,943	$ 12,393
Loans payable, net of discount	33,026	13,772

Deferred revenue and research and development reimbursements	1,072	2,716
PIPE Warrant liability	-	199
Operating lease liability	380	705
Other liabilities	2,432	1,833
Stockholders' equity:	51,234	35,294
Total liabilities and stockholders' equity	$ 109,087	$ 66,912

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