



AVEO Oncology Reports Second Quarter 2022 Financial Results

August 4, 2022

- Total Q2 2022 Net Revenue of \$25.3 million including \$25.0 million of FOTIVDA® (tivozanib) U.S. Net Product Revenue –
- Q2 2022 FOTIVDA U.S. Net Product Revenue Growth of 24% Compared with Q1 2022 –
- Company Reaffirms Full Year 2022 FOTIVDA U.S. Net Product Revenue Guidance of \$100.0 million to \$110.0 million –
- Company Streamlines Planned R&D Spending and Lowers Guidance to \$50.0 million from \$60.0 million to \$70.0 million –
- Company to host conference call today at 4:30 p.m. ET –

BOSTON, Aug. 04, 2022 (GLOBE NEWSWIRE) -- AVEO Oncology (Nasdaq: AVEO), a commercial stage, oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for patients with cancer, today reported financial results for the second quarter ended June 30, 2022.

"At the beginning of April 2022, we entered the second year of the FOTIVDA commercial launch with increased momentum and confidence as demonstrated by continued sales growth and, most recently, FOTIVDA's elevated status by the National Comprehensive Cancer Network® (NCCN). We believe this momentum will continue to build in the second half of 2022 and we continue to be confident in our FOTIVDA U.S. net product revenue guidance for fiscal year 2022 of \$100.0 million to \$110.0 million," stated Michael Bailey, President and Chief Executive Officer of AVEO. "In addition to the strong sales momentum and elevated NCCN status, we were pleased to see the success of the FOTIVDA commercial launch recently recognized as having 'overperformed' in an independent market analysis¹ of first launches by emerging pharmaceutical and biotech companies. With this growing external recognition of our commercial acumen, we believe that we can further leverage our capabilities by identifying potential additional commercial stage assets to add to our portfolio."

"On the clinical development front, our Phase 3 TiNivo-2 trial, remains on track to complete patient enrollment in the second quarter of 2023. For the balance of the portfolio, we have reduced our planned R&D spend to focus exclusively on development initiatives that we believe will effectively position our pipeline assets to create partnering opportunities. This partnering focused R&D strategy is consistent with our overall strategy of leveraging partners to provide funding for the development of our portfolio and minimizing R&D investment from AVEO while retaining all, or a portion of, the North American oncology commercial rights related to these product candidates," said Mr. Bailey.

Second Quarter 2022 and Recent Highlights

- **Continued quarter over quarter growth of FOTIVDA U.S. net product revenue and prescriptions in Q2 2022.**
 - Second quarter 2022 U.S. net product revenue increased 24% to \$25.0 million compared with U.S. net product revenue of \$20.1 million in the first quarter of 2022, and increased 271% compared with \$6.7 million of U.S. net product revenue in the second quarter of 2021.
 - Second quarter 2022 gross-to-net estimate of 17.8%.
 - In the second quarter of 2022, 1,157 commercial prescriptions were filled, representing an 18% increase compared with 977 filled in the first quarter of 2022 and a 309% increase compared with 283 filled in the second quarter of 2021.
 - Based on third party data, AVEO continues to be a leader in the number of new third-line R/R RCC patient starts during the second quarter of 2022.
 - AVEO was recognized by ZS Associates for its commercial launch and received the "Distinguished Excellence" Award at the 28th Annual Communicator Awards sponsored by the Academy of Interactive and Visual Arts for AVEO's Multi-Media/Public Relations Campaign that supported the commercial launch of FOTIVDA.
- **Announced Updated National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines Elevating FOTIVDA® (tivozanib) to Category 1 Treatment for R/R RCC Patients.**
 - FOTIVDA elevated to Category 1 status as a subsequent therapy for RCC patients who have received two or more prior therapies in the latest Kidney Cancer Treatment Guidelines released on June 17, 2022.
 - NCCN is a recognized standard for clinical policy in cancer care, which impacts physician treatment decisions, reimbursement and treatment pathways.
 - In a recent third party market research survey, 80% of respondents indicated that the elevation of FOTIVDA to Category 1 status would positively impact their prescribing decisions.

- **Presented additional analysis on overall survival (OS) from the TIVO-3 trial and tivozanib activity and safety profile in non-clear cell (ncc) RCC at the 2022 ASCO Annual Meeting.**
 - Exploratory long-term OS analyses of data from the TIVO-3 trial continues to trend in favor of tivozanib demonstrating an OS hazard ratio of 0.89.
 - A conditional survival analysis was performed at the 12 month progression free survival landmark, showing a statistically significant 55% relative reduction (HR 0.45; 95% CI 0.22–0.91) in the risk of death with tivozanib over sorafenib in this third- and fourth-line treatment population and a median OS of 48.3 months in patients receiving tivozanib compared with a median OS of 32.8 months in patients receiving sorafenib, a non-selective VEGFR-TKI.
 - Tivozanib demonstrated activity and a favorable safety profile in a subgroup analysis of patients with nccRCC from the 2010 Phase 2 randomized discontinuation trial evaluating tivozanib in patients with nccRCC.
- **Enrollment ongoing for Phase 3 TiNivo-2 Trial in R/R RCC following prior immunotherapy; Expect to complete enrollment in the second quarter of 2023.**
 - AVEO continues to enroll patients in the Phase 3 TiNivo-2 clinical trial evaluating tivozanib in combination with nivolumab (OPDIVO®), Bristol Myers Squibb's antibody directed against PD-1, as compared with tivozanib monotherapy in patients with R/R RCC who have progressed following prior immune checkpoint inhibitor therapy. If successful, the company believes data from this trial has the potential to support U.S. Food and Drug Administration (FDA) approval of tivozanib in combination with nivolumab in R/R RCC and expand the market opportunity for FOTIVDA into the larger second line R/R RCC setting. AVEO currently expects enrollment in the TiNivo-2 trial to be completed in the second quarter of 2023.
- **Completed drug substance manufacturing for Ficlatusumab and entered into a clinical trial collaboration and supply agreement in North America with Eli Lilly and Company (Lilly) to provide ERBITUX® (cetuximab).**
 - AVEO completed drug substance manufacturing for ficlatusumab in the second quarter of 2022. The drug substance is expected to be used in connection with a potential Phase 3 registrational clinical trial in human papillomavirus (HPV) negative recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC) in the first half of 2023.
 - The Lilly agreement is similar to the clinical trial collaboration and supply agreement the company entered into with Merck KGaA, Darmstadt, Germany earlier this year to provide ERBITUX® (cetuximab), an anti-EGFR antibody, clinical drug supply outside of North America for the potential Phase 3 registrational trial.
 - AVEO expects to continue to discuss potential registrational clinical trial designs with the FDA and to continue to seek a strategic partner to fund development expenses. In September 2021, AVEO announced that the FDA granted Fast Track designation for the investigation of the combination of ficlatusumab and cetuximab for the treatment of patients with R/R HNSCC.

Second Quarter 2022 Financial Highlights

- At June 30, 2022, AVEO reported \$77.2 million in cash, cash equivalents and marketable securities, as compared with \$87.3 million at December 31, 2021.
- Total revenue for the second quarter of 2022 was approximately \$25.3 million compared with \$7.6 million for the second quarter of 2021.
- FOTIVDA U.S. net product revenue was \$25.0 million for the second quarter of 2022 compared with \$6.7 million for the second quarter of 2021.
- Research and development expense for the second quarter of 2022 was \$12.3 million compared with \$6.9 million for the second quarter of 2021.
- Selling, general and administrative expense for the second quarter of 2022 was \$17.1 million compared with \$14.9 million for the second quarter of 2021.
- Net loss for the second quarter of 2022 was \$8.3 million, or net loss of \$0.24 per basic and diluted share, compared with a net loss of \$13.6 million for the second quarter of 2021, or net loss of \$0.40 per basic and diluted share.

Financial Guidance

AVEO believes that its \$77.2 million in cash, cash equivalents and marketable securities as of June 30, 2022, along with expected net product revenues from the sales of FOTIVDA in the United States, will enable AVEO to maintain its current operations for a period of more than 12 months from the date of filing of its Quarterly Report on Form 10-Q for the quarter ended June 30, 2022.

AVEO has reaffirmed its full year 2022 FOTIVDA U.S. net product revenue guidance of \$100.0 million to \$110.0 million. AVEO expects that commercial expenses will be approximately \$50.0 million in 2022. AVEO expects general and administrative expenses will remain at approximately \$20.0 million for the year. Research and development expenses are now expected to be approximately \$50.0 million in 2022, a reduction from the prior range of \$60.0 million to \$70.0 million as the company will focus its spending on clinical development programs to expand the commercial opportunity of tivozanib for the treatment of RCC and to position the company's other product candidates for further development by partners and minimize R&D investment from AVEO while retaining all, or a portion of, the North American oncology commercial rights related to these product candidates. One of these initiatives includes the company's decision, along with its partner at AstraZeneca, to close further enrollment in the second-line cohort of the

DEDUCTIVE trial, a Phase 1b/2 clinical trial studying the combination of IMFINZI (durvalumab) and tivozanib in patients with advanced, unresectable hepatocellular carcinoma as part of its efforts to streamline R&D spend. In addition, AVEO expects that gross margins will continue to be in the mid-to-high 80th percentile in 2022.

Conference Call and Webcast

In connection with this announcement, AVEO will host a conference call and audio webcast today, August 4, 2022, at 4:30 P.M. Eastern Time. The call can be accessed by dialing (877) 423-9813 (U.S. and Canada) or (201) 689-8573 (international). The passcode for the conference call is 13730553. 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.² 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.³ 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,⁴ 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 advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. AVEO continues to develop FOTIVDA in immuno-oncology and other novel targeted combinations in RCC and other indications, and has 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 "advance," "aim," "anticipate," "believe," "continue," "could," "design," "estimate," "expect," "goal," "intend," "look forward," "may," "plan," "potential," "project," "promising," "seek," "should," "strategy," "will," "would," 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: FOTIVDA's elevated status by the National Comprehensive Cancer Network® (NCCN) and AVEO's expectations that FOTIVDA's elevated status in the NCCN will impact the commercialization of FOTIVDA; AVEO's expectations of achieving quarter over quarter sales growth and an increase in the sales ramp of FOTIVDA in future periods; AVEO's plans, strategies and ability to successfully sell and distribute FOTIVDA to patients in the United States; AVEO's expectations for its fiscal year 2022 FOTIVDA U.S. net product revenue, commercial expenses, general and administrative expenses, research and development spend and gross margins; 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 other indications; AVEO's plans and strategies to leverage its commercial capacity and potentially acquire or in-license additional commercial stage assets to its portfolio; FOTIVDA's ability to maintain a leadership position in new patient starts in the R/R RCC third-line setting; the date enrollment will be completed for AVEO's pivotal Phase 3 TiNivo-2 trial; AVEO's plans, strategies and execution for current and future clinical trials and preclinical studies of tivozanib and ficlatuzumab; the 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 R/M HNSCC and other indications; AVEO's ability to pursue regulatory strategies based on the results of clinical trials and preclinical studies of its product candidates, including AVEO's ability to obtain FDA approval of tivozanib in combination with nivolumab for the treatment of R/R RCC; AVEO's strategy, prospects, plans and objectives for FOTIVDA and its product candidates and for AVEO generally; AVEO's plans and ability to position each of its product candidates for partnership opportunities outside of North America that may fund further development of these product candidates while retaining a portion, or all, of the North American commercial rights; the potential commercial opportunity of FOTIVDA and AVEO's other product candidates; AVEO's estimates for its cash runway and the contingencies on which such runway is dependent; and statements regarding AVEO's performance, including but not limited to statements in the section titled "Financial Guidance." 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 achieve quarter over quarter sales growth of FOTIVDA; the percentage of FOTIVDA prescriptions being made to patients who are in the third- and fourth-line treatment setting maintaining or increasing over time; 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 and collaborators, 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, AV-380 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 and maintain adequate protection for intellectual property rights relating to FOTIVDA and its product candidates; unplanned capital requirements; 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 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. ZS Associates. US emerging pharma and biotech first launches: A story of over-and underperformance. June 21, 2022.
2. Pawlowski N et al. AACR 2013. Poster 3971.
3. J Angulo and O Shapiro, *Cancers* (Basel) 2019 Sep; 11(9): 1227. [10.3390/cancers11091227]

4. Decision Resources. RCC landscape and forecast. December 12, 2019.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
FOTIVDA U.S. product revenue, net	\$ 25,006	\$ 6,735	\$ 45,092	\$ 7,801
Partnership licensing and royalty revenue	298	821	1,132	1,675
	<u>25,304</u>	<u>7,556</u>	<u>46,224</u>	<u>9,476</u>
Operating expenses:				
Cost of products sold	3,065	822	5,499	960
Research and development	12,318	6,878	22,478	12,675
Selling, general and administrative	17,075	14,920	34,412	30,020
	<u>32,458</u>	<u>22,620</u>	<u>62,389</u>	<u>43,655</u>
Loss from operations	(7,154)	(15,064)	(16,165)	(34,179)
Other income (expense), net:				
Interest expense, net	(1,165)	(1,128)	(2,353)	(1,739)
Change in fair value of PIPE Warrant liability	—	2,595	—	199
	<u>(1,165)</u>	<u>1,467</u>	<u>(2,353)</u>	<u>(1,540)</u>
Net loss	<u>\$ (8,319)</u>	<u>\$ (13,597)</u>	<u>(18,518)</u>	<u>(35,719)</u>
Net loss per share	\$ (0.24)	\$ (0.40)	\$ (0.54)	\$ (1.16)
Weighted average number of common shares outstanding	34,503	34,362	34,489	30,915

Consolidated Balance Sheet Data
(In thousands)

	June 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents and marketable securities	\$ 77,160	\$ 87,326
Trade receivables, net and partnership receivables	16,129	11,601
Inventory	1,320	1,656
Prepaid expenses and other current assets	2,979	4,153
Property and equipment, net	242	276
Operating lease right-of-use asset	81	178
Other assets	200	151
Total assets	<u>\$ 98,111</u>	<u>\$ 105,341</u>
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	\$ 26,310	\$ 18,142
Loans payable, net of discount	38,429	37,960
Deferred revenue and research and development reimbursements	—	578
Operating lease liability	5	11
Other liabilities	2,780	2,780
Stockholder's equity	<u>30,587</u>	<u>45,870</u>
Total liabilities and stockholders' equity	<u>\$ 98,111</u>	<u>\$ 105,341</u>



Source: AVEO Pharmaceuticals, Inc.