AVEO Oncology Announces Updated NCCN Clinical Practice Guidelines Elevate FOTIVDA® (tivozanib) to Category 1 Treatment for Relapsed or Refractory Advanced (R/R) Renal Cell Carcinoma (RCC) Patients

June 21, 2022

BOSTON, June 21, 2022 (GLOBE NEWSWIRE) -- AVEO Oncology (Nasdaq: AVEO), a commercial stage, oncology-focused biopharmaceutical company, today announced the National Comprehensive Cancer Network® (NCCN) has elevated FOTIVDA® (tivozanib) 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.

“Category 1 is the highest Category recommendation offered by NCCN, which is based on strong clinical evidence and perception of the product among the NCCN Panel Members. The NCCN guidelines are recognized and followed by both academic and community oncologists when selecting appropriate therapeutic options for their patients,” said Michael Bailey, president and chief executive officer of AVEO. “This year we presented encouraging long-term, progression free survival (PFS) and overall survival (OS) follow-up data from the Phase 3 TIVO-3 study. These new data demonstrate the durability of FOTIVDA's anti-tumor activity which has translated into an improving OS hazard ratio.”

The NCCN Clinical Practice Guidelines are the recognized standard for clinical policy in cancer care and are developed through review of evidence and recommendations from physicians and oncology researchers. The current NCCN RCC guidelines make treatment recommendations for first-line or subsequent therapy options for RCC patients and are referenced in the development of other clinical pathways.

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 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: the potential efficacy, safety and tolerability of tivozanib, both as a stand-alone drug candidate and in combination with other therapies, in R/R RCC; the extent to which the NCCN Clinical Practice Guidelines are recognized and followed by both academic and community oncologists when selecting therapeutic options for their patients; the potential for FOTIVDA to maintain Category 1 status as a subsequent therapy for RCC patients who have received two or more prior therapies; the potential that early and consistent PFS benefit with tivozanib ultimately may be associated with a trend toward improved overall survival; AVEO's plans, strategies and execution for current and future clinical trials and preclinical studies of tivozanib; AVEO's ability to pursue regulatory strategies based on the results of clinical trials and preclinical studies of tivozanib; and the potential commercial opportunity of tivozanib and AVEO's other product candidates. 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, 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 tivozanib, 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 tivozanib; 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 ability to maintain compliance with regulatory requirements applicable to tivozanib; AVEO's ability to obtain and maintain adequate protection for intellectual property rights relating to tivozanib; 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. 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.

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