AVEO Oncology Announces Addition of FOTIVDA® (tivozanib) into National Comprehensive Cancer Network Clinical Practice Guidelines

March 29, 2021

BOSTON--(BUSINESS WIRE)--Mar. 29, 2021-- AVEO Oncology (Nasdaq: AVEO) today announced that the National Comprehensive Cancer Network (NCCN) has updated its Clinical Practice Guidelines to include FOTIVDA® (tivozanib) as a recommended regimen for subsequent therapy. The subsequent therapy category follows the first-line treatment regimen recommendations for patients with clear cell histology renal cell carcinoma (ccRCC). On March 10, 2021, the U.S. Food and Drug Administration (FDA) approved FOTIVDA for the treatment of adults with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. FOTIVDA is an oral, next-generation vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI).

"FOTIVDA's addition to the NCCN Guidelines provides further validation for its potential to serve as an important evidence-based, well tolerated treatment option for patients with relapsed or refractory advanced RCC," said Michael Bailey, president and chief executive officer of AVEO. "As previously announced, launch efforts are now underway, and we are committed to bringing this promising therapy to as many appropriate patients as possible."

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 categorically make treatment recommendations for first-line or subsequent therapy options for RCC patients. FOTIVDA is now recommended by the NCCN Guidelines as a subsequent therapy for patients with ccRCC who have received two or more prior systemic therapies (Category 2a). FOTIVDA's addition to the NCCN Guidelines follows its recent U.S. FDA approval, which was based on AVEO's pivotal Phase 3 study, TIVO-3, comparing FOTIVDA to sorafenib in relapsed or refractory advanced RCC following two or more prior systemic therapies. The approval was also supported by three additional trials in RCC and included safety data from over 1,000 clinical trial subjects.

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 an oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for cancer patients. AVEO's strategy is to focus its resources toward the development and commercialization of its product candidates in North America, while leveraging partnerships to support development and commercialization in other geographies. AVEO's lead candidate, FOTIVDA ® (tivozanib), received U.S. Food and Drug Administration (FDA) approval on March 10, 2021 for the treatment of adult patients with relapsed or refractory 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 EUSA territory for the treatment of adult patients with advanced RCC. AVEO has previously reported promising early clinical data on ficlatuzumab (anti-HGF IgG1 mAb) in head and neck cancer, pancreatic cancer and acute myeloid leukemia and is conducting a randomized Phase 2 confirmatory clinical trial of ficlatuzumab for the potential treatment of head and neck cancer. AVEO's pipeline of product candidates also includes AV-380 (anti-GDF15 IgG1 mAb). AVEO has previously reported the acceptance of its investigational new drug application in the U.S. for AV-380 and its initiation of a Phase 1 clinical trial for the potential treatment of cancer cachexia. AVEO's earlier-stage pipeline includes monoclonal antibodies in oncology development, including AV-203 (anti-ErbB3 mAb) and AV-353 (anti-Notch 3 mAb). AVEO is committed to creating an environment of diversity and inclusion.

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 (tivozanib) to patients in the U.S. and to ensure it is available to as many patients as possible; the potential for FOTIVDA as a treatment option for patients with relapsed or refractory advanced RCC; the potential for FOTIVDA as a subsequent therapy for patients with ccRCC as recommended by NCCN Guidelines; 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 of the AVEO ACE Patient Support program to make patient access to FOTIVDA simple and to offer comprehensive services to patients regardless of insurance or financial circumstances; AVEO's execution of its clinical and regulatory strategy for tivozanib; AVEO's plans and strategies for current and future clinical trials of tivozanib, ficlatuzumab and AV-380 and for commercialization of FOTIVDA in the U.S.; the advancement of AVEO's pipeline, including the advancement of ficlatuzumab in multiple clinical studies; the potential outcomes from studies of ficlatuzumab to provide AVEO with opportunities to pursue regulatory strategies; the potential clinical utility of ficlatuzumab and AV-380 in areas of unmet need and AVEO's strategy, prospects, plans and objectives for FOTIVDA and its product candidates and for AVEO generally. 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 to raise the substantial additional funds required to achieve its goals,

including those goals pertaining to the commercialization 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 and supply of FOTIVDA and its product candidates; and 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; uncertainties related to AVEO's ability to access future borrowings under the Hercules loan agreement, which turns on the achievement of milestones related to the commercialization 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 successfully and timely enroll, complete and read-out data from its clinical trials; competitive factors; and those risks discussed in the sections 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 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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