AVEO Oncology to Present Positive New Long-Term PFS Data from Phase 3 TIVO-3 Study of FOTIVDA® (tivozanib) in Third- and Fourth-Line Renal Cell Carcinoma

February 14, 2022

Five year follow-up data show FOTIVDA® (tivozanib) patients up to 5X more likely to experience long-term PFS compared to Nexavar® (sorafenib)

Long-term data from pivotal TIVO-3 study continue to demonstrate durable disease control and positive trend for overall survival for FOTIVDA® (tivozanib)

Data Presented at the ASCO 2022 GU Cancers Symposium

BOSTON, Feb. 14, 2022 (GLOBE NEWSWIRE) -- AVEO Oncology (Nasdaq: AVEO), a commercial stage, oncology-focused biopharmaceutical company, today announced that new long-term progression free survival (PFS) data from the Phase 3 TIVO-3 study, which compares FOTIVDA® (tivozanib) to Nexavar® (sorafenib) in advanced renal cell carcinoma (RCC) patients following two or more prior systemic therapies, are being presented at the 2022 American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium being held in San Francisco on February 17^{th} – 19^{th}.

“The long-term PFS data we are presenting at the ASCO GU meeting this week further strengthen the body of data supporting FOTIVDA as a potential standard of care in third- and fourth-line RCC treatment. This marks the first presentation of five year follow-up data for patients being treated in the third- or fourth-line RCC setting and helps guide clinical treatment,” said Michael Bailey, President and Chief Executive Officer of AVEO. “We are excited to report that the five year follow-up data announced today show that patients receiving FOTIVDA are up to five times more likely to experience long-term progression free survival as compared to sorafenib. Long-term follow-up of the TIVO-3 study suggests early and consistent PFS benefit with FOTIVDA ultimately may be associated with the trend toward improved overall survival.”

ASCO GU 2022 TIVO-3 Phase 3 Five Year Follow-up Data include:

- Investigator-assessment of PFS with long-term follow-up for TIVO-3 is consistent with the primary independent review committee.
- Landmark five year follow-up data show PFS rates are consistently higher with FOTIVDA vs. sorafenib, with 12% vs. 2% and 8% vs. 0% at three and four years, respectively. Long-term PFS represents a clinically meaningful outcome for patients in the third- and fourth-line treatment setting.
- Long term OS was also analyzed, and a non significant trend favoring FOTIVDA continued to emerge with accumulation of events (HR, 0.89).

ASCO GU 2022 Poster/Abstract Details:
Title: Long-term PFS from TIVO-3: Tivozanib (TIVO) vs. sorafenib (SOR) in relapsed/refractory (R/R) advanced RCC
First Author: Michael B. Atkins MD
Abstract: 362
Track: Renal Cell Cancer
Date and Time: February 19, 2022 at 10 a.m. Eastern Time

Details on the presentation are available on the 2022 ASCO GU website (click here). The poster scheduled to be presented at the 2022 ASCO GU Cancers Symposium will be available on the Publications page of the AVEO Oncology website (click here) subsequent to the presentation.

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 United States 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 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: the potential efficacy, safety and tolerability of tivozanib, both as a stand-alone drug candidate and in combination with other therapies in RCC;

the potential that early and consistent PFS benefit with FOTIVDA ultimately may be associated with a trend toward improved overall survival; AVEO's plans, strategies and execution for current and future clinical trials of tivozanib; AVEO's strategy, prospects, plans and objectives for tivozanib and for AVEO generally; 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 tivozanib in combination with certain other therapies, 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 and its collaborators' ability to successfully enroll and complete clinical trials; AVEO's ability to maintain compliance with regulatory requirements applicable to tivozanib; AVEO's ability to obtain sufficient clinical supplies of tivozanib; AVEO's ability to obtain and maintain adequate protection for intellectual property rights relating to tivozanib; 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. Fotivda (Tivozanib) USPI March 2021
2. Fotivda (Tivozanib) SmPC August 2017
3. Motzer RJ, Nosov D, Eisen T, et al. J Clin Oncol 2013; 31(30): 3791-9
4. Pawlowski N et al. AACR 2013. Poster 3971

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Source: AVEO Oncology

Source: AVEO Pharmaceuticals, Inc.