AVEO Oncology, an LG Chem company, Announces Acceptance of Late-Breaking Oral Presentation of TiNivo-2 Results at ESMO 2024

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AVEO, an LG Chem company →
Sep 03, 2024, 08:10 ET

BOSTON, Sept. 3, 2024 /PRNewswire/ -- AVEO Oncology, an LG Chem company ("AVEO"), announced today their late-breaking abstract detailing their Phase 3 TiNivo-2 trial has been selected as a Proffered Paper oral presentation at the 2024 European Society for Medical Oncology (ESMO) Congress in Barcelona, Spain this September 13-17th.

The oral presentation will announce the results from the TiNivo-2 clinical trial, which was designed to evaluate the benefit of adding nivolumab, a PD-1 checkpoint inhibitor, to low dose (0.89mg) FOTIVDA® (tivozanib), a vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) versus standard dose (1.34mg) FOTIVDA in the second-line following immune checkpoint inhibitor (ICI) combinations or the third-line setting following prior ICI treatment. Details of the presentation are as follows:

Title:	Tivozanib Plus Nivolumab vs Tivozanib Monotherapy in Patients With Metastatic Renal Cell Carcinoma Following an Immune Checkpoint Inhibitor: Results of the Phase 3 TiNivo-2 Study
Speaker:	Toni Choueiri, MD, Director of the Lank Center for Genitourinary (GU) Oncology at Dana-Farber Cancer Institute, Boston, MA, United States of America
Presentation #:	LBA73
Category:	Proffered Paper session 1: GU tumors, non-prostate
Date & Time:	Friday, September 13, 2024; 2:00 – 2:10 pm CET

TiNivo-2 Clinical Trial Details

Phase 3 clinical trial designed to evaluate the safety and efficacy of tivozanib in combination with nivolumab, as compared to tivozanib as a monotherapy, in RCC patients whose tumors progressed following prior ICI therapy.

About FOTIVDA® (tivozanib)

FOTIVDA® (tivozanib) is an oral, next-generation VEGFR 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, based on data from the TIVO-3 trial comparing FOTIVDA to sorafenib. FOTIVDA was approved in August 2017 in the European Union and other countries in the territory of its partner Recordati UK Ltd. for the treatment of adult patients with advanced RCC. FOTIVDA was discovered by Kyowa Kirin.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTION

Hypertension was reported in 45% of patients (22% ≥ Grade 3). **Hypertensive crises** were reported in 0.8% of patients. Do not initiate FOTIVDA in patients with uncontrolled hypertension. Monitor for hypertension and treat as needed. Reduce the FOTIVDA dose for persistent hypertension not controlled by anti-hypertensive medications. Discontinue FOTIVDA for severe hypertension that cannot be controlled with anti-hypertensive therapy or for hypertensive crisis.

Cardiac failures were reported in 1.6% of patients (1% ≥ Grade 3); 0.6% of events were fatal. Monitor for signs or symptoms of cardiac failure during treatment with FOTIVDA. Manage with dose interruption, dose reduction, or discontinuation.

Cardiac ischemia were reported in 3.2% of patients; 0.4% of events were fatal. **Arterial thromboembolic events** were reported in 2.0% of patients, including death due to ischemic stroke (0.1%). Closely monitor patients at risk for, or who have a history of these events. Discontinue FOTIVDA in patients who develop severe arterial thromboembolic events, such as myocardial infarction and stroke.

Venous Thrombotic Events (VTE) were reported in 2.4% of patients, including 0.3% fatal events. Closely monitor patients who are at increased risk for these events. Discontinue in patients who develop serious VTEs.

Hemorrhagic Events were reported in 11% of patients; 0.2% of events were fatal. Use FOTIVDA with caution in patients who are at risk for or who have a history of bleeding.

Proteinuria was reported in 8% of patients (2% = Grade 3). Monitor during treatment with FOTIVDA. For moderate to severe proteinuria, reduce the dose or interrupt treatment. Discontinue in patients who develop nephrotic syndrome.

Gastrointestinal (GI) Perforation including fatal cases, has been reported in patients receiving FOTIVDA. Monitor for symptoms of GI perforation or **fistula formation** periodically throughout treatment with FOTIVDA. Permanently discontinue FOTIVDA in patients who develop severe or life-threatening GI perforation.

Thyroid Dysfunction events were reported in 11% of patients (0.3% ≥ Grade 3). Monitor thyroid function before and during treatment with FOTIVDA.

Wound Healing Complications: Withhold FOTIVDA for at least 24 days prior to elective surgery and do not administer for at least 2 weeks after major surgery and until adequate wound healing is observed.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS) can occur with FOTIVDA. Evaluate for RPLS in patients presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue if signs or symptoms of RPLS occur.

Embryo-fetal Toxicity: FOTIVDA can cause fetal harm. Advise patients of the potential risk to a fetus, to avoid becoming pregnant and to use contraception during treatment and for one month after the last dose of FOTIVDA. Advise males with female partners of reproductive potential to use effective contraception during treatment and for one month after the last dose of FOTIVDA.

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

ADVERSE REACTIONS

Common adverse reactions include fatigue/asthenia, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis.

Serious adverse reactions include bleeding (3.5%), venous thromboembolism (3.5%), arterial thromboembolism (2.9%), acute kidney injury (2.3%), and hepatobiliary disorders (2.3%).

DRUG INTERACTIONS

Avoid coadministration with strong CYP3A4 inducers.

USE IN SPECIFIC POPULATIONS

Advise women not to breastfeed during treatment and for at least 1 month after the last dose.

The recommended dosage for patients with end-stage renal disease has not been established.

Reduce the FOTIVDA dose for patients with moderate hepatic impairment. The recommended dosage in patients with severe hepatic impairment has not been established.

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 full Prescribing Information for FOTIVDA® (tivozanib).

About AVEO Pharmaceuticals, Inc.

AVEO is an oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for patients with cancer. AVEO currently markets FOTIVDA in the U.S. for the treatment of adult patients with relapsed or refractory advanced 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 became a wholly owned subsidiary of LG Chem Life Sciences USA, Inc. on January 19, 2023. AVEO continues to operate under the AVEO Oncology, an LG Chem company, name.

About LG Chem, Ltd. and LG Chem Life Sciences

LG Chem, Ltd. (LG Chem) is a leading global chemical company with a diversi½ed business portfolio in the key areas of petrochemicals, advanced materials, and life sciences. The company manufactures a wide range of products from high-value added petrochemicals to renewable plastics, specializing in cutting-edge electronic and battery materials, as well as drugs and vaccines to deliver differentiated solutions for its customers. LG Chem Life Sciences develops, manufactures, and globally commercializes pharmaceutical products, with a focus on Oncology, Immunology, and Metabolic diseases. Our mission is to transform people's lives through inspiring science and leading innovation. For more information, please visit **www.lgchem.com**.

References

1. ClinicalTrials.gov. *Study to Compare Tivozanib in Combination with Nivolumab to Tivozanib Monotherapy in Subjects with Renal Cell Carcinoma*. Accessed July 12, 2024. https://clinicaltrials.gov/ct2/show/NCT04987203

2. FOTIVDA (tivozanib)[https://www.fotivda.com/fotivdapi.pdf].Boston, MA: AVEO Pharmaceuticals, Inc.

3. OPDIVO (nivolumab)[https://packageinserts.bms.com/pi/pi_opdivo.pdf].Princeton, NJ: Bristol-Myers Squibb Company.

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