AVEO Oncology, an LG Chem company, Presents Three Posters at ASCO 2025 Annual Meeting

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AVEO, an LG Chem company →
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– TiNivo-2 exploratory subgroup analysis following ICI combination treatments –

– AV-380 anti-GDF15 candidate receives generic name Rilogrotug –

– Ficlatuzumab and Rilogrotug highlighted in trials in progress posters –

BOSTON, June 3, 2025 /PRNewswire/ -- AVEO Oncology, an LG Chem company ("AVEO"), a biopharmaceutical company committed to providing differentiated solutions to improve cancer patients lives, presented three posters during the American Society of Clinical Oncology (ASCO) 2025 annual meeting in Chicago, IL, including one exploratory sub-analysis for tivozanib and two trials in progress.

Michael Bailey, president and Chief Executive Officer, stated, "We were really excited to present these three posters at this year's ASCO annual meeting, which we believe further showcase the use of tivozanib after frontline ICI-based combination therapy, but also AVEO's pipeline which is focused on developing therapies that improve the lives of patients with cancer."

Poster title: "Efficacy of second line (2L) treatment with tivozanib (Tivo) as monotherapy or with nivolumab (Nivo) in patients (pts) with metastatic renal cell carcinoma (mRCC) previously treated with an immune checkpoint inhibitor (ICI) combination of ipilimumab (Ipi)/Nivo or vascular endothelial growth factor receptor-tyrosine kinase inhibitor (VEGFR-TKI)/ICI in the Phase 3 TiNivo-2 study." – (Abstract: 4540; Poster: 340)

AVEO presented data from an exploratory sub-analysis of the TiNivo-2 study, evaluating the efficacy of tivozanib as a 2nd line treatment option in patients who failed 1st line vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) and immune checkpoint inhibitor combination therapy. The subgroup analysis indicates that tivozanib monotherapy at 1.34mg daily showed activity, including substantial tumor size reduction, in patients who previously received a contemporary 1st line metastatic renal cell carcinoma (mRCC) treatment regimen. Additionally, the sub-analysis showed no benefit in the addition of nivolumab to tivozanib in this context, akin to the results of the parent TiNivo-2 trial.

Poster Title: "FIERCE-HN: A multicenter, randomized, double-blind, placebo-controlled, phase 3 study of ficlatuzumab (HGF/cMET Mab) in combination with cetuximab in participants with recurrent or metastatic (R/M) HPV negative head and neck squamous cell carcinoma (HNSCC)."– (Abstract: TPS6115; Poster: 520a)

AVEO presented a trial in progress poster for the Phase 3 FIERCE-HN trial, which is evaluating the combination of ficlatuzumab and cetuximab in patients with recurrent or metastatic (R/M) HPV-negative head and neck squamous cell carcinoma (HNSCC). The purpose of this study is to evaluate the efficacy and safety of ficlatuzumab (10 or 20 mg/kg) in combination with cetuximab (500 mg/kg) against placebo plus cetuximab in participants with HPV-negative R/M HNSCC. The study is evaluating whether ficlatuzumab combined with cetuximab is superior to cetuximab alone in terms of overall survival.

FIERCE-HN opened for enrollment in December 2023 and currently expects to complete enrollment by May 2026. For more information, visit **www.FIERCEHN.com**.

Poster Title: "A phase 1b dose escalation study of AV-380 (anti-GDF15 monoclonal antibody) in combination with standard-of-care therapy in cancer patients with cachexia."– (Abstract: TPS12142; Poster: 159a)

AVEO presented a second trial in progress poster for their AV-380 phase 1b dose escalation study. During the meeting, the company also announced the official molecule name for AV-380: rilogrotug (*pronounced rye-low-grow-tug*). Rilogrotug is an immunoglobulin (Ig) G1 monoclonal antibody (mAb) intended to bind circulating human growth differentiation factor 15 (GDF-15), a cytokine involved in cancer-induced cachexia. This open label ascending dose study is designed to evaluate the safety, pharmacokinetics, pharmacodynamics, and immunogenicity of rilogrotug in cancer patients with cachexia.

FOTIVDA (tivozanib)

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 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 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, 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.

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® (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 and its strategic partners continue to develop FOTIVDA in other novel targeted combinations in RCC. The company also has investigational programs in other areas of high unmet need, including ficlatuzumab in HPV-negative refractory head and neck squamous cell carcinoma and AV-380 in cancer cachexia. 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 diversified 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**.

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