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AVEO Oncology Enrolls First Patient in Pivotal FIERCE-HN Clinical Trial to Evaluate Ficlatuzumab in Combination with ERBITUX® (cetuximab) in Patients with HPV-negative Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC)

- *Phase 3 Registrational Trial Seeks to Improve Survival Outcomes in Underserved HPV-negative R/M Head and Neck Cancer Patient Population*
- *Trial Launch Follows FDA Fast Track Designation of Ficlatuzumab/cetuximab Combination for Treatment of Relapsed/Recurrent HNSCC*

BOSTON, Jan. 16, 2024 (GLOBE NEWSWIRE) -- AVEO Oncology ("AVEO"), an LG Chem company, today announced enrollment of the first patient in the FIERCE-HN trial, a global, multicenter, randomized, double-blind, placebo-controlled, phase 3 clinical trial evaluating ficlatuzumab in combination with ERBITUX® (cetuximab), an anti-EGFR antibody, in patients with human papillomavirus (HPV)-negative recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC). Ficlatuzumab is AVEO's investigational antibody that targets hepatocyte growth factor (HGF).

"The start of enrollment for the pivotal FIERCE-HN trial is an important milestone in the advancement of the combination of ficlatuzumab and cetuximab, as it brings us a step closer to offering a new potential therapy to a patient population that has limited effective treatment options available to them today," said Michael Bailey, president and chief executive officer of AVEO Oncology. "We are excited about the potential to extend the survival for this population of cancer patients where a significant unmet need currently exists."

The U.S. Food and Drug Administration designated the investigation of ficlatuzumab and ERBITUX® (cetuximab) a Fast Track development program for relapsed/recurrent HNSCC in September 2021. That designation followed AVEO's June 2021 announcement of positive results from a randomized phase 2 study of ficlatuzumab alone or in combination with cetuximab in patients with pan-refractory, metastatic HNSCC. In that study, patients with HPV-negative disease, a subgroup normally associated with poorer outcomes, who received the ficlatuzumab and cetuximab combination demonstrated an overall response rate of 38% versus 0% in the HPV positive subgroup, including 13% of HPV-negative patients with complete responses.

"Despite the advent of immune checkpoint inhibitor therapy for recurrent and metastatic head and neck squamous cell carcinoma, few patients with advanced disease survive for longer than one year," commented Julie E. Bauman, MD, MPH, director of the George Washington Cancer Center as well as associate dean of cancer and professor of medicine at the George Washington School of Medicine & Health Sciences. "We therefore approach the FIERCE-HN trial with a mix of urgency and

optimism, as the combination of ficlatuzumab and cetuximab has the potential to expand the range of viable therapeutic options for this underserved population."

About the FIERCE-HN Trial

The **FI**clatuzumab in combination with **ER**BITUX® (cetuximab) **C**linical **E**valuation in **H**ead and **N**eck cancer patients (FIERCE-HN trial) is designed to initially compare the efficacy and safety of two dose levels of ficlatuzumab plus cetuximab and then will proceed to a registrational stage to compare the optimal dose level to a control arm of placebo plus cetuximab in participants with HPV-negative R/M HNSCC. The trial is open to adults with a primary diagnosis of R/M HNSCC. Eligible participants must have failed prior therapy with an anti-programmed cell death protein 1, also known as PD-1, or programmed cell death ligand 1, also known as PD-L1, immune checkpoint inhibitor and with platinum-based chemotherapy, administered in combination or sequentially. Failure of prior treatment may be due to disease progression or intolerance to treatment.

The primary FIERCE-HN endpoint is overall survival. Secondary endpoints include progression-free survival, objective response rate, duration of response, safety and tolerability, and pharmacokinetics of the ficlatuzumab and cetuximab combination. AVEO aims to enroll 410 participants across the clinical trial's three arms. For more details about the clinical trial, please visit clinicaltrials.gov (NCT06064877) or the FIERCE-HN trial website at www.fiercehn.com.

About Ficlatuzumab

Ficlatuzumab (formerly known as AV-299) is a potent hepatocyte growth factor (HGF) immunoglobulin G1 inhibitory antibody that binds to the HGF ligand with high affinity and specificity. HGF is the natural ligand of c-Met and blocking HGF inhibits signaling through the HGF/c-Met signaling pathway. The U.S. Food and Drug Administration designated as a Fast Track development program the investigation of ficlatuzumab and ERBITUX® (cetuximab) for relapsed/recurrent HNSCC in September 2021.

ERBITUX is a registered trademark owned by or licensed to Eli Lilly and Company, its subsidiaries, or affiliates.

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 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 became a wholly owned subsidiary of LG Chem Life Sciences Innovation Center, Inc. on January 19, 2023. AVEO continues to operate under the AVEO Oncology, an LG Chem company, name. For more information, please visit www.aveooncology.com.

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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