AVEO Oncology, an LG Chem company, Announces Completion of the First Interim Analysis in the Global Phase 3 FIERCE-HN Study

NEWS PROVIDED BY
AVEO, an LG Chem company ➞
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– *Global enrollment continues in the Phase 3 registrational study following the planned first interim analysis for patients with HPV-negative recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC)* –

– *20mg/kg dose of ficlatuzumab selected for the combination arm of ficlatuzumab and cetuximab* –

– *Trials in Progress poster to be presented at the Multidisciplinary Head and Neck Cancers Symposium* –

BOSTON, Feb. 18, 2026 /PRNewswire/ -- AVEO Oncology, an LG Chem company, (AVEO) announced today that the 20mg/kg dose of ficlatuzumab was selected for the combination arm of the Phase 3 registrational FIERCE-HN clinical trial. This dose selection decision follows the recommendation of the Independent Data Monitoring Committee and alignment with the U.S. Food & Drug Administration. The ongoing FIERCE-HN trial continues to enroll patients with human papillomavirus (HPV)-negative recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC) with the aim to enroll 410 to 500 patients.

FIERCE-HN is a global, multicenter, randomized, double-blind, placebo-controlled, Phase 3 clinical trial evaluating ficlatuzumab in combination with ERBITUX® (cetuximab), an anti-epidermal growth factor receptor (EGFR) antibody, as compared to placebo plus cetuximab 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).

"This is a significant milestone for AVEO, as we are dedicated to improving patient outcomes through novel clinical research," said Michael P. Bailey, President and CEO of AVEO. "The selection of the ficlatuzumab dose in combination with cetuximab advances us towards understanding the potential clinical value of this combination in a patient population that has limited effective treatment options available to them today."

"Today's announcement is a defining moment and one that brings us one step closer to determining the potential clinical benefit of the combination of ficlatuzumab and cetuximab in this underserved population," commented Julie E. Bauman, MD, MPH. Dr. Bauman is the Director of the George Washington Cancer Center and Associate Dean of Cancer and Professor of Medicine at the George Washington School of Medicine & Health Sciences as well as the principal investigator of the FIERCE-HN clinical trial. "While I remain a blinded investigator, identifying the optimal dose is a significant inflection point for the clinical trial. We are keen on completing enrollment and continuing to advance the FIERCE-HN study."

In addition, at the upcoming Multidisciplinary Head and Neck Cancers Symposium being held February 19-21, 2026, in Palm Desert, California, Dr. Bauman will be presenting a Trials in Progress poster: *FIERCE-HN: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Ficlatuzumab (HGF/cMET MAb) in Combination with Cetuximab in Patients with Recurrent or Metastatic (R/M) HPV Negative Head and Neck Squamous Cell Carcinoma (HNSCC).*

2026 Multidisciplinary Head and Neck Cancers Symposium

Date: February 20, 2026

Time: 3:00 P.M. – 3:30 P.M. PT

Poster No.: 9

Abstract No.: 2128

Location: JW Marriott Desert Springs, Spring Ballroom

About AVEO Pharmaceuticals, Inc.

AVEO Pharmaceuticals, Inc., an LG Chem company, (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 rilogrotug (also known as 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 is a leading global chemical company with a diversified business portfolio spanning across petrochemicals, advanced materials, and life sciences. **LG Chem Life Sciences**, the life sciences business division of LG Chem, is dedicated to developing and delivering innovative medicines across a broad range of therapeutic areas. Guided by its mission to transform people's lives through inspiring science and leading innovation, LG Chem Life Sciences is offering differentiated solutions to its customers. For more information, please visit **www.lgchem.com**.

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 a registrational Phase 3 randomized trial designed to compare the efficacy and safety of ficlatuzumab plus cetuximab 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 chemotherapy and an anti-programmed cell death protein 1 inhibitor, also known as PD-1, or immune checkpoint inhibitor, 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 patient reported outcomes. AVEO aims to enroll 410 to 500 participants across the clinical trial's three arms. The clinical trial is being conducted by AVEO, with Eli Lilly and Company (Lilly) serving as a collaborator. Under the collaboration agreement, Lilly is responsible for supplying cetuximab for North American trial sites for all three arms of the study. 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.

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