Bicara Therapeutics Announces Publication of an Abstract with Preliminary Phase 1b Expansion Cohort Data Evaluating 750mg of Ficerafusp Alfa Weekly Plus Pembrolizumab in 1L HPV-negative R/M HNSCC at ESMO Asia 2025

Dec 1, 2025

Ficerafusp alfa 750mg QW in combination with pembrolizumab demonstrates overall response rate and safety profile consistent with the 1500mg QW dose

Data inform and advance progress toward dose selection for ongoing pivotal FORTIFI-HN01 clinical trial of ficerafusp alfa in combination with pembrolizumab in 1L HPV-negative R/M HNSCC

Company to host conference call and webcast on Saturday, December 6, 2025 at 9:00 a.m. ET

BOSTON, Dec. 01, 2025 (GLOBE NEWSWIRE) -- Bicara Therapeutics Inc. (Nasdaq: BCAX), a clinical-stage biopharmaceutical company committed to bringing transformative bifunctional therapies to patients with solid tumors, today announced the publication of an abstract with early data from a Phase 1b expansion cohort evaluating 750mg of ficerafusp alfa weekly (QW) in combination with pembrolizumab in first-line (1L) human papillomavirus (HPV)-negative recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC). The results will be highlighted in an oral presentation at the upcoming European Society for Medical Oncology (ESMO) Asia Congress and will be discussed on a company conference call and webcast on Saturday, December 6, at 9:00 a.m. ET.

"The preliminary data for 750mg of ficerafusp alfa are encouraging, with a consistently high overall response rate now observed across both dose levels of ficerafusp alfa under evaluation for the optimal biologic dose for our ongoing, pivotal FORTIFI-HN01 study," said David Raben, MD, Chief Medical Officer of Bicara Therapeutics. "Importantly, these results provide valuable context around the safety and efficacy profile of ficerafusp alfa in patients with HPV-negative head and neck squamous cell carcinoma and were used to support our FDA Breakthrough Therapy Designation. The consistent overall response rate across both doses of ficerafusp alfa reinforces our confidence that the interim analysis in the pivotal trial could support accelerated approval."

Presentation Details

Title: Ficerafusp alfa 750 mg QW and pembrolizumab in HPV-negative first line (1L) recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC)
Abstract #: 6670
Session Name: Proffered Paper session: Head and neck cancer
Presentation Date and Time: Saturday, December 6, 2025, 4:50 – 5:00 p.m. SGT / 3:50 – 4:00 a.m. EST
Presenter: Deborah J. Wong, MD, PhD, Director of the Head and Neck Medical Oncology Program, UCLA
Location: Hall 401, Suntec Singapore, Singapore, Singapore

Key highlights of the abstract include:

- Expansion cohort data (July 9, 2025 cutoff date) from the Phase 1/1b clinical trial of ficerafusp alfa in patients with 1L HPV-negative R/M HNSCC evaluating 750mg of ficerafusp alfa weekly in combination with pembrolizumab.
- In the efficacy evaluable population (n=30):
    - 57% (17/30) objective response rate, including 50% (15/30) of patients who achieved a partial response and 7% (2/30) of patients who achieved a complete response.
    - 83% (n=25/30) disease control rate.
    - Complete, prolonged neutralization of TGF-β1 observed.
- Safety findings were consistent with the known safety profile of ficerafusp alfa plus pembrolizumab in R/M HNSCC.

Conference Call and Webcast Details
Bicara Therapeutics will host a conference call and webcast on Saturday, December 6, 2025 at 9:00 a.m. ET. Individuals may register for the conference call by clicking the link here. Once registered, participants will receive dial-in details and a unique PIN which will allow them to access the call. An audio webcast will be accessible through the Investor Relations section of Bicara's website under Events and Presentations. An archived replay will also be available for 30 days following the webcast.

About Head and Neck Squamous Cell Carcinoma
Head and neck squamous cell carcinomas (HNSCCs) develop from the mucosal epithelium in the oral cavity, pharynx and larynx and are the most common malignancies that arise in the head and neck. HNSCC is one of the most common cancers in the United States and globally with a rising incidence anticipated to reach one million new global cases annually by 2030. Ten percent of HNSCC patients are diagnosed with metastatic disease and up to 30% develop a recurrence or metastases over time after

receiving initial treatment for advanced HNSCC.

Most cases of HNSCC are thought to result from accumulated mutations caused by carcinogenic exposures such as tobacco smoke or HPV infection. Approximately 80% of patients with R/M HNSCC are HPV-negative. These HPV-negative tumors often exhibit a recurrence pattern that is primarily local and are associated with severe morbidities, including fatal tumor bleeding, intense pain, difficulty swallowing, significant weight loss, and cachexia. This highlights a critical unmet need for therapies that have the potential to deliver durable anti-tumor responses, ultimately leading to meaningful improvements in patients' quality of life.

About Ficerafusp Alfa
Ficerafusp alfa is a first-in-class bifunctional antibody designed to drive tumor penetration by breaking barriers in the tumor microenvironment that have challenged the treatment of multiple solid tumor cancers. Specifically, ficerafusp alfa combines two clinically validated targets: an epidermal growth factor receptor (EGFR) directed monoclonal antibody with a domain that binds to human transforming growth factor beta (TGF-β). Through this targeted mechanism, ficerafusp alfa reverses the fibrotic and immune-excluded tumor microenvironment driven by TGF-β signaling to enable tumor penetration that drives deep and durable responses. The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to ficerafusp alfa in combination with pembrolizumab for the first line (1L) treatment of patients with metastatic or with unresectable, recurrent (R/M) head and neck squamous cell carcinoma (HNSCC) whose tumors express programmed death-ligand 1 with combined positive score (CPS) ≥1, excluding human papillomavirus (HPV)-positive oropharyngeal squamous cell carcinoma.

Ficerafusp alfa is currently being evaluated in FORTIFI-HN01, a pivotal Phase 2/3 clinical trial in patients with 1L R/M HNSCC.

About Bicara Therapeutics
Bicara Therapeutics is a clinical-stage biopharmaceutical company committed to bringing transformative bifunctional therapies to patients with solid tumors. Bicara's lead program, ficerafusp alfa, is a first-in-class bifunctional antibody designed to drive tumor penetration by breaking barriers in the tumor microenvironment that have challenged the treatment of multiple solid tumor cancers. Specifically, ficerafusp alfa combines two clinically validated targets: an epidermal growth factor receptor (EGFR) directed monoclonal antibody with a domain that binds to human transforming growth factor beta (TGF-β). Through this targeted mechanism, ficerafusp alfa reverses the fibrotic and immune-excluded tumor microenvironment driven by TGF-β signaling to enable tumor penetration that drives deep and durable responses. Ficerafusp alfa is being developed in head and neck squamous cell carcinoma, where there remains a significant unmet need, as well as other solid tumor types. For more information, please visit www.bicara.com or follow us on LinkedIn and X.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by words such as "may," "might," "will," "could," "would," "should," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions, or the negative thereof, are intended to identify forward-looking statements, although not all contain identifying words. Any statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, express or implied statements regarding Bicara's clinical development of ficerafusp alfa in combination with pembrolizumab and presentation of early data from a Phase 1b expansion cohort evaluating 750 mg of ficerafusp alfa weekly (QW) in combination with pembrolizumab in first-line (1L) human papillomavirus (HPV)-negative recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC), and the expected therapeutic potential and clinical benefits of ficerafusp alfa, including potential efficacy and tolerability. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks and uncertainties that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to uncertainties inherent in the development of product candidates, including the conduct of research activities and the conduct of clinical trials; uncertainties as to the availability and timing of results and data from clinical trials; whether results from prior preclinical studies and clinical trials will be predictive of the results of subsequent preclinical studies and clinical trials; regulatory developments in the United States and foreign countries; whether Bicara's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in Bicara's filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2024, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2025 and any subsequent filings Bicara makes with the SEC. In addition, any forward-looking statements represent Bicara's views only as of today and should not be relied upon as representing its views as of any subsequent date. Bicara explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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