



Bicara Therapeutics Demonstrates Deep and Durable Responses with Ficerafusp Alfa Plus Pembrolizumab in 1L HPV-Negative R/M HNSCC at ASCO 2025

Jun 1, 2025

Median DOR of 21.7 months with 80% of responders achieving a deep response (≥80% tumor shrinkage)

Depth and durability translating to prolonged OS with median OS of 21.3 months and 2-year OS of 46% in HPV-negative HNSCC

Conference call and webcast today at 3:00 p.m. CT / 4:00 p.m. ET

BOSTON, June 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 presented updated data from the company's Phase 1/1b clinical trial of ficerafusp alfa in combination with pembrolizumab in patients with first line (1L) recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. Ficerafusp alfa is a first-in-class bifunctional antibody designed to enhance 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).

"Ficerafusp alfa was specifically designed to impact the tumor stroma and drive tumor penetration with the goal of leading to deeper and more durable responses. We've now begun to see this translate clinically, with responses lasting nearly two years and contributing to prolonged overall survival in HPV-negative patients, a population that typically faces poor outcomes due to resistance to available therapies," said David Raben, MD, Chief Medical Officer of Bicara Therapeutics. "The strength of the totality of this updated dataset, including 80% of responders achieving a deep response of at least 80% tumor shrinkage, median duration of response of 21.7 months, median progression free survival of 9.9 months, overall survival of 21.3 months, and a 2-year overall survival rate of 46%, provides compelling support for the continued advancement of FORTIFI-HN01, our pivotal Phase 2/3 trial in the first-line recurrent/metastatic setting."

Key highlights from the presentation include:

- In the Phase 1/1b trial, ficerafusp alfa in combination with pembrolizumab resulted in deep and durable anti-tumor activity with improved overall survival (OS) compared to historical benchmarks in patients with 1L R/M human papillomavirus (HPV)-negative HNSCC with a PD-L1 combined positive score (CPS) of ≥1 and with at least 24 months of follow-up.
- In the efficacy evaluable human papillomavirus (HPV)-negative population (n=28):
 - Median duration of response (DOR) of 21.7 months amongst responders (n=15).
 - Median OS of 21.3 months; 2-year OS rate of 46%.
 - 54% (15/28) confirmed objective response rate (ORR); 64% (18/28) ORR, including an additional three unconfirmed responses.
 - 21% (6/28) complete response rate.
 - 80% (12/15) of responders achieved a deep response (≥80% tumor shrinkage).
 - Disease control rate of 89% (25/28 patients).
 - Median progression-free survival of 9.9 months.
 - Manageable safety profile consistent with previously reported adverse events.

"These latest Phase 1/1b data are impressive, particularly the duration of response, which represents a significant advance over historical controls in patients with HPV-negative recurrent/metastatic head and neck squamous cell carcinoma, including anti-PD-1 combinations with chemotherapy or EGFR inhibitors," said Christine H. Chung, MD, Chair of the Department of Head and Neck-Endocrine Oncology and Deputy Physician-in-Chief at the Moffitt Cancer Center. "This reflects the enhanced ability of ficerafusp alfa to remodel the tumor microenvironment allowing the tumor penetration of immune cells required for deep and durable responses in these patients. In addition, the prolonged overall survival, highlighted by a median OS of 21.3 months, reinforces the potential of ficerafusp alfa to address a critical unmet need by delivering durable anti-tumor responses and meaningful improvements in patients' quality of life."

Conference Call and Webcast Information

Bicara Therapeutics will host a conference call and webcast today, June 1, 2025 at 3:00 p.m. CT / 4:00 p.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](#). Following the live webcast, an archived replay will also be available.

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.

Ficerafusp alfa is currently being evaluated in FORTIFI-HN01, a pivotal Phase 2/3 clinical trial in patients with first line (1L) recurrent/metastatic (R/M) head and neck squamous cell carcinoma (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 or 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, including, without limitation, implied and express statements regarding Bicara's clinical development of ficerafusp alfa in combination with pembrolizumab and presentation of updated results from an open-label, multicenter Phase 1/1b trial of ficerafusp alfa with pembrolizumab in patients with recurrent or metastatic head and neck squamous cell carcinoma, and the expected therapeutic potential and ability, profile and clinical benefits of ficerafusp alfa, including potential and anticipated efficacy, depth, durability, tolerability, and success, and the potential clinical results from the Phase 2/3 pivotal trial of ficerafusp alfa. The words "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 forward-looking statements contain these identifying words. 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 and enrollment 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 and 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 in Bicara's most recent Annual Report on Form 10-K, as well as any subsequent filings that Bicara makes with the SEC. In addition, 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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