Bicara Therapeutics Announces Publication of an Abstract with Updated Interim Data from Phase 1/1b Trial of Ficerafusp alfa in 1L R/M HNSCC at the 2025 ASCO Annual Meeting

May 22, 2025

Company to host conference call on Sunday, June 1, 2025 at 3:00 p.m. CT / 4:00 p.m. ET to discuss fulsome dataset

BOSTON, May 22, 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 updated interim 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) on the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting website. The company will host a conference call on Sunday, June 1, 2025 at 3:00 p.m. CT / 4:00 p.m. ET to present the fulsome dataset, including overall survival (OS) and duration of response (DOR) data, following an oral presentation of the data at the ASCO Annual Meeting. Ficerafusp alfa is a first-in-class bifunctional antibody designed to enhance tumor penetration by breaking barriers within 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).

"We are pleased to present the fulsome dataset from our Phase 1/1b trial of ficerafusp alfa in patients with recurrent/metastatic head and neck squamous cell carcinoma during our upcoming oral presentation at ASCO," said David Raben, MD, Chief Medical Officer of Bicara Therapeutics. "The interim data featured in the ASCO abstract demonstrate encouraging signals that represent a meaningful improvement over historical benchmarks in patients with HPV-negative disease, a population with high unmet need and worse survival outcomes than those with HPV-positive disease. Notably, we're encouraged to see how ficerafusp alfa, specifically designed to drive tumor penetration within the tumor microenvironment, is leading to deep, and now, durable responses that appear to be translating to prolonged overall survival."

ASCO Presentation Details

Christine Chung, MD, Chair, Department of Head and Neck-Endocrine Oncology and Program Leader of Head and Neck Oncology at Moffitt Cancer Center will present the fulsome dataset during an oral presentation at the 2025 ASCO Annual Meeting, on behalf of the patients and investigators who have contributed to this clinical trial.

Title: Ficerafusp alfa with pembrolizumab in patients with recurrent or metastatic head and neck squamous cell carcinoma: Updated results from an expansion cohort of an open-label, multicenter, phase 1/1b trial

- Abstract #: 6017
- Session Title: Rapid Oral Abstract Session
- Session Category: Rapid Oral Abstract Session
- Session Date and Time: 6/1/2025 12:12 - 12:18 p.m. CT
- Location: McCormick Place Convention Center

Key highlights of the abstract include:

- Updated interim data (December 16, 2024 cutoff date) from the Phase 1/1b clinical trial of ficerafusp alfa in patients with 1L R/M HNSCC patients with a PD-L1 combined positive score (CPS) of ≥1.
- In the efficacy evaluable human papillomavirus (HPV)-negative population (n=28):
  - 64% (18/28) objective response rate, including 21% (6/28) of patients who achieved a complete response.
  - Median progression-free survival was 9.8 months (95% CI: 4.4–23.2) and the 12-month OS rate was 61% (95% CI: 40–76%).
  - Median overall survival (mOS) and median DOR had not been reached yet, with mOS surpassing 20 months.
  - Safety findings were consistent with the known safety profile of ficerafusp alfa plus pembrolizumab.
  - Data from paired tumor biopsies demonstrated encouraging post-treatment downregulation of phospho-SMAD2, supporting targeted TGF-β inhibition.

Company Conference Call Details
Bicara Therapeutics will host a conference call and webcast on Sunday, 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 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 bifunctional antibody that 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 dual-targeting mechanism, ficerafusp alfa has the potential to exert potent anti-tumor activity by simultaneously blocking both cancer cell-intrinsic EGFR survival and proliferation, as well as the immunosuppressive TGF-β signaling within the tumor microenvironment. 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 clinical benefits of ficerafusp alfa, including potential efficacy, depth, durability and tolerability. 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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