Ficerafusp Alfa 2000mg Q2W Demonstrates Deep, Durable Responses in 1L R/M HPV-Negative HNSCC and Supports Development of Less Frequent Dosing Regimen

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Phase 1b expansion cohort data evaluating 2000mg of ficerafusp alfa every other week in combination with pembrolizumab in 1L HPV-negative R/M HNSCC patients demonstrate rapid, deep and durable responses with generally well-tolerated safety profile

Company plans to develop a loading and every-three-week maintenance regimen for ficerafusp alfa, pending regulatory alignment

Company to host conference call and webcast on Friday, February 20, 2026 at 8:30 a.m. ET

BOSTON, Feb. 19, 2026 (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 preliminary safety and efficacy data from an exploratory Phase 1b expansion cohort evaluating 2000mg of ficerafusp alfa every other week (Q2W) in combination with pembrolizumab in first-line (1L) human papillomavirus (HPV)-negative recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC). The expansion cohort data, which explore a higher dose and less-frequent dosing regimen of ficerafusp alfa, are being highlighted in a plenary presentation today at the 2026 Multidisciplinary Head and Neck Cancers Symposium (MHNCS).

Ficerafusp alfa is the first and only bifunctional epidermal growth factor receptor (EGFR)-directed antibody combined with a TGF-β ligand trap designed to drive increased tumor penetration and improve survival outcomes. Bicara is currently evaluating ficerafusp alfa at 1500mg weekly (QW) in Phase 3 of the ongoing FORTIFI-HN01 pivotal study.

“Results from this alternative dosing cohort, including rapid, deep and durable responses, a consistent safety profile, and sustained TGF-β neutralization in 1L HPV-negative R/M HNSCC patients, reinforce the strength of ficerafusp alfa’s differentiated mechanism of action,” said David Raben, MD, Chief Medical Officer of Bicara Therapeutics. “TGF-β inhibition is established quickly and sustained with less frequent dosing while maintaining deep and durable responses, creating a compelling opportunity to pursue a loading and maintenance regimen for ficerafusp alfa. We remain confident that ficerafusp alfa uniquely enables both meaningful tumor penetration and long-term benefit, and we are committed to advancing dosing options that strengthen both patient experience and outcomes.”

The Phase 1b expansion cohort data presented at MHNCS show that 2000mg Q2W ficerafusp alfa in combination with pembrolizumab was generally well-tolerated, with a safety profile consistent with the known safety profile of ficerafusp alfa plus pembrolizumab in R/M HNSCC. 2000mg Q2W of ficerafusp alfa demonstrated a 48% confirmed overall response rate (ORR), with 26% of patients achieving a complete response (CR) and 77% of responders demonstrating deep responses of at least 80% tumor shrinkage. Preliminary efficacy data demonstrated enhanced durability and additional outcomes data continue to mature.

Table 1. Results from Phase 1b expansion cohorts of ficerafusp alfa in combination with pembrolizumab in 1L R/M HPV-negative HNSCC

	2000mg Q2W[1] (n=27)	**1500mg QW[2] (n=28)**
Confirmed ORR	48%	54%
CR rate	26%	21%
Deep (≥80%) responses	77%	80%
Median time to response	1.6 months	1.4 months
Median PFS	NE	9.9 months
Median DoR	NE	21.7 months
Median OS	NE	21.3 months
Depth of response at 24-weeks	**(n=11)**	**(n=11)**
Median depth of response at 24-weeks	100%	82%
Percent of responders achieving deep (≥80%) response at 24-weeks	73%	64%

1. Data snapshot as of December 16, 2025. 2. Data snapshot as of March 20, 2025. Chung CH, et al. J Clin Oncol. 2025;43(16 suppl):6017.

Updated biomarker results demonstrated that 2000mg Q2W maintains TGF-β inhibition and immune activation while delivering deep responses, consistent with the differentiated clinical profile established by 1500mg QW of ficerafusp alfa. The growing body of pharmacokinetic, translational and clinical data supports development of an additional dose regimen that optimizes efficacy, safety and convenience without compromising the depth nor durability of response that are characteristic of ficerafusp alfa's differentiated clinical profile.

Bicara plans to develop ficerafusp alfa with a loading and every-three-week maintenance schedule and aims to achieve regulatory alignment to enable data generation by potential U.S. approval. The ongoing FORTIFI-HN01 pivotal study continues to enroll patients globally to be treated with 1500mg weekly of ficerafusp alfa in combination with pembrolizumab.

Conference Call and Webcast Details
Bicara Therapeutics will host a conference call and webcast on Friday, February 20, 2026 at 8:30 am 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 that 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 in 1L HPV-negative R/M HNSCC, including expectations for safety, efficacy, and depth and durability of response; the potential for a less frequent dosing regimen based on data from the Phase 1b expansion cohort of 2000mg Q2W, including expectations for future U.S. regulatory alignment and improvements in convenience, patient experience and outcomes with a loading and Q3W maintenance dosing regimen; the planned presentation of data from the 2000mg expansion cohort during an upcoming corporate call and webcast; enrollment and progress of the ongoing pivotal FORTIFI-HN01 clinical trial; potential for U.S. regulatory approval and launch of ficerafusp alfa; and the commercial opportunity for ficerafusp alfa, if approved. 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, preliminary or interim data from earlier stage 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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