Bicara Therapeutics Announces First Patients Enrolled in FORTIFI-HN01, a Pivotal Phase 2/3 Clinical Trial of Ficerafusp Alfa in 1L Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma

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BOSTON, Feb. 11, 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 first patients have been enrolled in FORTIFI-HN01, a pivotal Phase 2/3 trial of ficerafusp alfa in combination with pembrolizumab in 1L (first line) recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC). Ficerafusp alfa is a first-in-class 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).

“This is a key milestone for Bicara and represents our transition into a late-stage clinical development company,” said David Raben, MD, Chief Medical Officer of Bicara Therapeutics. “Supported by encouraging interim Phase 1/1b data, which demonstrated durable and clinically meaningful anti-tumor activity with ficerafusp alfa in combination with pembrolizumab, FORTIFI-HN01 will evaluate the potential of ficerafusp alfa as a first-in-class treatment option for patients with advanced head and neck squamous cell carcinoma. The thoughtful and efficient design of this trial underscores our strategic approach to rapidly advancing treatment options for these patients, with the goal of addressing the significant unmet needs in this challenging disease.”

“Head and neck squamous cell carcinoma is a cancer of growing concern across the world,” said John Kaczmar, MD, Medical University of South Carolina Hollings Cancer Center. “Incidence is rising, yet survival rates remain low, particularly for patients with HPV-negative disease, underscoring the urgent need for innovative treatment options. I’m encouraged by the early signs of clinical activity in these patients we have seen treated with ficerafusp alfa and hopeful it will help address this area of significant unmet need. I look forward to contributing to this important trial to advance new possibilities for our patients.”

FORTIFI-HN01 is a global, randomized, double-blinded, placebo-controlled, pivotal Phase 2/3 trial that aims to enroll approximately 650 R/M HNSCC patients, excluding patients with human papillomavirus (HPV)-positive with oropharyngeal squamous cell carcinoma. Patients enrolled in the trial must have a PD-L1 CPS greater than or equal to one, and not have received systemic therapy in the R/M setting. The primary endpoints are overall response rate based on RECIST v1.1 and overall survival, with results potentially supporting filings for both accelerated approval and full approval. Secondary endpoints include progression free survival and duration of response.

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 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-b signaling within the tumor microenvironment.

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 plans and timelines for the clinical development of ficerafusp alfa in combination with pembrolizumab, the expected therapeutic potential and clinical benefits of ficerafusp alfa, including potential efficacy and tolerability, the FORTIFI-HN01 trial design and Bicara's regulatory approval plans. 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. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Bicara's most recent Quarterly Report on Form 10-Q for the period ended September 30, 2024 and filed with the Securities and Exchange Commission (SEC), as well as any subsequent filings that 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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