



Bicara Therapeutics Presents Phase 1/1b Dose Expansion Results with Ficerafusp Alfa in Advanced Squamous Cancer of the Anal Canal at the 2025 ASCO Gastrointestinal Cancers Symposium

Jan 27, 2025

BOSTON, Jan. 27, 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 presentation of data from the Phase 1/1b dose expansion cohort of ficerafusp alfa in combination with pembrolizumab in patients with second line (2L) or later squamous cancer of the anal canal (SCAC). The results were presented in a poster session during the 2025 ASCO Gastrointestinal (GI) Cancers Symposium on Saturday, January 25, 2025. 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), and is being evaluated in multiple solid tumor types.

"We are encouraged by the preliminary data in SCAC, which demonstrate enhanced efficacy of the combination of ficerafusp alfa and pembrolizumab in a high-need patient population," said David Raben, MD, Chief Medical Officer of Bicara Therapeutics. "The addition of ficerafusp alfa shows the potential to improve efficacy compared to historical data with pembrolizumab monotherapy in SCAC, with increased overall response rate, disease control rate, and 12-month progression-free survival, indicative of improved speed, depth, and durability of response. Importantly, responses were observed even in patients with liver metastases, which is a significant outcome in this setting. These data provide additional insights into the complementary mechanisms of ficerafusp alfa and pembrolizumab, and support further development in squamous cell carcinomas, including first-line recurrent/metastatic head and neck squamous cell carcinoma."

"These early data with ficerafusp alfa and pembrolizumab suggest that ficerafusp alfa could play an important role in the future treatment of SCAC, underscoring the need for further investigation to assess the combination's potential in improving outcomes for patients," said Van K. Morris, MD, Associate Professor of Gastrointestinal Medical Oncology at The University of Texas MD Anderson Cancer Center.

Presentation Highlights:

- As of the data cut-off date of December 5, 2024, the single-arm, multicenter dose expansion cohort from an ongoing Phase 1/1b trial evaluated ficerafusp alfa in combination with pembrolizumab in 28 patients with immune checkpoint inhibitor-naïve SCAC that was locally advanced/unresectable or metastatic, and who had received 1-2 prior lines of chemotherapy.
- The confirmed overall response rate was 25.0% (7/28 patients), irrespective of PD-L1 CPS score, including 6 partial responses (PR) and 1 complete response. In addition to the confirmed responses, there was 1 patient pending a confirmed PR.
- Median progression-free survival (PFS) was 2.9 months and the PFS rate at 12 months was 40.7% (27 evaluable patients).
- Tolerable safety profile with the most common treatment-related adverse events of any grade including, acneiform dermatitis (16/28 patients; 57.1%), epistaxis (14/28 patients; 50.0%), and pruritus (13/28 patients; 46.4%).

Presentation Details:

- Title: Preliminary Phase 1/1b dose expansion results of the bifunctional EGFR/TGF β inhibitor ficerafusp alfa (BCA101) with pembrolizumab in patients with squamous cell carcinoma of the anal canal
- Presenter: Van K. Morris, MD, Associate Professor, Department of Gastrointestinal Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center

The poster presentation is available on the Bicara [website](#) under the Presentations & Publications section.

About Squamous Cancer of the Anal Canal

Squamous cancer of the anal canal (SCAC) is the most common type of anal canal cancer, with an incidence in the United States. SCAC is typically associated with prior human papillomavirus (HPV) infection. Treatment is most commonly chemoradiation for patients with localized disease at diagnosis.

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- β 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 the therapeutic potential and clinical benefits of ficerafusp alfa, the potential efficacy and safety of ficerafusp alfa in combination with pembrolizumab in SCAC, and plans for the clinical development of ficerafusp alfa in combination with pembrolizumab. 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, particularly those inherent in the process of discovering, developing and commercializing safe and effective human therapeutics. 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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