



Bicara Therapeutics Presents New Data from Ongoing Phase 1/1b Trial of Lead First-in-Class Bifunctional Program, BCA101, at the European Society for Medical Oncology (ESMO) Congress 2022

September 10, 2022

- *Stage one efficacy threshold achieved in dose expansion in patients with squamous cell carcinoma of the head and neck*
- *Webinar to review data to be held Monday, September 12th at 10:30 a.m. ET, featuring Principal Investigator Glenn J. Hanna, M.D.*

CAMBRIDGE, Mass., September 10, 2022 – Bicara Therapeutics, a clinical-stage biotechnology company developing dual-action biologics designed to modulate the tumor microenvironment to elicit a potent and durable anti-tumor response, today presented new clinical data from the ongoing Phase 1/1b trial of BCA101, an EGFR / TGF- β bifunctional antibody, as a monotherapy and in combination with pembrolizumab. These data were presented in an oral presentation session at the European Society for Medical Oncology (ESMO) Congress 2022, being held in Paris, France.

“Seeing durable responses in our patients with head and neck cancer at this early stage of clinical development is very encouraging,” said Glenn J. Hanna, M.D., Director of the Center for Salivary and Rare Head and Neck Cancers, Dana-Farber Cancer Institute, and Principal Investigator for the Phase 1/1b clinical trial of BCA101. “BCA101, a first-in-class molecule, may represent a potential new option for our patients. We look forward to continuing enrollment in the dose expansion portion of the study.”

“The data presented today underline the significant progress we have made in the last few months to demonstrate the efficacy of BCA101,” said Liviu Niculescu, M.D., Chief Medical Officer of Bicara Therapeutics. “We are extremely encouraged by the durable responses we are seeing in heavily pre-treated patients, and by the responses we are seeing in combination with pembrolizumab in a front-line head and neck patient population, enabling us to achieve the first efficacy threshold in dose expansion.”

BCA101 Data Highlights:

- In the first-line recurrent/metastatic HNSCC dose expansion combination cohort, the four partial responses needed to open Stage 2 have been observed prior to completing Stage 1 enrollment.
- BCA101 is well tolerated and clinically active as a single agent and in combination with pembrolizumab in patients with head and neck squamous cell carcinoma (HNSCC), squamous cell carcinoma of the anal canal (SCAC) and squamous non-small cell lung cancer (SqNSCLC).
- In dose escalation, single-agent activity, including one durable partial response, was observed among late-line patients treated with BCA101. A disease control rate of 58% was observed in evaluable patients at doses above 1000 mg.
- In the combination dose escalation arm, a partial response was observed in four out of 13 (31%) evaluable patients (two each in SCAC and HNSCC) as well as a disease control rate of 69%. Patients had a median of four prior lines of therapy prior to entering the BCA101 study.
- All four patients with responses have been on study for more than eight months, including one HNSCC patient who was refractory to anti-PD-1 therapy and cetuximab.

BCA101 is currently being evaluated in a Phase 1/1b study as monotherapy and in combination with pembrolizumab as a first-line therapy in patients with unresectable, recurrent or metastatic HNSCC and as second-line therapy in patients with advanced SCAC who have received prior chemotherapy. A third cohort of patients with advanced or incurable cutaneous squamous cell carcinoma who have received previous anti-PD-1 therapy will be treated with BCA101 as monotherapy. Bicara initiated the dose expansion arm of this study in February 2022.

Webcast Details:

- **Date and time:** Monday, September 12, 2022 at 10:30 a.m. ET
- **To register:** Please visit the [Online Experiences website](#) to register for the live event. Following the live webcast, an archived replay will be available on the [Bicara website](#).

About BCA101

BCA101 is a first-in-class EGFR / TGF- β -trap bifunctional antibody designed to enhance both innate and adaptive immune responses directly at the site of the tumor by binding to the well-validated EGFR antigen and disabling TGF- β , a signaling

molecule that plays a key role in suppressing the immune response in the tumor microenvironment. Promising preclinical data suggest that BCA101 is superior to the anti-EGFR antibody cetuximab in preventing tumor recurrence, as well as in restoring immune activation. An ongoing Phase 1/1b dose-escalation clinical trial of BCA101 is currently enrolling in front-line HNSCC and additional solid tumors. For more information, please visit study number NCT04429542 at www.clinicaltrials.gov.

About Bicara Therapeutics

Bicara Therapeutics is a clinical-stage biotechnology company developing first-in-class biologics engineered to bring together the precision of targeted therapy and the power of immunotherapy. The company's bifunctional antibodies are designed to deliver an immunomodulatory payload directly to the tumor microenvironment to ramp up immune cell activity, potentially offering long-lasting efficacy. Bicara's lead asset, BCA101, a first-in-class EGFR / TGF- β -trap bifunctional antibody, is currently enrolling patients in a Phase 1/1b study. Bicara's experienced team brings deep expertise across immunology, oncology, clinical development, business development and operational strategy.

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