Bicara Therapeutics' First-in-class Bifunctional EGFR/TGF-β Inhibitor, BCA101, Demonstrates 65% ORR in Combination with Pembrolizumab in 1L HPV-negative Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC)

June 5, 2023

Phase 1/1b results to be highlighted in an oral presentation at 2023 ASCO Annual Meeting

CAMBRIDGE, Mass., June 5, 2023 – Bicara Therapeutics, a clinical-stage biotechnology company developing dual-action biologics to elicit a potent and durable immune response, today will present positive interim data from its ongoing, open-label Phase 1/1b dose expansion study of BCA101, a first-in-class bifunctional EGFR/TGF-β antibody, at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. In the Phase 1/1b study, BCA101 in combination with pembrolizumab demonstrated a 65% overall response rate (ORR) in frontline, human papillomavirus (HPV)-negative, recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC), with a tolerable safety profile.

"Head and neck squamous cell carcinoma has limited treatment options and generally carries a poor prognosis, particularly for those with HPV-negative disease, which represent the majority of patients in the R/M setting," said Glenn J. Hanna, M.D., Center for Head and Neck Oncology, Dana-Farber Cancer Institute, and principal investigator for the Phase 1/1b clinical trial of BCA101. "These data demonstrate exciting and clinically meaningful activity among first-line R/M HPV-negative HNSCC patients and underscore the potential for BCA101 in combination with pembrolizumab in this underserved patient population."

"A 65% ORR in front-line HPV-negative R/M HNSCC is a significant improvement over pembrolizumab monotherapy and we are thrilled to be showcasing these data in an oral presentation at ASCO," said Claire Mazumdar, Ph.D., MBA, chief executive officer of Bicara Therapeutics. "HNSCC is one of the most common cancers worldwide, with increasing prevalence, and represents a significant unmet need. With this promising proof-of-concept data, we look forward to advancing BCA101 in combination with pembrolizumab in frontline R/M HNSCC, while also continuing to explore the utility of BCA101 in other cancer types."

Presentation Highlights:

- Interim data (May 22, 2023 cut-off date) from the Phase 1/1b dose expansion cohort include 31 evaluable R/M HNSCC patients. None of the patients received prior systemic therapy and had a PD-L1 combined positive score (CPS) of ≥1. 20 patients were human papillomavirus (HPV)-negative and 11 patients were HPV-positive.
- 65% ORR in HPV-negative population (13/20 patients), including 12 confirmed partial responses (PR) and one confirmed complete response (CR), with responses observed across different degrees of PD-L1 expression (CPS 1-19 (5/10, 50%) and CPS ≥20 (8/10, 80%)) and varying disease subgroups (distant metastatic (9/14, 64%) and loco-regional disease (4/6, 67%)).
- Preliminary median progression free survival (mPFS) in HPV-negative patients (in stage 1) of at least 6.6 months with 6/12 patients ongoing.
- 48% ORR in total evaluable population (15/31 patients).
- Tolerable safety profile with the most common treatment-related adverse events (TRAEs). including acneiform rash (73%, with majority being Grade 1), fatigue (36%), hypophosphatemia (36%) and anemia (30%).

Presentation Details:

Title: Dose expansion results of the bifunctional EGFR/TGF-β inhibitor BCA101 with pembrolizumab in patients with recurrent, metastatic head and neck squamous cell carcinoma.
Presenter: Glenn J. Hanna, M.D.
Abstract Number: 6005
Session Type/Title: Oral Abstract Session – Head and Neck Cancer
Date/Time: June 5, 2023 from 8:00-11:00 a.m. CT
Location: McCormick Place Convention Center, Chicacgo, IL

In addition, Bicara will be hosting a webinar with two leading head and neck oncologists, Glenn J. Hanna, M.D., Center for Head and Neck Oncology, Dana-Farber Cancer Institute,and Ezra Cohen, M.D., FRCPSC, FASCO, University of California San Diego. The webinar will be made available on Bicara's website shortly after today's ASCO oral presentation at www.bicara.com/news/.

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.

Oral cavity and larynx cancers are generally associated with tobacco consumption, alcohol abuse or both, whereas pharynx cancers are increasingly attributed to infection with human papillomavirus (HPV), primarily HPV-16. Thus, HNSCC can be biologically separated into HPV-negative and HPV-positive HNSCC, the latter carrying a more favorable prognosis. Treatment approaches for locally advanced HNSCC generally consist of surgery followed by chemoradiotherapy (CRT) for oral cavity cancers and primary or definitive CRT for pharynx and larynx cancers. The immune checkpoint inhibitors pembrolizumab and nivolumab are approved by the U.S. FDA for treatment of platinum-refractory recurrent or metastatic HNSCC, and pembrolizumab is approved as first-line monotherapy in patients with unresectable or metastatic disease with a CPS ≥1 or combined with platinum and 5-fluorouracil for patients with any CPS score.

HNSCC is the sixth most common cancer worldwide, with approximately 890,000 new cases and 450,000 deaths in 2018. The incidence of HNSCC continues to rise and is anticipated to increase by 30% by 2030.[1]

About BCA101
BCA101 is a first-in-class, dual-action, bifunctional antibody designed to inhibit the epidermal growth factor receptor (EGFR) and disable transforming growth factor beta (TGF-β) directly at the tumor site. This approach allows BCA101 to inhibit tumor proliferation, while restoring the cytolytic activity of the local immune cells.

BCA101 is currently being evaluated in a dose expansion phase of an open-label Phase 1/1b study as a monotherapy for cutaneous squamous cell carcinoma and in combination with pembrolizumab in patients with unresectable R/M HNSCC and advanced squamous non-small cell lung cancer (SqNSCLC).

About Bicara Therapeutics
Bicara Therapeutics is a clinical-stage biotechnology company developing first-in-class biologics engineered to combine the precision of well-validated, tumor-targeting antibodies with the power of tumor microenvironment modulators. The company's bifunctional antibodies are designed to deliver an immunomodulatory payload directly to the tumor microenvironment to ramp up immune cell activity, offering the potential for synergistic therapeutic impact at the site of the tumor. Bicara's lead product candidate, BCA101, is a first-in-class EGFR / TGF-β-trap bifunctional antibody currently being evaluated in a Phase 1/1b study. For more information, please visit www.bicara.com or follow us on LinkedIn or Twitter.

[1]Johnson, D.E., Burtness, B., Leemans, C.R. et al. Head and neck squamous cell carcinoma. Nat Rev Dis Primers 6, 92 (2020). https://doi.org/10.1038/s41572-020-00224-3

Note: Dr. Hanna receives institutional research support and serves in a consulting/advisory role for Bicara.

Contacts:
Investors
Sarah McCabe
Stern Investor Relations, Inc.
sarah.mccabe@sternir.com

Media
Dan Budwick
1AB
dan@1abmedia.com