Bicara Therapeutics Presents Updated Interim Data from Ongoing Phase 1/1b Study of BCA101 in 1L HPV-negative Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC) at ESMO Congress 2023

Oct 23, 2023

First-in-class bifunctional EGFR/TGF-β inhibitor, BCA101, in combination with pembrolizumab continues to demonstrate clinically meaningful preliminary anti-tumor activity consistent with previous results

BOSTON, Mass., October 23, 2023 – Bicara Therapeutics, a clinical-stage biotechnology company developing dual-action biologics to elicit a potent and durable immune response, today announced the presentation of updated, 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 European Society for Medical Oncology (ESMO) Congress 2023. In the Phase 1/1b study, BCA101 in combination with pembrolizumab continues to demonstrate clinically meaningful preliminary anti-tumor activity consistent with previous results, with a 57% overall response rate (ORR), 89% disease control rate, and a tolerable safety profile in frontline human papillomavirus (HPV)-negative, recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC).

"We are excited to showcase these updated Phase 1/1b data at ESMO, which continue to demonstrate a significant response rate and underscore the potential of BCA101 as a new treatment option for HPV-negative R/M HNSCC," said David Raben, M.D., chief medical officer of Bicara Therapeutics. "This is a very difficult population to treat and patients are in desperate need of new therapeutic options. We look forward to continuing to advance BCA101 in combination with pembrolizumab in frontline R/M HNSCC and to evaluating BCA101 in other tumor types."

Presentation Highlights:

- Updated interim data (August 27, 2023 cut-off date) from the Phase 1/1b dose expansion cohort include 39 evaluable frontline R/M HNSCC patients with a PD-L1 combined positive score (CPS) of ≥1. 28 patients were HPV-negative and 11 patients were HPV-positive, as determined by p16 testing.
- 57% ORR in HPV-negative population (16/28 patients) with responses observed across different levels of PD-L1 expression (CPS 1-19 (7/13, 54%) and CPS ≥20 (9/15, 60%)) and in both distant metastatic (12/22, 55%) and loco-regional disease (4/6, 67%).
- 89% disease control rate in HPV-negative population (25/28 patients).
- Median progression free survival (mPFS) in HPV-negative patients has not been reached.
- 46% ORR in total evaluable study population including the 11 HPV-positive patients.
- Tolerable safety profile with the most common treatment-related adverse events (TRAEs) including acneiform rash (74%, with majority being Grade 1), fatigue (45%), and hypophosphatemia (36%).

Presentation Details:
Title: Dose expansion results of the bifunctional EGFR/TGFβ inhibitor BCA101 with pembrolizumab in patients with recurrent, metastatic head and neck squamous cell carcinoma
Abstract Number: 922P
Poster Session: Head and neck cancer
Date/Time: Sunday, October 22, 12:00 p.m. – 1:00 p.m. CEST

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 is designed with the intent to allow 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 in clinical development for multiple tumor types. For more information, please visit www.bicara.com or follow us on LinkedIn or X.

[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*

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