Bicara Therapeutics Announces Oversubscribed $165 Million Series C Financing

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Proceeds to accelerate clinical development of first-in-class bifunctional EGFR/TGF-β inhibitor, BCA101, for multiple cancer types, including 1L HPV-negative recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC)

Presented positive interim clinical data at 2023 ASCO Annual Meeting and ESMO Congress 2023 from ongoing Phase 1/1b dose expansion study of BCA101 in combination with pembrolizumab demonstrating clinically meaningful anti-tumor activity and tolerable safety profile in 1L HPV-negative R/M HNSCC

Financing co-led by Braidwell LP and TPG, with participation from other new and existing leading healthcare investors

BOSTON, Mass., December 12, 2023 – Bicara Therapeutics, a clinical-stage biotechnology company developing dual-action biologics to elicit a potent and durable immune response, today announced the completion of an oversubscribed $165 million Series C financing. The financing was co-led by Braidwell LP and TPG, which is investing in the company through TPG Life Sciences Innovations (TPG LSI) and The Rise Fund, with additional new investors including Deerfield Management, Fairmount, Aisling Capital and a leading biotechnology investor associated with one of the largest alternative asset managers. All existing Series B investors also participated in the round.

- Proceeds from the Series C financing will be used to support the continued advancement of Bicara's lead product candidate, BCA101, a first-in-class bifunctional EGFR/TGF-β inhibitor that is currently in clinical development for multiple cancer types including frontline human papillomavirus (HPV)-negative, recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC), advanced squamous non-small cell lung cancer (SqNSCLC) and cutaneous squamous cell carcinoma.
- At the 2023 ASCO Annual Meeting and ESMO Congress 2023, Bicara presented positive interim clinical data from its ongoing, open-label Phase 1/1b dose expansion study of BCA101 in combination with pembrolizumab demonstrating clinically meaningful anti-tumor activity and a tolerable safety profile in frontline HPV-negative R/M HNSCC, a cancer with limited treatment options that generally carries a poor prognosis and is increasing in prevalence.
- Additional data updates from Bicara's ongoing Phase 1/1b dose expansion study of BCA101, including in advanced SqNSCLC, are anticipated in 2024.

"Momentum at Bicara is increasing following our BCA101 Phase 1/1b data presentations at key 2023 medical meetings," said Claire Mazumdar, Ph.D., MBA, Chief Executive Officer of Bicara Therapeutics. "Our proof-of-concept data in frontline HPV-negative R/M HNSCC, a very difficult patient population to treat, underscore the promise of BCA101 as a new precision therapeutic option for these patients. With additional data readouts anticipated in 2024, we remain excited about the overall potential of BCA101 to help patients with HPV-negative R/M HNSCC, as well as other solid tumor types. We are thrilled to partner with this syndicate of new and existing leading healthcare investors, who share in our vision for BCA101 and Bicara's bifunctional antibody platform."

In connection with the Series C financing, Carolyn Ng, Ph.D., Business Unit Partner with TPG LSI, has joined Bicara's board of directors.

"Bicara's Phase 1/1b dose expansion study of BCA101 has delivered encouraging, clinically meaningful interim results and offers an excellent foundation from which to continue to build Bicara into a leading oncology company," said Dr. Ng. "I am excited to join Bicara's board of directors at such an important time and look forward to working with this talented management team and distinguished board of directors to advance new treatments for cancer patients."

With the completion of the Series C financing, Bicara has raised $273 million in 2023.

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 in combination with pembrolizumab in patients with unresectable R/M HNSCC and advanced SqNSCLC and as a monotherapy for cutaneous squamous cell carcinoma.

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 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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