# BioAtla Announces Regulatory Update on Clinical Development Plan for Ozuriftamab Vedotin in Oropharyngeal Squamous Cell Carcinoma (OPSCC) Following Productive Type B (End of Phase 2) Meeting with FDA

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- **FDA alignment on Phase 3 ozuriftamab vedotin (Oz-V) trial design, including dosing regimen and endpoints to support potential accelerated approval**
- **Company continues preparations for enabling initiation of the Phase 3 study with the goal of advancing the study with a strategic partner early next year**
- **Company maintains previous guidance for completion of a strategic partnership with one of our advanced clinical assets this year**

SAN DIEGO, Sept. 08, 2025 (GLOBE NEWSWIRE) -- **BioAtla, Inc. (Nasdaq: BCAB)**, a global clinical-stage biotechnology company focused on the development of Conditionally Active Biologic (CAB) antibody therapeutics using its proprietary CAB platform for the treatment of solid tumors, today announced outcomes from its Type B meeting with the United States Food and Drug Administration (FDA).

Ozuriftamab vedotin (Oz-V), CAB-ROR2-ADC, is a conditionally and reversibly active antibody drug conjugate directed against ROR2 which is expressed across many different solid tumors including head and neck cancer. Overexpression of ROR2 is driven by E6 / E7 oncoproteins associated with human papillomavirus (HPV) infection and is associated with poor prognosis and resistance to chemo- and immunotherapies. OPSCC is recognized as a distinct anatomical entity within head and neck cancers with up to 80% of cases in the United States caused by HPV infection.

As previously reported, Oz-V has demonstrated compelling clinical data in HPV+ OPSCC in a Phase 2 trial with an overall response rate (ORR) of 45% (confirmed and unconfirmed) and a median overall survival (OS) of 11.6 months, ongoing. Other studies using either cetuximab, docetaxel, or methotrexate monotherapy have reported an ORR of 0 - 3.4% and a median OS of 4.4 months in a similar patient population. OPSCC represents a sizable and rapidly growing patient population that is poorly served by EGFR inhibitors and other standard of care regimens.

**Key Outcomes from the FDA Type B Meeting**

**Pivotal Trial Design:** For full approval, approximately 300 OPSCC patients prospectively randomized and stratified, one to one between two open label treatment arms.

**Oz-V Dose and Regimen:** Patients randomized to the investigational arm will receive 1.8 mg/kg every other week.

**Investigator's Choice (IC) control arm :** Patients randomized to the control arm will receive either cetuximab, docetaxel, or methotrexate monotherapy.

**Accelerated Approval Endpoint:** Based on interim analysis of enrolled patients, statistically significant improvement of confirmed ORR by Blinded Independent Central Review (BICR) supported by an adequately characterized Duration of Response (DOR) without detriment in OS.

**Full Approval Endpoint:** Statistically significant improvement of OS.

"The actionable regulatory alignment represents an important milestone for BioAtla as it enables initiation of the first Phase 3 study of a CAB ADC in an indication that represents a sizable and steadily growing population that is poorly served by current standard of care agents, including EGFR inhibitors," said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. "Having a clear registrational path with the potential for accelerated approval is very positive for our near-term strategic partnering objectives and enabling initiation of the Oz-V Phase 3 study with a partner. This underscores the potential of the CAB platform technology, which includes clinical readouts on our dual CAB EpCAM T-cell engager (BA3182) later this year."

**About Ozuriftamab Vedotin**

Ozuriftamab vedotin (Oz-V), CAB-Platform-ROR2-ADC, is a conditionally and reversibly active antibody drug conjugate directed against ROR2, a transmembrane receptor tyrosine kinase that is present across many different solid tumors including head and neck, lung, triple-negative breast cancer and melanoma. Overexpression of ROR2, a noncanonical wnt5A signaling receptor, is driven by oncoproteins associated with HPV infection and forms a cancer axis that is associated with poor prognosis and resistance to chemo- and immunotherapies. The FDA granted Fast Track Designation to Oz-V for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) who have previously experienced progression on PD-1/L1 therapies and platinum chemotherapy.

**About OPSCC**

OPSCC is a subset of SCCHN arising from the squamous cells that line the oropharynx, the middle part of the throat. This anatomic region is located behind the oral cavity and OPSCC typically involves the tonsils, soft palate, pharyngeal walls, and/or the base of the tongue. A striking year-to-year increase in OPSCC is due to the rapidly increasing incidence of HPV infections which currently represents approximately 80% of OPSCC in the United States. The prognosis is currently poor for patients with recurrent/metastatic OPSCC who have previously received standard treatments including surgery, radiation, platinum-based chemotherapy, and PD-1 inhibitor therapy.

**About CAB-EpCAM x CAB-CD3 Bispecific T-cell Engager Antibody**

BioAtla is developing BA3182 as a potential anticancer therapy for patients with advanced adenocarcinoma. BA3182 is a (CAB) EpCAM x (CAB) CD3 bispecific T cell engager antibody that contains two binding sites for EpCAM and two binding sites for CD3ε. The binding sites for EpCAM and CD3ε have been designed to bind their respective targets specifically and reversibly under the conditions found in the TME and to have reduced binding outside of the TME. The CAB selective binding to both the CAB EpCAM and CAB CD3ε arms are required to activate the T cell engagement against the tumor, thus

enabling the combined selectivity of each CAB binding arm in the bispecific antibody. BioAtla continues to advance the ongoing Phase 1 study to evaluate the safety, pharmacokinetics, and efficacy of BA3182 in advanced adenocarcinoma patients.

**About BioAtla®, Inc.**

BioAtla is a global clinical-stage biotechnology company with operations in San Diego, California, and in Beijing, China through its contractual relationship with BioDuro-Sundia, a provider of preclinical development services. Utilizing its proprietary CAB platform technology, BioAtla develops novel, reversibly active monoclonal and bispecific antibodies and other protein therapeutic product candidates. CAB product candidates are designed to have more selective targeting, greater efficacy with lower toxicity, and more cost-efficient and predictable manufacturing than traditional antibodies. BioAtla has extensive and worldwide patent coverage for its CAB platform technology and products with greater than 780 active patent matters, more than 500 of which are issued patents. Broad patent coverage in all major markets include methods of making, screening and manufacturing CAB product candidates in a wide range of formats and composition of matter coverage for specific products. To learn more about BioAtla, Inc., visit www.bioatla.com.

**Forward-looking Statements**

Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "expect," "believe," "will," "may," "should," "estimate," "project," "outlook," "forecast" or other similar words. Examples of forward-looking statements include, among others, statements we make regarding BioAtla's business plans and prospects, whether our clinical trials will support registration, the potential regulatory approval path for Oz-V, the expected timing to initiate a phase 3 study; the ability of Oz-V to progress to a phase 3 study and receive accelerated or full approval, the potential for Oz-V to address the OPSCC population, the timing of and the ability to establish collaborations or other strategic partnerships and plans and expectations regarding future data updates. Forward-looking statements are based on BioAtla's current expectations and are subject to inherent uncertainties, risks and assumptions, many of which are beyond our control, difficult to predict and could cause actual results to differ materially from what we expect. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Factors that could cause actual results to differ include, among others: factors that raise substantial doubt about our ability to continue as a going concern and that we will need additional funding to continue development of our CAB technology platform and our CAB product candidates; potential delays in clinical and preclinical trials; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, or regulatory approval dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; whether regulatory authorities will be satisfied with the design of and results from the clinical studies or take favorable regulatory actions based on results from the clinical studies; our dependence on the success of our CAB technology platform; our ability to enroll patients in our ongoing and future clinical trials; the successful selection and prioritization of assets to focus development on selected product candidates and indications; our ability to form collaborations and partnerships with third parties and the success of such collaborations and partnerships; our reliance on third parties for the manufacture and supply of our product candidates for clinical trials; our reliance on third parties to conduct our clinical trials and some aspects of our research and preclinical testing; potential adverse impacts due to geopolitical or macroeconomic events outside of our control, including health epidemics or pandemics; and those other risks and uncertainties described in the section titled "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 27, 2025, our Quarterly Reports on Form 10-Q filed with the SEC on May 6, 2025 and August 7, 2025 and our other reports as filed with the SEC. Forward-looking statements contained in this press release are made as of this date, and BioAtla undertakes no duty to update such information except as required under applicable laws.

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