BioAtla Presents Phase 2 Ozuriftamab Vedotin (Oz-V) Clinical Trial Data Demonstrating Compelling Antitumor Activity in HPV-Associated Oropharyngeal Squamous Cell Carcinoma (HPV+ OPSCC) at the 1.8 mg/kg Q2W dosing regimen

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45% overall response rate (ORR) and a 100% disease control rate (DCR) in HPV+ OPSCC patients treated with a median of 3 prior lines of therapy

Marked unmet need exists in 2L+ HPV+ OPSCC patients; standard of care agents (methotrexate, docetaxel, or cetuximab) report an ORR of 3.4%

Plan to finalize Phase 3 trial design in 2L+ HPV+ OPSCC with the U.S. Food and Drug Administration (FDA)

SAN DIEGO, June 02, 2025 (GLOBE NEWSWIRE) -- BioAtla, Inc. (Nasdaq: BCAB) (the “Company”), a global clinical-stage biotechnology company focused on the development of Conditionally Active Biologic (CAB) antibody therapeutics for the treatment of solid tumors, today announced data in a poster titled, “Phase 2 Trial of Ozuriftamab Vedotin (Oz-V), a Conditionally Binding CAB-ROR2-ADC, in Patients with Heavily Pretreated Squamous Cell Carcinoma of the Head and Neck.” The poster will be presented today at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting at the McCormick Place Convention Center in Chicago, Illinois.

In the Phase 2 clinical trial, patients with heavily pretreated squamous cell carcinoma of the head and neck (SCCHN) received 1.8 mg/kg of Oz-V given in two schedules: once every two weeks (Q2W) or days 1 and 8 of a 21-day cycle (2Q3W). Tumor assessments were conducted by CT or MRI every 6 weeks from cycle 1 day 1 until week 12, then every 8 weeks up to one year. Response-evaluable patients included those with at least one post-treatment scan.

HPV associated expression of E6 and/or E7 oncoproteins drives cancer progression by upregulating ROR2 expression, which is expressed at high rates in OPSCC. Thus, there is a compelling rationale to evaluate Oz-V in HPV associated OPSCC patients.

“Patients with HPV+ OPSCC who experience progression after initial therapy represent a sizable and rapidly 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. “We believe that there is a potential opportunity for accelerated approval, and subsequently, full approval of Oz-V in HPV+ OPSCC.”

Data highlights from the abstract and poster include:

- 40 patients (pts) received Oz-V either Q2W (n=20) or 2Q3W (n=20) for a median of 85 days.
- Patients received a median of 3 prior lines of therapy; all pts had experienced prior failure of anti–PD-1 therapy and 85% of pts experienced prior failure of platinum therapy.
- For the efficacy analysis, 22 pts had HPV+ OPSCC (as of May 14, 2025); safety data presented (as of April 13, 2025) were based on the full dataset (n=40)
- In HPV+ OPSCC pts, Oz-V demonstrated compelling antitumor activity in patients receiving 1.8 mg/kg Q2W
    - ORR 45% (5/11), 27% (3/11) confirmed, DCR 100% (11/11), continuing follow-up.
    - Median duration of response 9.9 months, median progression-free survival 4.7 months, and median overall survival 11.6 months and ongoing.
    - Other studies using standard of care agents (methotrexate, docetaxel, or cetuximab) have reported ORR of 3.4% and OS of 4.4 months among HPV+ OPSCC pts.
- Based on the head and neck cancer dataset (n=40), most adverse events were low grade; fatigue (57%) and anemia (32%) were most frequent.
- At the 1.8 mg/kg Q2W regimen, to date, only 3 patients (15%) experienced related grade ≥3 AEs, and there were no related serious AEs; also, only 1 patient (5%) discontinued due to a related AE.
- Oz-V has the potential to address the marked unmet need among the recurrent/metastatic HPV+ OPSCC population.
- Oz-V has Fast Track Designation to facilitate additional discussions with the FDA for final agreement on a proposed Phase 3 study.

A copy of the presentation materials can be accessed on the “Publication” section of the Company’s website at www.bioatla.com once the presentation has concluded.

About Ozuriftamab Vedotin

Ozuriftamab vedotin (Oz-V), CAB-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, forms a cancer axis that is associated with poor prognosis and resistance to chemo- and immunotherapies. This late-stage clinical asset is targeting multiple solid tumor indications, including initially the treatment of SCCHN patients who have previously progressed on PD-1/L1 therapies with or without platinum chemotherapy. The FDA granted Fast Track Designation to ozuriftamab vedotin for the treatment of patients with recurrent or metastatic SCCHN.

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 ability of Oz-V to progress to a phase 3 study and receive accelerated or full approval and the potential for Oz-V to address the HPV+ OPSCC population. 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 Report on Form 10-Q filed with the SEC on May 6, 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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