BioAtla Presented Phase 2 Ozuriftamab Vedotin Clinical Trial Data Demonstrating Meaningful Antitumor Activity with Manageable Tolerability among Heavily Pretreated Patients with Squamous Cell Carcinoma of the Head and Neck (SCCHN) at the 2024 European Society for Medical Oncology (ESMO) Annual Meeting

September 16, 2024 at 8:00 AM EDT

An ongoing complete response (CR) with an overall response rate (ORR) of 32% achieved across two dosing regimens

Underscores ozuriftamab vedotin's activity in a high unmet need SCCHN patient population

The conditionally binding ADC targeting ROR2 was notably well tolerated

The Company intends to meet with the FDA to discuss a SCCHN potential registrational trial in 2H 2024

SAN DIEGO, Sept. 16, 2024 (GLOBE NEWSWIRE) -- BioAtla, Inc. (Nasdaq: BCAB), a global clinical-stage biotechnology company focused on the development of Conditionally Active Biologic (CAB) antibody therapeutics for the treatment of solid tumors, today presented a poster of promising Phase 2 trial data at the European Society for Medical Oncology (ESMO) Annual Meeting. The poster presentation entitled, "Phase 2 trial of ozuriftamab vedotin (BA3021), a conditionally active biologic (CAB)-ROR2-ADC, in patients with recurrent or metastatic squamous cell carcinoma of the head and neck," reported multiple confirmed responses among heavily pretreated patients who tolerated treatment well. The Company's novel, conditionally active anti-ROR2-ADC was recently granted FDA Fast Track Designation for treatment of patients with recurrent or metastatic (R/M) SCCHN.

"We continue to see promising antitumor activity associated with an excellent tolerability profile among heavily pretreated head and neck cancer patients with our CAB ROR2-ADC, ozuriftamab vedotin," said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. "Strikingly, we have observed an ongoing complete response and disease control rate of 77%, which underscores the CAB-ROR2-ADC's activity in this difficult-to-treat population with profound unmet medical need. We remain on track to meet with the FDA later this year to discuss a potential randomized registrational trial evaluating ozuriftamab vedotin monotherapy versus investigator's choice among patients with R/M SCCHN who have previously received platinum/PD-1 inhibitor agents."

In the Phase 2 clinical trial, inclusion criteria were patients ≥18 years of age, confirmed to have recurrent or metastatic, stage III/IV SCCHN, ≥1 measurable lesion by RECIST v1.1, ECOG performance status 0 or 1, and treatment failure of no more than 1 approved PD-1/L1 inhibitor. At 1.8 mg/kg, ozuriftamab vedotin was administered either Q2W (every other week dosing) or 2Q3W (days 1 and 8 of ongoing three-week cycles). Best overall response (complete response [CR], partial response [PR], or stable disease [SD]) assessment was performed per RECIST v1.1 in evaluable patients (defined as those who had ≥1 tumor scan after receiving ozuriftamab vedotin). Tumor assessment was confirmed by CT or MRI every 6 weeks from cycle 1 day 1 until 12 weeks, then every 8 weeks up to 1 year, then every 12 weeks thereafter. Disease control rate (DCR) was defined as any CR, PR or SD. Adverse events (AEs) were evaluated according to NCI CTCAE v5.0.

Data highlights from the poster include:

- A Phase 2 clinical trial evaluated ozuriftamab vedotin, conducted in 32 patients (all results are from a data cutoff date of May 31, 2024)
  - Patients were heavily pretreated, with a median of 3 prior lines of therapy
  - 100% and 97% of patients had experienced prior failure of anti-PD-1 therapy and/or platinum-based chemotherapy, respectively
  - Patients were treated with ozuriftamab vedotin either Q2W (n=12) or 2Q3W (n=20)
- Among 31 evaluable patients (one patient withdrew consent prior to tumor assessment):
  - Ten responses overall:
    - ORR 32% across both dosing regimens
    - 1 CR, 9 PRs and 14 SD
  - Responses and SD were observed regardless of HPV status and ROR2 expression
    - At the Q2W dosing regimen (n=12): 1 CR, 2 PRs, and 5 SD
    - At the 2Q3W dosing regimen (n=19): 7 PRs and 9 SD
  - Overall DCR across both dosing regimens was 77% (n=24/31)
  - Responses were confirmed among 6 responding patients (1 CR and 5 PRs)
  - Median duration of response (DOR) for all confirmed responders is not yet reached (>3.6 months, 95% CI, 0.4–NE)
- Treatment with ozuriftamab vedotin was well tolerated
  - Most adverse events (AEs) were low-grade; fatigue (59%), anemia (34%), and nausea (34%) were the most frequent AEs
  - Six patients (19%) had grade 3 treatment-related adverse events (TRAEs) (nausea, diarrhea, decreased lymphocyte count, decreased neutrophil count, peripheral neuropathy, elevated liver enzymes, hyperglycemia, soft tissue infection, febrile neutropenia, asthenia, and dysphagia)

- One patient (3%) experienced a TRAE of grade 4 hyponatremia
- No grade 5 TRAEs were observed

- Two patients experienced related AEs leading to study drug discontinuation (peripheral neuropathy in Q2W and 2Q3W)

A copy of the presentation materials can be accessed on the "Publications" section of the Company's website at www.bioatla.com once the presentation has concluded.

About Ozuriftamab Vedotin

Ozuriftamab vedotin, 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, TNBC and melanoma. Overexpression of ROR2, a non-canonical wnt5A signaling receptor, forms a cancer axis that is associated with poor prognosis and resistance to chemo- and immunotherapies. This first-in-class Phase 2 stage clinical asset is targeting multiple solid tumor indications, including the treatment of SCCHN patients who have previously received PD-1 and platinum-based therapies for which Fast Track designation has been granted by the FDA.

About BioAtla®, Inc.

BioAtla is a global clinical-stage biotechnology company with operations in San Diego, California, and in Beijing, China through our contractual relationship with BioDuro-Sundia, a provider of preclinical development services. Utilizing its proprietary Conditionally Active Biologics (CAB) 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 technology and products with greater than 765 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. BioAtla has two first-in-class CAB programs currently in Phase 2 clinical testing, mecbotamab vedotin, a novel conditionally active AXL-targeted antibody-drug conjugate (CAB-AXL-ADC), and ozuriftamab vedotin, a novel conditionally active ROR2-targeted antibody-drug conjugate (CAB-ROR2-ADC). The Phase 2 stage CAB-CTLA-4 antibody, evalstotug, is a novel CTLA-4 inhibitor designed to reduce systemic toxicity and potentially enable safer combination therapies with checkpoint inhibitors such as anti-PD-1 antibody. The company's first dual CAB bispecific T-cell engager antibody, BA3182, is currently in Phase 1 development. BA3182 targets EpCAM, which is highly and frequently expressed on many adenocarcinomas while engaging human CD3 expressing T cells. BioAtla has an FDA-cleared IND for its next-gen CAB-Nectin4-ADC, BA3361, the Company's first glycoconjugate. 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 and whether its clinical trials will support registration; and the potential regulatory approval path for its product candidates. 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: potential delays in clinical and pre-clinical 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 any resurgence of COVID-19 and its variants; 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 (SEC) on March 26, 2024, in our Quarterly Report on Form 10-Q filed with the SEC on May 14, 2024, and August 8, 2024 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 law.

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