# BioAtla Presenting Phase 1 Evalstotug Clinical Trial Data Demonstrating Clinical Benefit at the Upcoming 2024 American Society of Clinical Oncology (ASCO) Annual Meeting

May 23, 2024 at 5:05 PM EDT

*Multiple refractory PD1 failure patients experienced prolonged progression free survival (10 months ongoing); confirmed responses observed in patients receiving evalstotug*

*High doses of evalstotug as either a monotherapy or in combination with PD1 are associated with manageable safety with relatively low incidence and severity of immune-mediated AEs allowing patients to continue treatment for extended intervals*

*On track for completion of Phase 1 dose-escalation of evalstotug at 1 gram (14.2 mg/kg for a 70 kg person) and Phase 2 monotherapy study with multiple scans in refractory melanoma and carcinoma patients; ongoing enrollment in 1st line combination therapy expansion cohorts for 2H readout*

*A Phase 3 trial of evalstotug in first-line metastatic, unresectable BRAF-mutated melanoma is anticipated to initiate in 2H of 2024 following planned FDA meeting*

SAN DIEGO, May 23, 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 announced expanded data at an upcoming presentation entitled, “Phase 1 study of evalstotug (BA3071), an anti-CTLA-4 Conditionally Active Biologic, in combination with nivolumab in advanced solid tumors”, demonstrating confirmed responses with a potentially differentiated tolerability profile with the Company’s novel, conditionally active anti-CTLA-4 agent, evalstotug, in combination with anti-PD-1 therapy. The poster will be presented at the upcoming 2024 American Society of Clinical Oncology (ASCO) Annual Meeting at the McCormick Place Convention Center in Chicago, Illinois on Saturday, June 1, 2024.

“Given the emerging clinical profile observed, we believe evalstotug has the potential to be best-in-class CTLA-4 antibody and holds the promise to be used as often as a PD-1 inhibitor,” said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. “Strikingly, we have observed prolonged PFS of greater than 10 months and confirmed responses at high doses (350 mg), of evalstotug, suggesting increased exposure of CTLA-4 blockade in combination with PD-1 inhibition drives clinical benefit. We continue to enroll in the Phase 2 first-line melanoma and mutated NSCLC combination cohorts at the 700 mg flat dose and we anticipate moving to the 1 gram flat dose in June following clearance of the DLT observation period and remain on track for monotherapy and combination data readouts later this year. We anticipate enabling a Phase 3 trial of evalstotug in first-line metastatic or unresectable BRAF-mutated melanoma in the second half of this year.

**Data highlights from poster include:**

- A Phase 1 dose-escalation study evaluated evalstotug (7 mg – 1 g Q3W) in combination with nivolumab (240 mg), conducted in 21 patients
  - Data cut of March 29, 2024 unless otherwise specified
  - Patients received a median of 3 prior lines of systemic therapy
  - All patients had experienced failure of anti–PD-1 therapy
  - Patients treated with 350 mg evalstotug received more doses (mean, 7.2) compared with reported ipilimumab or tremelimumab dosing; no dose reductions occurred
  - Three patients have tolerated their first 1-gram evalstotug infusion; clearing the DLT observation period is anticipated by early June
    - Population PK modeling suggests that 1 g flat dose will enable over 98% of patients to maintain $C_{min}$ levels greater than EC50 throughout treatment potentially driving clinical benefit
- Evalstotug was generally well-tolerated with relatively low incidence and severity of immune-mediated AEs
  - Four patients experienced Grade 3 related treatment-emergent AEs
  - No Grade 4 or 5 related TEAEs were observed
  - Two patients experienced Grade 3 immune-related TEAEs (diarrhea [evalstotug 350 mg] and diabetic ketoacidosis [evalstotug 700 mg])
  - Only two treatment related discontinuations
- Evalstotug demonstrated clinical benefit in heavily pre-treated patients (data cut as of April 30, 2024)
  - Responses in three of eight patients who received evalstotug 350mg
    - One confirmed complete response in cervical carcinoma
    - One confirmed partial response in gastroesophageal carcinoma
    - One unconfirmed partial response in cutaneous melanoma patient who was dose escalated and who remains on therapy
  - Disease control rate of 52%
    - Three patients (two with cutaneous melanoma, one with metastatic small cell lung cancer) remained without progression for greater than 1 year (69 weeks)
    - One uveal melanoma patient without progression for 9.8 months

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 Evalstotug (BA3071)**

Evalstotug, is a CAB anti-CTLA-4 antibody that is being developed as an immuno-oncology agent with the goal of delivering efficacy at least comparable to the approved anti-CTLA-4 antibodies, but with lower toxicities due to the CAB's tumor microenvironment-restricted activity. This may enable safer anti-CTLA-4 antibody combination therapies, such as with anti-PD-1 antibody checkpoint inhibitors, and potentially broaden the patient population tolerant to combination therapy and deliver greater efficacy. Like our other CAB candidates, this Phase 2 clinical asset is designed to be conditionally and reversibly active in the tumor microenvironment. Evalstotug is being developed as a potential therapeutic for several solid tumor indications that are known to be responsive to CTLA-4 treatment in combination with a PD-1 blocking agent.

**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 485 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, 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, BA3071, 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 our business plans and prospects, evalstotug's potential as a CTLA-4 agent, evalstotug's potential as a PD-1 inhibitor, clearance of the DLT observation period, expected transition in dosing, schedule for monotherapy and combination data readouts, and timing of a Phase 3 trial of evalstotug in first-line metastatic or unresectable BRAF-mutated melanoma by the end of this year. 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 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.

**Internal Contact:**
Richard Waldron
Chief Financial Officer
BioAtla, Inc.
rwaldron@bioatla.com
858.356.8945

**External Contact:**
Bruce Mackle
LifeSci Advisors, LLC
bmackle@lifesciadvisors.com