# BioAtla Presented Phase 2 Clinical Trial Data at the IASLC 2023 North America Conference on Lung Cancer and Virtual KOL Event

December 5, 2023 at 8:00 AM EST

*Results from the Phase 2 BA3011 clinical non-small cell lung cancer (NSCLC) study demonstrated promising clinical benefits in heavily pre-treated non-squamous histology patients across key endpoints*

*BA3011 is a CAB-AXL antibody-drug conjugate (ADC) being studied in refractory NSCLC patients*

SAN DIEGO, Dec. 05, 2023 (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, presented a poster and discussion entitled "Phase 2 Trial of Mecbotamab Vedotin (BA3011), a CAB-AXL-ADC, Alone or in Combination with Nivolumab in Patients with Non-Squamous NSCLC" at the IASLC Conference December 1–3 and at a virtual KOL Event held December 4, 2023.

"Patients with AXL-positive treatment-refractory NSCLC have an unusually poor prognosis, few treatment options, and we don't typically see clinical benefit in these patients," said Dr. Gay, MD, PhD, Assistant Professor, Department of Thoracic-Head & Neck Medical Oncology at MD Anderson Cancer Center. "Observing promising antitumor activity, including mulltiple partial responses (PRs) and over 4 months duration of response, following BA3011 is particularly exciting and a significant achievement in heavily pre-treated refractory patients."

"The results from the Phase 2 trial in NSCLC continue to show the potential of BA3011 in refractory NSCLC," said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. "Our recent regulatory feedback as well as the benefit-risk profile we have observed to date with our 1.8 mg/kg Q2W BA3011 dosing regimen support advancing this dose in a potentially registrational study. Furthermore, the meaningful antitumor activity among patients with AXL expression of only 1% supports the development of BA3011 in target agnostic populations. Taken together, we believe BioAtla has a significant commercial opportunity to access a larger market and treat more patients with our CAB-AXL-ADC asset."

**Data highlights from the poster presentation and KOL event include:**

- In the BA3011 monotherapy arm (n = 23), 1.8 mg/kg BA3011 Q2W showed encouraging efficacy signals:
  - AXL-positive patients were enrolled and had received a median of at least 3 prior lines of therapy
  - Patients who previously experienced PD-1/L1 treatment failure were evaluable for efficacy at 12 weeks (n=18); objective response rate (ORR) was 27.8% and disease control rate (responses plus stable disease) was 55.6%
  - Five of 15 evaluable patients (33.3%) with EGFR wild-type NSCLC who previously experienced PD-1/L1 treatment failure responded to BA3011 monotherapy; among these five responders, two patients with AXL TmPS of 1% experienced a PR
  - Median duration of response was estimated to be 4.8 months (range, 2.3–12.1+ months)
- Overall, treatment with BA3011 was well-tolerated with a manageable safety profile
  - The most frequent treatment-emergent AEs (TEAEs) of any grade observed (>20%) were fatigue, diarrhea, constipation, and decreased appetite; no grade 4+ TEAEs among most frequent
  - TEAEs leading to treatment discontinuation occurred in 1/23 patients (4.3%) who received monotherapy and 1/17 patients (5.9%) who received combination therapy
- In summary, the observations of multiple responses among such heavily pre-treated patients, including those with AXL TmPS of only 1%, support further evaluation of BA3011 in a Phase 3 registrational study

More details, including the IASLC poster and KOL event slides and recorded KOL webcast, are available on BioAtla's website at https://www.bioatla.com/publications under the "Publications" section and https://ir.bioatla.com under the "Events and Presentations" section, respectively.

**About Mecbotamab Vedotin (BA3011)**

Mecbotamab vedotin, CAB-AXL-ADC, is a conditionally and reversibly active antibody drug conjugate targeting the receptor tyrosine kinase AXL. This Phase 2 stage clinical asset is targeting multiple solid tumor types, including soft tissue and bone sarcoma and non-small cell lung cancer (NSCLC) that have previously progressed on PD-1/L1, EGFR or ALK inhibitor therapies. The Office of Orphan Drug Products (OODP) at FDA granted Orphan Drug Designation to mecbotamab vedotin for the treatment of soft tissue sarcoma.

**About BA3011 Study**

BioAtla has an ongoing multicenter, Phase 2, open-label clinical study evaluating the efficacy and safety of BA3011 alone and in combination with nivolumab. As of June 30, 2023, the study has enrolled 40 non-squamous and 4 squamous histology patients who are confirmed with locally advanced or metastatic NSCLC, ECOG performance status of 0 or 1, treatment failure of a PD-1/L1 inhibitor or approved therapy for EGFR or ALK genomic tumor aberrations, and AXL-positive tumor statining (TmPS ≥1%). Primary endpoints of the study are ORR via RECIST v1.1 and incidence and severity of adverse events. Secondary endpoints of the study include duration of response, progression-free survival, best overall response, disease control rate, time to response, and overall survival.

**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 700 patents filed, more than 400 of which have been issued. 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, BA3011, a novel conditionally active AXL-targeted antibody-drug conjugate (CAB-AXL-ADC), and ozuriftamab vedotin, BA3021, 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 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. 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 and whether our clinical trials will support registration; results, conduct, progress and timing of our research and development programs and clinical trials; and the potential regulatory approval path for our 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 23, 2023, in our Quarterly Report on Form 10-Q filed with the SEC on May 11, 2023, August 1, 2023 and November 7, 2023 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