



BioAtla Highlighted Clinical Program and Pipeline Updates at Virtual R&D Day

July 25, 2024 at 5:40 PM EDT

- *Clinical benefit observed among non-small cell lung cancer (NSCLC) patients harboring mutant KRAS (mKRAS) variants in the Phase 2 mecbotamab vedotin (CAB-AXL-ADC) study; AXL tumoral expression highly associated with multiple mKRAS variants*
- *Evalstotug (CAB-CTLA-4 antibody) as a monotherapy and in combination with PD-1 continues to provide promising anti-tumor activity with a differentiated safety profile associated with a low incidence of immune-related adverse events*

SAN DIEGO, July 25, 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 hosted a virtual R&D Day on its novel conditionally and reversibly active antibody drug conjugate mecbotamab vedotin, targeting the receptor tyrosine kinase AXL, and its antibody targeting CTLA-4, evalstotug. The R&D Day also featured renowned key opinion leaders, Dr. Edwin Yau, Dr. Omid Hamid and Dr. Ankit Mangla.

"It is promising to see confirmed responses following mecbotamab vedotin treatment among heavily pretreated patients with tumors expressing KRAS mutations, including in a patient previously treated with a KRAS inhibitor," said Dr. Yau.

"Now that we are administering evalstotug doses that exceed 10 mg/kg equivalent of marketed CTLA-4 products in combination with PD-1 antibody, I continue to be gratified to observe such a low incidence and severity of immune related adverse events," said Dr. Hamid.

"Every one of my patients who has received evalstotug has experienced clinical benefit, including an advanced melanoma patient who achieved no evidence of disease, which I consider a clinical complete response," said Dr. Mangla.

Details of the presentation and a replay of the event will be available on BioAtla's "[Events and Presentations](#)" website after the event.

Key R&D Day Topics and Highlights:

- **Phase 2 Trial of mecbotamab vedotin, CAB-AXL-ADC, in NSCLC (NCT04681131)**
 - Additional expansion cohort completed evaluating AXL expression, dose and genotype
 - Subgroup results:
 - AXL expression $\geq 1\%$ correlated with clinical benefit in heavily pretreated patients with a median three prior lines of therapy
 - Initial clinical benefit observed in both Q2W and 2Q3W dosing regimens
 - Initial clinical benefit with multiple confirmed responses among patients with tumors expressing mutated KRAS:
 - Responses across multiple KRAS mutation variants to date including G12A, G12C, and G12V
 - Findings support overall survival benefit trend among patients expressing the KRAS mutation compared to KRAS wildtype
 - mKRAS variant highly correlated with AXL expression
 - Manageable safety continues, no new safety signals identified
- **Phase 1/2 dose-escalation trial of evalstotug, CAB-CTLA-4 (NCT05180799) across multiple solid tumor types responsive to CTLA-4**
 - Phase 1 dose-escalation study evaluated evalstotug monotherapy followed by combination with nivolumab, conducted in 21 patients (19 of which are evaluable patients) who experienced failure of prior PD1 treatment and a median of at least three prior lines of treatment
 - Cleared DLT observation period at 1 gram (14.2mg/kg for 70kg person)
 - 3 out of 8 confirmed responses at the 350mg dose level
 - Patients treated with ≥ 350 mg evalstotug received more doses (mean, 7.2) compared with reported ipilimumab (3.4) or tremelimumab (4.3); no dose reductions occurred
 - Multiple patients on therapy with durable disease control for >1 year
 - Only 2 out of 21 patients experienced grade 3 immune-related adverse events; no related grade 4 or 5 events
 - Initial Phase 2 monotherapy data readout with two scans in treatment-refractory solid tumors at 350mg (n=17) or 700mg (n=2) (5 or 10mg/kg for 70 kg person, respectively) to evaluate safety and immune-related adverse events
 - Low incidence (2/19) and severity of immune-related AEs observed, which is consistent with low incidence of immune-related adverse events in Phase 1
 - No grade 3/4 colitis, no grade 4/5 related treatment-emergent adverse events (TEAEs)
 - Across 14 different tumor types enrolled to characterize safety, observed 10 patients with stable disease

- Phase 2 study exploring 700mg evalstotug + pembrolizumab in 1st line melanoma is currently enrolling

Edwin Yau, MD, PhD, is a physician-scientist at the Roswell Park Comprehensive Cancer Center where he is an assistant professor in oncology and serves as the clinical chief for Thoracic Medicine. He is involved in translational research focused on KRAS mutant lung cancers in the Department of Genetics and Genomics and a member of the Roswell Park Developmental Therapeutics research program. He served as the principal investigator of multiple clinical trials for KRAS inhibitors such Adagrasib and RMC-6291.

Omid Hamid, MD, is Chief, Translational Research and Immunotherapy, and Director, Melanoma Therapeutics at The Angeles Clinic and Research Institute. Dr. Hamid has been instrumental in bringing new therapies to clinic for patient benefit such as: PD-1 inhibitors (pembrolizumab, nivolumab, atezolizumab), checkpoint inhibitors (ipilimumab), therapies against tumor angiogenesis, and targeted agents that block internal processes in tumor cell's function (BRAF/MEK). Dr. Hamid is recognized internationally as a key opinion leader in Immuno-Oncologic Drug Development and Melanoma Therapeutics.

Ankit Mangla, MD, is a medical oncologist at University Hospitals Seidman Cancer Center with expertise in treating patients with melanoma and rare tumors such as Merkel cell cancer and soft tissue sarcoma. Dr. Mangla was one of the Investigators for the SWOG-1801 defining a new standard of care for patient with stage 3 melanoma. Dr. Mangla serves as editor or reviewer for *Current Problems in Cancer: Case Reports Translational Oncology*, *Cancer Treatment and Research Communications*, *World Journal of Clinical Cases*, *Journal of Oncology Practice*, *Annals of Translational Oncology*, and *Thoracic Cancers*. Dr. Mangla has been an invited lecturer, expert panelist and poster presenter at numerous annual meetings and conferences.

About Mecbotamab Vedotin

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 indications, including the treatment of soft tissue and bone sarcoma and non-small cell lung cancer (NSCLC) patients who have previously progressed on PD-1/L1, EGFR or ALK inhibitor therapies. The Office of Orphan Products Development (OOPD) at FDA granted Orphan Drug Designation to mecbotamab vedotin for the treatment of soft tissue sarcoma.

About Evalstotug

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 multiple 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 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, 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 results, conduct, progress and timing of our research and development programs and clinical trials. 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