BioAtla Presented Data Characterizing Mutated KRAS Genotype and Clinical Outcomes in Patients with Advanced NSCLC Treated with Mecbotamab Vedotin (Mec-V), a CAB-AXL-ADC, at the IASLC 2024 Hot Topic in Basic & Translational Science Meeting

December 16, 2024 at 8:00 AM EST

Improved median overall survival (OS) for Mec-V treated patients with treatment-refractory non-small cell lung cancer (NSCLC) expressing mutated KRAS (mKRAS) as compared to Mec-V treated patient with treatment-refractory NSCLC expressing wild-type KRAS (wtKRAS)

One-year OS was 58% for patients with NSCLC expressing mKRAS versus 23% for wtKRAS

Mec-V antitumor activity observed across 9 different mKRAS variants

Strong association of AXL expression by mKRAS NSCLC confirmed

SAN DIEGO, Dec. 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, presented a poster entitled "Characterization of Mutated KRAS Genotype and Clinical Outcomes in Patients With Advanced NSCLC Treated With Mecbotamab Vedotin, a CAB-AXL-ADC" at the IASLC 2024 Hot Topic in Basic & Translational Science Meeting on December 14, 2024.

"Mutations in KRAS are present in approximately 30% of lung cancer patients and we have now confirmed a strong correlation with expression of AXL, the target of our CAB- AXL-ADC, Mec-V. Among all 78 patients treated with Mec-V, 58% of those with tumors harboring mKRAS were alive at one year compared to only 23% lacking the mutation," said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. "The observed and unprecedented one-year survival among such a heavily pretreated NSCLC population suggests that Mec-V may be a promising treatment option for NSCLC patients across all KRAS mutation variants. Based on these findings and previous discussions with the FDA, a randomized trial of Mec-V in patients with treatment-refractory mKRAS NSCLC is planned for initiation in 2025."

Data highlights:

- Phase 2 trial of Mec-V, CAB-AXL-ADC (NCT04681131) in NSCLC
  - 78 patients were enrolled and received either Mec-V monotherapy (n=59) or Mec-V + nivolumab (n=19).
  - Patients received a median of 3 prior lines of therapy.
  - Among the 78 treated patients, 24 (30.7%) had mKRAS NSCLC.
  - Overall survival analyses:
    - Landmark OS at one year: 58% for patients with mKRAS NSCLC vs. 23% for patients with wtKRAS NSCLC.
    - Median OS was not yet reached (6.5-Not Estimable) for patients with mKRAS NSCLC vs. 8.7 (5.8–10.2) months for patients with wtKRAS NSCLC.
  - Among 21 efficacy-evaluable patients with mKRAS NSCLC:
    - 6 responses (ORR=28.6%; including 1 patient previously treated with sotorasib).
    - Antitumor activity observed across 9 different mutated KRAS (mKRAS) variants
    - 1 patient treated with Mec-V + nivolumab Q2W continues in Complete Response (CR) after >2 years of follow-up.
  - Treatment with Mec-V was well tolerated with a manageable safety profile.
  - No new safety signals were observed.
- AXL is highly expressed in mKRAS NSCLC
  - 113 screening tissue samples were evaluated for KRAS mutation status and AXL expression by immunohistochemistry assay.
  - Among 27 NSCLC samples harboring any KRAS mutation, AXL was highly expressed (tumor membrane expression of AXL ≥ 1% of tumor cells):
    - 19 of 27 (70.3%).
    - 9 of 11 (81.8%), among the mKRAS G12C variant subset of the 27 total.

The poster is available on BioAtla's website at https://www.bioatla.com under the "Publications" section.

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, as well as patients with mKRAS NSCLC who have previously progressed on PD-1/L1, epidermal growth factor receptor or ALK inhibitor therapies. The Office of Orphan Products Development at the Food and Drug Administration granted Orphan Drug Designation to mecbotamab vedotin for the treatment of soft tissue sarcoma.

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 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 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. 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. 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 "plan," "may," "design," "potential," "promising," or other similar words. Examples of forward-looking statements include, among others, statements we make regarding BioAtla's plan and timing to initiate a randomized trial of Mec-V in patients with treatment-refractory mKRAS NSCLC; Mec-V's potential to treat NSCLC patients across all KRAS mutation variants; and potential efficacy of our CAB 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 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 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 (the "SEC") on March 26, 2024, in our Quarterly Report on Form 10-Q filed with the SEC on May 14, 2024, August 8, 2024 and November 7, 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 laws.

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