Bioatla Reports Second Quarter 2024 Financial Results and Highlights Recent Progress

August 8, 2024 at 4:05 PM EDT

- **Ozuriftamab vedotin (CAB-ROR2-ADC) granted Fast Track Designation by FDA in squamous cell carcinoma of the head and neck (SCCHN); anticipate FDA meeting for SCCHN potential registrational trial in 2H 2024**

- **Evalstotug (CAB-CTLA-4 antibody) demonstrated a similar low incidence and severity of immune-related adverse events across both Phase 1 and 2 studies; Phase 2 combination with pembrolizumab study continues to enroll and on track for initial data readout in 2H 2024**

- **Mecbotamab vedotin (CAB-AXL-ADC) Phase 2 trial in NSCLC showed trend for improved overall survival among treated patients with tumors expressing mutated KRAS variants compared to KRAS wildtype; anti-tumor activity across multiple KRAS mutation variants including G12A, G12C, and G12V**

- **Current cash balance projected to fund operations through Q3 2025 sufficient to deliver clinical readouts in multiple indications, position our programs for one or more potentially registrational trials, and enhance our position in advancing strategic collaboration discussions**

- **Management to host conference call and webcast today at 4:30 PM Eastern Time**

SAN DIEGO, Aug. 08, 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 its financial results for the second quarter ended June 30, 2024, and provided highlights on its clinical programs.

“BioAtla continues to execute across our CAB portfolio, highlighted by ongoing positive clinical responses and a potentially differentiated safety profile observed with our CAB Phase 2 assets,” said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. “We are pleased to receive Fast Track Designation for ozuriftamab vedotin in the treatment of recurrent or metastatic head and neck cancer and are on track to meet with the FDA this year. The clinical profile of evalstotug, in particular the low incidence and severity of immune-related AEs, supports a potentially best-in-class CTLA-4 antibody for the treatment of multiple solid tumors. Further, we are encouraged with the emerging clinical profile of mecbotamab vedotin in patients with NSCLC harboring KRAS mutation variants. The company remains well-positioned for multiple FDA meetings by year end to discuss potentially registrational trials while we continue to advance discussions with potential strategic partners.”

Key Developments, Operational Updates and Upcoming Milestones

- **Phase 2 Trials of ozuriftamab vedotin, CAB-ROR2-ADC in treatment-refractory SCCHN (NCT05271604) (median 3 prior lines of treatment)**
  - In the 29 evaluable patients to date, a total of 11 responses at the combined 2Q3W and Q2W dose regimens
    - Fast Track Designation granted by FDA
    - Data to be presented at upcoming poster presentation at ESMO in September
- **Phase 1/2 dose-escalation trial of evalstotug, CAB-CTLA-4 (NCT05180799) across multiple solid tumor types (median 3 prior lines of treatment)**
  - Phase 1 dose-escalation study evaluated evalstotug in combination with nivolumab in patients who experienced failure of prior PD1 treatment
    - Confirmed responses (3/8) with evalstotug (350 mg) in combination with PD-1
    - Patients treated with ≥350mg evalstotug received more doses (mean, 7.2) compared with reported ipilimumab (3.4) or tremelimumab (4.3); no dose reductions occured
    - Multiple patients on therapy without progression for >1 year
  - Initial Phase 2 monotherapy data readout with two scans in treatment-refractory solid tumors at 350 mg (n=17) or 700 mg (n=2) (5 or 10 mg/kg for 70 kg person, respectively) to evaluate safety and immune-related adverse events
    - Study ongoing
    - Across 14 different tumor types, 10 patients with stable disease following monotherapy treatment; multiple patients experienced prolonged PFS (>10 months) to date
  - Combined Phase 1 and Phase 2 safety (n=40) demonstrated low rate of grade 3 immune-related adverse events (irAEs) (4/40); no related grade 4 or 5 events; incidence and severity of irAEs consistent across Phase 1 and Phase 2 studies
  - Data to be presented as oral presentation at the Society for Melanoma Research Congress in October and a poster presentation at the Society for Immunotherapy of Cancer in November

- Phase 2 first-line melanoma and first-line NSCLC patients at 700 mg (10 mg/kg for 70 kg person) in combination with pembrolizumab and in combination with pembrolizumab plus chemotherapy continues to enroll; on track for initial melanoma data readout in 2H 2024

- **Phase 2 trial of mecbotamab vedotin, CAB-AXL-ADC (NCT04681131) in NSCLC (median 3 prior lines of treatment)**
  - Additional expansion cohort (n=33) 2Q3W evaluating AXL expression, dose, subtype and safety
  - Subgroup results:
    - AXL expression ≥1% correlated with anti-tumor activity in both Q2W and 2Q3W dosing regimens
    - Anti-tumor activity with multiple confirmed responses among patients with tumors expressing mutated KRAS:
      - Overall survival benefit trend observed among treated patients whose tumors express mutated KRAS compared to those with wildtype KRAS genotype
      - Responses observed across patients with tumors expressing multiple KRAS mutation variants to date, including G12A, G12C, and G12V
      - Response observed in a patient whose tumor expressed a mutated KRAS G12C variant who had experienced prior failure of sotorasib
      - One patient treated in combination with PD-1 antibody remains in complete response for greater than 2 years
      - mKRAS variants represent 30% of all NSCLC patients and is highly correlated with AXL expression
  - Manageable safety continues with no new safety signals identified
- **Phase 1/2 dose-escalation for CAB-EpCAM x CAB-CD3 TCE (BA3182, NCT05808634)**
  - Study is progressing and ongoing; on track for data readout of Phase 1 study in 2H 2024

Second Quarter 2024 Financial Results
Research and development expenses were $16.2 million for the quarter ended June 30, 2024 compared to $31.0 million for the same quarter in 2023. The decrease of $14.8 million was primarily due to completion of pre-clinical development for our Nectin-4 ADC which received IND clearance in May 2024, and the impact of prioritization of our clinical programs in 2023 resulting in less expense for our pre-clinical programs in 2024. Our clinical program expense decreased related to completion of Phase 2 enrollment for our ongoing ADC trials for mecbotamab vedotin and ozuriftamab vedotin. We expect our R&D expenses to continue to decrease in the near-term as we complete our planned Phase 2 clinical trials and meet with the FDA to discuss potentially registrational trials for our Phase 2 programs.

General and administrative expenses were $5.8 million for the quarter ended June 30, 2024 compared to $6.2 million for the same quarter in 2023. The $0.5 million decrease was primarily due to lower stock based compensation expense.

Net loss for the quarter ended June 30, 2024 was $21.1 million compared to a net loss of $35.8 million for the same quarter in 2023.

Net cash used in operating activities for the six months ended June 30, 2024 was $50.0 million compared to net cash used in operating activities of $46.7 million for the same period in 2023. Our cash used for the quarter ended June 30, 2024 was $19.0 million in line with guidance, compared to $30.8 million during the quarter ended March 31, 2024.

Cash and cash equivalents as of June 30, 2024 were $61.7 million, compared to $111.5 million as of December 31, 2023. We expect current cash and cash equivalents to fund planned operations through Q3 of 2025 which is sufficient to deliver clinical readouts in multiple indications, position our programs for one or more potentially registrational trials, and enhance our position in advancing strategic collaboration discussions.

Second Quarter 2024 Conference Call and Webcast Details
The management of BioAtla, Inc. will host a conference call and webcast for the investment community today, August 8, 2024, at 4:30 pm Eastern Time. A live webcast may be accessed here:

https://viavid.webcasts.com/starthere.jsp?ei=1677714&tp_key=f44f1624a8. The conference call can be accessed by dialing toll-free (800) 579-2543 (domestic) or (785) 424-1789 (international). The passcode for the conference call is BIOATLA.

A replay of the webcast and slides with topline interim clinical data referenced on the call will be available through "Events & Presentations" in the Investors section of the company's website after the conclusion of the presentation and will be archived on the BioAtla website for one year.

About Ozuriftamab Vedotin (BA3021)
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 noncanonical wnt5A signaling receptor, forms a cancer axis that is associated with poor prognosis and resistance to chemo- and immunotherapies. This Phase 2 stage clinical asset is targeting multiple solid tumor indications, including the treatment of SCCHN patients who have previously progressed on PD-1/L1 therapies with or without platinum chemotherapy.

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 multiple solid tumor indications that are known to be responsive to CTLA-4 treatment in combination with a PD-1 blocking agent.

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 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 CAB-EpCAM x CAB-CD3 Bispecific T-cell Engager Antibody (BA3182)
BioAtla is developing BA3182 as a potential anticancer therapy for patients with advanced adenocarcinoma. BA3182 is a (CAB) EpCAM x (CAB) CD3 bispecific T cell engager antibody that contains two binding sites for EpCAM and two binding sites for CD3ε. The binding sites for EpCAM and CD3ε have been designed to bind their respective targets specifically and reversibly under the conditions found in the tumor microenvironment (TME) and to have reduced binding outside of the TME. The CAB selective binding to both the CAB EpCAM and CAB CD3ε arms are required to activate the T cell engagement against the tumor, thus enabling the combined selectivity of each CAB binding arm in the bispecific antibody. BioAtla continues to advance the ongoing Phase 1 study to evaluate the safety, pharmacokinetics, and efficacy of BA3182 in advanced adenocarcinoma patients.

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, 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; achievement of milestones; results, conduct, progress and timing of our research and development programs and clinical trials; expectations with respect to enrollment and dosing in its clinical trials, plans and expectations regarding future data updates, clinical trials, regulatory meetings and regulatory submissions; the potential regulatory approval path for its product candidates; expectations about the sufficiency of its cash and cash equivalents to fund operations and expectations regarding R&D expenses and cash burn. 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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BioAtla, Inc.
Unaudited Condensed Statements of Operations and Comprehensive Loss
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023

Operating expenses:				
Research and development expense	$ 16,198	$ 30,960	$ 35,050	$ 52,657
General and administrative expense	5,774	6,241	11,379	13,474
Total operating expenses	21,972	37,201	46,429	66,131
Loss from operations	(21,972)	(37,201)	(46,429)	(66,131)
Other income:				
Interest income	900	1,460	2,123	2,940
Other expense	—	(11)	—	(21)
Total other income	900	1,449	2,123	2,919
Net loss and comprehensive loss	$ (21,072)	$ (35,752)	$ (44,306)	$ (63,212)
Net loss per common share, basic and diluted	(0.44)	(0.75)	(0.92)	(1.33)
Weighted-average shares of common stock outstanding, basic and diluted	48,214,893	47,706,426	48,151,176	47,639,977

BioAtla, Inc.
Condensed Consolidated Balance Sheets Data
(in thousands)

	June 30, 2024	December 31, 2023
	(unaudited)	
Cash and cash equivalents	$ 61,662	$ 111,471
Total assets	68,638	119,658
Total current liabilities	17,462	28,344
Total liabilities	37,268	48,986
Total stockholders' equity	31,370	70,672
Total liabilities and stockholders' equity	68,638	119,658