BioAtla Reports Third Quarter 2024 Financial Results and Highlights Recent Progress

November 7, 2024 at 4:01 PM EST

- **Ozuriftamab vedotin (CAB-ROR2-ADC) Phase 2 trial in squamous cell carcinoma of the head and neck (SCCHN) continues to demonstrate durable clinical responses and median overall survival (OS) of approximately 9 months (ongoing) in a heavily pretreated population; actionable feedback received from the U.S. Food and Drug Administration (the "FDA") regarding our proposed pivotal trial in second-line (2L) plus SCCHN**
- **Evalstotug (CAB-CTLA-4) in combination with PD-1 demonstrates tumor reduction in all eight, first-line unresectable or metastatic melanoma patients with 4 responses including a complete response (CR), ongoing, with relatively low incidence and severity of immune-related adverse events; FDA guidance received on ongoing dose optimization and control arm anticipated to enable Phase 3 trial**
- **Mecbotamab vedotin (CAB-AXL-ADC) Phase 2 trial in non-small cell lung cancer (NSCLC) shows tumor reduction across nine different mutant KRAS ("mKRAS") variants; an improved median OS of 12.6 months, ongoing, among treated patients with tumors expressing mKRAS variants compared to KRAS wildtype**
- **Recent worldwide license agreement for preclinical CAB-Nectin-4 bispecific T-cell engager; current cash balance now projected to fund operations into early 2026**
- **Management to host conference call and webcast today at 4:30 PM Eastern Time**

SAN DIEGO, Nov. 07, 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 third quarter ended September 30, 2024, and provided highlights on its clinical programs.

"BioAtla remains focused on execution of key business drivers, as evident by the recent successful out-licensing of our CAB-nectin-4 bispecific T-cell engager and extending operating runway into 2026, while also advancing our lead clinical programs," said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc., "We are seeing clinical data with encouraging overall survival in both of our ADC programs and promising antitumor activity and tolerability with our CAB-CTLA4 antibody, evalstotug. Following recent, positive interactions with the FDA regarding ozuriftamab vedotin and evalstotug, we believe the company is well-positioned for two potentially registrational trials in 2025. Given our ongoing discussions with potential strategic partners, we remain confident in establishing a near-term collaboration for one of our Phase 2 clinical assets."

Key Developments, Operational Updates and Upcoming Milestones

- **Phase 2 Trial of ozuriftamab vedotin, CAB-ROR2-ADC (NCT05271604) in treatment-refractory SCCHN (median of 3 prior lines of treatment)**
  - Earlier data cut presented at the European Society for Medical Oncology in September 2024 showed a 38% response rate in heavily pre-treated patients.
  - New updated data as of data cutoff of September 10, 2024:
    - Median duration of response (DOR) for all confirmed responders now 4.4 months
    - Median OS now approximately 9 months (ongoing)
  - FDA actionable guidance received on pivotal trial in 2L plus SCCHN:
    - At the current dose of 1.8 mg/kg of ozuriftamab vedotin, the FDA supported a limited randomized evaluation of the Q2W and 2Q3W dosing schedules.
    - Supportive of proposed prospective randomized trial design, investigator choice treatment options, and endpoints that have the potential to support a possible accelerated marketing authorization followed by confirmation of clinical benefit in the same trial with additional follow-up.
  - Granted Fast Track Designation by the FDA
- **Phase 1/2 dose-escalation trial of evalstotug, CAB-CTLA-4 (NCT05180799) across multiple solid tumor types (median of 3 prior lines of treatment)**
  - Presented preclinical and clinical data in oral format at the Society for Melanoma Research in September 2024
    - Evalstotug was generated from ipilimumab (ipi) for conditionally active binding activity and is similar to ipi with respect to epitope, affinity and half-life.
    - Evalstotug *differs* from ipi with respect to protecting normal tissues and safety (*e.g.*, targeting reduced frequency and less severe immune-related adverse events, irAEs, and extended treatment).
    - Intra-patient evalstotug dose escalation re-achieved disease control with acceptable safety:
      - Two first-line cutaneous melanoma patients - one patient who was dose escalated from 70 mg to 210 mg and finally to 350 mg experienced a confirmed partial response (PR) at the higher dose; one

patient who was dose escalated from 700 mg to 1000 mg re-experienced decreasing tumor volume stable disease (both ongoing).
        - One recurrent metastatic melanoma patient who was dose escalated from 210 mg to 350 mg re-achieved stable disease (ongoing).
    - First-line unresectable or metastatic melanoma data to be presented at the Society for Immunotherapy of Cancer on November 8, 2024
        - All eight patients treated with evalstotug plus PD-1 showed tumor reduction with 4 responders (including 3 PRs and 1 CR to date) with acceptable tolerability; no patients have discontinued due to disease progression to date.
        - FDA guidance received on ongoing dose optimization and control arm for Phase 3 registrational trial in first line patients with unresectable or metastatic melanoma anticipated to enable study initiation in 2025.
- **Phase 2 trial of mecbotamab vedotin, CAB-AXL-ADC (NCT04681131) in NSCLC (median of 3 prior lines of treatment)**
    - Anti-tumor activity with multiple confirmed responses among 21 evaluable patients with tumors expressing mKRAS
        - Continue to observe OS benefit trend among treated patients whose tumors express mKRAS (median OS = 12.6 months) compared to those with wildtype KRAS genotype (median OS = 8.7 months).
        - Responses and preliminary clinical benefit demonstrated across nine different mKRAS variants.
    - Continue to observe a high correlation of AXL and mKRAS expression.
    - Manageable safety continues with no new safety signals identified.
    - Potential for a pan mKRAS strategy in NSCLC; currently determining the most efficient path forward for a future pivotal trial.
- **Phase 1/2 dose-escalation for BA3182 (CAB-EpCAM x CAB-CD3 TCE) (NCT05808634)**
    - Observed multiple patients with tumor reduction, including one colorectal cancer patient with stable disease for one year (ongoing).
    - Implemented priming dose to modulate cytokine release syndrome that is commonly observed with T-cell engagers and can also occur in patients with heavy tumor volume.
    - Maximally tolerated dose has not yet been reached; dose escalation ongoing.
    - Given the encouraging continued ongoing dose escalation with increasing antitumor activity, we now anticipate data readout of Phase 1 study around mid-2025.

Third Quarter 2024 Financial Results

Research and development expenses were $16.4 million for the quarter ended September 30, 2024 compared to $28.4 million for the same quarter in 2023. The decrease of $12.0 million was due to completion of pre-clinical development for our Nectin-4 ADC which received investigational new drug 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. The decrease in our clinical program expense was related to completion of targeted Phase 2 enrollment for our ongoing ADC trials for mecbotamab vedotin and ozuriftamab vedotin. We expect to further reduce our operating expense in the coming quarters as we complete certain of our Phase 2 clinical trials and meet with the FDA to finalize the paths forward for the potentially registrational trials.

General and administrative expenses were $5.9 million for the quarter ended September 30, 2024 compared to $6.6 million for the same quarter in 2023. The $0.7 million decrease was primarily due to lower stock-based compensation expense.

We recognized revenue related to our exclusive worldwide license agreement with Context Therapeutics which was announced in September. As part of the agreement, BioAtla will receive up to $133.5 million in aggregate payments, including $15.0 million in upfront and near-term milestone payments. The Nectin-4 T-cell engaging bispecific CAB antibody was in pre-clinical development at the time of the agreement.

Net loss for the quarter ended September 30, 2024, including $11.0 million in collaboration revenue, was $10.6 million compared to a net loss of $33.3 million for the same quarter in 2023.

Net cash used in operating activities for the nine months ended September 30, 2024 was $55.2 million compared to net cash used in operating activities of $74.1 million for the same period in 2023. Our net cash used for the quarter ended September 30, 2024 was $5.1 million.

Cash and cash equivalents as of September 30, 2024 were $56.5 million, compared to $111.5 million as of December 31, 2023. We expect current cash and cash equivalents to fund planned operations into early 2026 which we believe is sufficient to complete any remaining dose optimization for CAB-ROR2 and CAB-CTLA4, position these two programs for potentially registrational trials, and maintain our near-term guidance for a strategic collaboration with at least one of our P2 assets.

Third Quarter 2024 Conference Call and Webcast Details

The management of BioAtla, Inc. will host a conference call and webcast for the investment community today, November 7, 2024, at 4:30 pm Eastern Time. A live webcast may be accessed here:

https://viavid.webcasts.com/starthere.jsp?ei=1689701&tp_key=570dcb79e1

The conference call can be accessed by dialing toll-free (800) 343-4136 (domestic) or (203) 518-9848 (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
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, triple-negative breast cancer 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 initially the treatment of SCCHN patients who have previously progressed on PD-1/L1 therapies with or without platinum chemotherapy. The FDA granted Fast Track Designation to ozuriftamab vedotin for the treatment of patients with recurrent or metastatic SCCHN.

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 (TME)-restricted activity. This is anticipated to 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 TME. 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
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 mKRAS NSCLC patients who have previously progressed on PD-1/L1, epidermal growth factor receptor or ALK inhibitor therapies. The Office of Orphan Products Development at the 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
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 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 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 "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 our clinical trials will support registration; achievement of milestones; results, progress and timing of our research and development programs and clinical trials; expectations with respect to enrollment and dosing in our clinical trials, plans and expectations regarding future data updates, clinical trials, regulatory meetings and regulatory submissions; the timing of and the ability to establish collaborations or other strategic partnerships for selected assets; the potential regulatory approval path for our product candidates; expectations about the sufficiency of our 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 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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BioAtla, Inc.
Unaudited Condensed Statements of Operations and Comprehensive Loss
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration and other revenue	$ 11,000	$ —	$ 11,000	$ —
Operating expenses:				
Research and development expense	16,395	28,400	51,445	81,057
General and administrative expense	5,875	6,620	17,254	20,094
Total operating expenses	22,270	35,020	68,699	101,151
Loss from operations	(11,270)	(35,020)	(57,699)	(101,151)
Other income:				
Interest income	692	1,734	2,815	4,674
Other expense	(8)	(39)	(8)	(60)
Total other income	684	1,695	2,807	4,614
Net loss and comprehensive loss	$ (10,586)	$ (33,325)	$ (54,892)	$ (96,537)
Net loss per common share, basic and diluted	(0.22)	(0.70)	(1.14)	(2.02)
Weighted-average shares of common stock outstanding, basic and diluted	48,335,847	47,834,122	48,213,183	47,707,259

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

	September 30, 2024	December 31, 2023
	(unaudited)	
Cash and cash equivalents	$ 56,516	$ 111,471
Total assets	62,236	119,658
Total current liabilities	19,462	28,344
Total liabilities	39,268	48,986
Total stockholders' equity	22,968	70,672
Total liabilities and stockholders' equity	62,236	119,658