BioAtla Reports Second Quarter 2023 Financial Results and Highlights Recent Progress

August 1, 2023 at 4:01 PM EDT

- **Achieved first patient in (FPI) and continuing to enroll CAB-AXL BA3011 in a Phase 2 potentially registrational study in Undifferentiated Pleomorphic Sarcoma (UPS)**
- **Submitted Food & Drug Administration (FDA) meeting request for potentially registrational study of BA3011 in non-small cell lung cancer (NSCLC) study; FDA feedback and initiation of study remain on track for 2H23**
- **Continuing to enroll BA3021 Phase 2 NSCLC, melanoma and squamous cell carcinoma of the head & neck (SSCHN) studies; anticipate data across indications to prioritize and make a 'go' decision in 2H2023**
- **Cleared fifth cohort at 5 mg/kg monotherapy and in combination with PD-1 in Phase 1 dose-escalation CAB-CTLA-4 (BA3071) study with no dose-limiting toxicities (DLTs) reported; currently enrolling patients in sixth cohort at 10 mg/kg; anticipated Phase 1 data readout and initiation of Phase 2 remain on track for 2H23**
- **Cash balance of $168.7 million expected to provide funding into 2025**
- **Management to host conference call and webcast today at 4:30 PM Eastern Time**

SAN DIEGO, Aug. 01, 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, today announced its financial results for the second quarter ended June 30, 2023, and provided highlights on its clinical programs.

“BioAtla continues to progress our robust CAB pipeline, including the recent clearance of the fifth cohort with no DLTs observed in our Phase 1 BA3071 CTLA-4 study,” said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. “BioAtla has several important near-term value inflection points, including data readouts in the second half of this year. Additionally, we anticipate FDA feedback for our Phase 2, part 2 potentially registrational BA3011 trial in NSCLC, and initiation of our Phase 2 CAB-CTLA-4 BA3071 trial in multiple indications. We continue to work diligently to progress our programs while managing our resources to preserve cash into 2025.”

Key Developments, Operational Updates and Upcoming Milestones

- **Phase 2 Trial of Mecbotamab Vedotin in Patients with:**
  - **AXL-positive Soft Tissue and Primary Bone Sarcomas (BA3011, NCT03425279)**
    - Phase 2, part 1:
      - Continuing to enroll remaining cohorts
      - LMS cohort data readout remains on track for 2H23 using a more frequent, dose-intensive regimens
    - Phase 2, part 2:
      - Continuing to enroll and dose patients in potentially registrational Phase 2 UPS study
  - **AXL-positive NSCLC (BA3011, NCT04681131)**
    - Phase 2, part 1:
      - Continuing to enroll more frequent, dose-intensive regimens; anticipated data for all dosing regimens to enable decision on selected dose for Phase 2, part 2 remains on track for 2H23
    - Phase 2, part 2 (potentially registrational):
      - Submitted meeting request to the FDA for the study design; anticipate FDA feedback in 2H23
      - Initiation of study on track for 2H23
  - **AXL-positive platinum-resistant ovarian cancer (BA3011, NCT04918186)**
    - Phase 2 investigator-initiated trial is on track with interim data (n=10) anticipated in 2H23

- **Phase 2 Trials of Ozuriftamab Vedotin in Patients with:**
  - **ROR2-positive NSCLC (BA3021, NCT03504488)**
    - Continuing to enroll in the more frequent, dose-intensive regimen
  - **ROR2-positive melanoma (BA3021, NCT03504488)**
    - Identified ROR2-positive tumors using liquid biopsy assay
    - Anticipate dosing patients in 2H23
  - **ROR2-positive SCCHN (BA3021, NCT05271604)**
    - Multiple patients dosed and continuing to enroll patients
  - **ROR2-positive platinum-resistant ovarian cancer (BA3021, NCT04918186)**

        - Phase 2 investigator-initiated trial is on track with interim data (n=10) anticipated in 2H23
    - **Anticipated data across indications to prioritize and make a 'go' decision for indications to further pursue remains on track for 2H23**

- **Phase 1/2 dose-escalation trial of CAB-CTLA-4 (BA3071, NCT05180799) across multiple solid tumor types responsive to CTLA-4**
    - DLT observation period cleared for fifth cohort (350 mg [5 mg/kg]) as monotherapy and in combination with nivolumab 3 mg/kg every three weeks (Q3W)
    - Enrolling 700 mg (10mg/kg) as sixth dose cohort as monotherapy and in combination with nivolumab 3mg/kg Q3W
    - Anticipated Phase 1 data readout remains on track for 2H23
    - Initiation of the Phase 2 part of the study remains on track for 2H23

- **Phase 1/2 dose-escalation for CAB-EpCAM x CAB-CD3 TCE (BA3182)**
    - Enrolling Phase 1 study for the treatment of advanced adenocarcinoma
    - Anticipated completion of Phase 1 data readout remains on track in 2024

- **Since the first quarter, two additional accepted and upcoming poster presentations for trials in progress (for BA3011 and BA3021) at the upcoming World Conference on Lung Cancer (WCLC), to be held September 9-12, titled:**
    - “A Phase 2 Study of Mecbotamab Vedotin (BA3011), a CAB-AXL-ADC, Alone or in Combination with Nivolumab”
    - “A Phase 1/2 Dose Escalation and Dose Expansion Study of Ozuriftamab Vedotin (BA3021) Alone and in Combination with Nivolumab”

Second Quarter 2023 Financial Results
Cash and cash equivalents as of June 30, 2023 were $168.7 million, compared to $215.5 million as of December 31, 2022. We expect current cash and cash equivalents will be sufficient to fund planned operations including all ongoing CAB product development programs into 2025.

Research and development (R&D) expenses were $31.0 million for the quarter ended June 30, 2023 compared to $20.7 million for the same quarter in 2022. The increase of $10.3 million was primarily driven by our preclinical and clinical product development efforts. We expect our R&D expenses to remain variable from quarter to quarter and generally increase as we continue to invest in R&D activities to advance our product candidates and our clinical programs.

General and administrative (G&A) expenses were $6.2 million for the quarter ended June 30, 2023 compared to $8.3 million for the same quarter in 2022. The $2.1 million change was attributable to a decrease in various administrative expenses for the 2023 period. We expect our G&A expenses to moderately increase to support development of our product candidates, advance our intellectual property portfolio, support focused pre-commercialization activities for our product candidate mecbotamab vedotin (BA3011) and satisfy requirements as a public company.

Net loss for the second quarter ended June 30, 2023 was $35.8 million compared to a net loss of $28.9 million for the same quarter in 2022.

Net cash used in operating activities for the months ended June 30, 2023 was $46.7 million compared to net cash used in operating activities of $42.1 million for the same period in 2022. The increase in net cash used in operating activities for the first six months of 2023 is primarily due to an increase in research and development expense related to our program development efforts as compared to the first six months of 2022.

Second Quarter 2023 Conference Call and Webcast Details
The management of BioAtla, Inc. will host a conference call and webcast for the investment community today, August 1, 2023, at 4:30 pm Eastern Time. A live webcast may be accessed here: https://viavid.webcasts.com/starthere.jsp?ei=1619442&tp_key=871a8141a7. The conference call can be accessed by dialing toll-free (877) 425-9470 or (201) 389-0878 (international). The passcode for the conference call is 13739244.

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 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. We are also supporting a multi-center investigator-initiated clinical trial in combination with durvalumab, a PD-L1-blocking antibody, in patients with platinum-resistant ovarian cancer, in addition to other potential indications in the future. The Office of Orphan Drug Products (OODP) at FDA granted Orphan Drug Designation to mecbotamab vedotin for the treatment of soft tissue sarcoma.

About Ozuriftamab Vedotin (BA3021)
Ozuriftamab vedotin, CAB-ROR2-ADC, is a conditionally and reversibly active antibody drug conjugate directed against ROR2, a receptor tyrosine kinase that is overexpressed across many different solid tumors including lung, head and neck and melanoma. We are advancing this Phase 2 stage clinical asset for multiple solid tumor types, including NSCLC that have previously progressed on PD-1/L1, EGFR or ALK inhibitor therapies, melanoma that have previously progressed on PD-1/L1 therapy and SCCHN that have previously progressed on PD-1/L1 therapies with or without platinum chemotherapy. We are also supporting a multi-center investigator-initiated clinical trial in combination with durvalumab, a PD-L1-blocking

antibody, in patients with platinum-resistant ovarian cancer, in addition to other potential indications in the future.

About BA3071
BA3071, 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, BA3071 is designed to be conditionally and reversibly active in the tumor microenvironment. BA3071 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 BA3182
BioAtla is developing BA3182 as a potential anticancer therapy for patients with advanced adenocarcinoma. BA3182 is a conditionally active biologic (CAB) EpCAM/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 recently received FDA IND clearance to conduct a first-in-human, Phase 1 study to evaluate the safety, pharmacokinetics, and efficacy of BA3182 in advanced adenocarcinoma patients.

About EpCAM
EpCAM is involved in the maintenance of epithelial integrity, and its expression is associated with proliferation during morphogenesis, tissue regeneration, and stem cell maintenance. Expression levels of EpCAM vary amongst different organs and cell types, with epithelia of colon, small intestine, lung, pancreas, liver and gall bladder expressing the highest levels of EpCAM protein. Given the functions and properties of EpCAM protein, high levels of EpCAM expression have been found in many carcinomas. EpCAM is highly and frequently expressed in the vast majority of carcinomas and their metastasis and has been considered as a potential prognostic and therapeutic marker for many carcinomas.

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 1 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 antibody, 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, including our plans to initiate and advance a Phase 1 dose-escalation and expansion clinical study for BA3182, whether our 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 our clinical trials, plans and expectations regarding future data updates, clinical trials, regulatory meetings and regulatory submissions; the potential regulatory approval path for our product candidates; expectations about the sufficiency of our cash and cash equivalents; and expected R&D and G&A expenses. 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 due to the global COVID-19 pandemic; other potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; 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 success of our current and future collaborations with third parties; 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; 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 and August 1, 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.

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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,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development expense	30,960	20,711	$ 52,657	$ 37,634
General and administrative expense	6,241	8,344	13,474	15,767
Total operating expenses	37,201	29,055	66,131	53,401
Loss from operations	(37,201)	(29,055)	(66,131)	(53,401)
Other income (expense):				
Interest income	1,460	146	2,940	231
Other income (expense)	(11)	3	(21)	10
Total other income (expense)	1,449	149	2,919	241
Net loss and comprehensive loss	$ (35,752)	$ (28,906)	$ (63,212)	$ (53,160)

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

	June 30, 2023	**December 31, 2022**
Cash and cash equivalents	$ 168,693	$ 215,507
Total assets	179,637	225,736
Total current liabilities	33,653	23,131
Total liabilities	55,121	45,397
Total stockholders' equity	124,516	180,339
Total liabilities and stockholders' equity	179,637	225,736