



## BioAtla Reports First Quarter 2023 Financial Results and Highlights Recent Progress

May 11, 2023 at 4:01 PM EDT

- Advancing CAB-AXL BA3011 in ongoing sarcoma Phase 2 studies including a potentially registrational study in Undifferentiated Pleomorphic Sarcoma (UPS); expect Leiomyosarcoma (LMS) cohort readout in 2H23
- On track for submitting a meeting request to the Food & Drug Administration (FDA) for the potentially registrational BA3011 Phase 2, part 2 non-small cell lung cancer (NSCLC) study in 1H23; FDA feedback and initiation of Phase 2, part 2 remain on track for 2H23
- Enrolling BA3021 Phase 2 NSCLC study including more frequent, dose-intensive regimen; anticipated interim readout remains on track for 2H23
- Enrolling CAB-ROR2 BA3021 Phase 2 squamous cell carcinoma of the head & neck (SCCHN) study as anticipated
- Phase 1 dose-escalation CAB-CTLA-4 (BA3071) study ongoing including with PD-1 combination; anticipated data readout and initiation of Phase 2 remain on track for 2H23
- FPI anticipated for CAB-EpCAM x CAB-CD3 bispecific T-cell engager (TCE) (BA3182) Phase 1 study in 1H23
- Cash balance of \$192.7 million expected to provide funding into 2025
- Management to host conference call and webcast today at 4:30 PM Eastern Time

SAN DIEGO, May 11, 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 first quarter ended March 31, 2023, and provided highlights on its clinical programs.

"BioAtla continues to progress our robust CAB pipeline, including our Phase 2, part 2 potentially registrational BA3011 UPS study and successful identification of ROR2-positive tumors using our validated CTC assay in metastatic melanoma patients," said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. "BioAtla has several important milestones and value inflection points that remain on track for this year, including initiation of our Phase 2, part 2 potentially registrational BA3011 trial in NSCLC following anticipated FDA feedback, Phase 2 interim readout for BA3021 in NSCLC, Phase 1 data readout for our CAB-CTLA-4 basket trial and initiation of our Phase 2 BA3071 trial in multiple indications. In addition, we are opening centers for our first CAB bispecific antibody, BA3182 for the potential treatment of adenocarcinomas, while continuing to manage our resources to carry the company into 2025. Importantly, all of our programs are focused on providing novel cancer therapies for patients with high unmet medical need."

### 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:
      - Continue to enroll multiple cohorts
      - Anticipated LMS cohort data readout remains on track for 2H23 using the more frequent, dose-intensive regimen
    - Phase 2, part 2:
      - Continue to enroll in potentially registrational Phase 2 UPS study
  - **AXL-positive NSCLC (BA3011, NCT04681131)**
    - Phase 2, part 1:
      - Continuing to enroll more frequent, dose-intensive regimen; anticipated data readout remains on track for 2H23
    - Phase 2, part 2:
      - On-track to submit study design in 1H23; anticipate FDA feedback in 2H23
      - Initiate potentially registrational study; anticipated 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; anticipated interim data readout remains on-track for 2H23
  - **ROR2-positive melanoma (BA3021, NCT03504488)**
    - Identifying ROR2-positive tumors using liquid biopsy assay
    - Anticipate increased enrollment in 2H23
  - **ROR2-positive SCCHN (BA3021, NCT05271604)**

- Continuing to enroll patients; ROR2 positivity rate remains high as anticipated
  - **ROR2-positive platinum-resistant ovarian cancer (BA3021, NCT04918186)**
    - Phase 2 investigator-initiated trial is on track with interim data (n=10) anticipated in 2H23
- **Phase 1/2 dose-escalation trial of CAB-CTLA-4 (BA3071, NCT05180799) across multiple solid tumor types responsive to CTLA-4**
  - Enrolling 350mg (5mg/kg) 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
- **FDA clearance of IND for CAB-EpCAM x CAB-CD3 TCE (BA3182)**
  - FPI for Phase 1 study anticipated for 1H23 for the treatment of advanced adenocarcinoma
- **Potential additional IND submissions for pre-clinical CAB bispecific and next generation ADC candidates in 2023 through 2024**
- **Several accepted and upcoming poster presentations, including online publication and Trials in Progress (TiP) poster presentation at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting, to be held June 2-6, titled:**
  - Online publication, "Population Pharmacokinetic and Exposure-Response Safety Analyses of Mecbotamab Vedotin (BA3011) in Patients with Advanced Solid Tumors"
  - TiP poster, "A Phase 2 Open-Label Study of Conditionally Active Biologic, Ozuriftamab Vedotin (BA3021) in PD-1/L1 Failure Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck"

#### **First Quarter 2023 Financial Results**

Cash and cash equivalents as of March 31, 2023 were \$192.7 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 \$21.7 million for the quarter ended March 31, 2023 compared to \$16.9 million for the same quarter in 2022. The increase of \$4.8 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 \$7.2 million for the quarter ended March 31, 2023 compared to \$7.4 million for the same quarter in 2022. The \$0.2 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 first quarter ended March 31, 2023 was \$27.5 million compared to a net loss of \$24.3 million for the same quarter in 2022.

Net cash used in operating activities for the first quarter ended March 31, 2023 was \$22.7 million compared to net cash used in operating activities of \$25.1 million for the same period in 2022.

#### **First Quarter 2023 Conference Call and Webcast Details**

The management of BioAtla, Inc. will host a conference call and webcast for the investment community today, May 11, 2023, at 4:30 pm Eastern Time. A live webcast may be accessed here: [https://viaid.webcasts.com/starthere.jsp?ei=1609324&tp\\_key=f982141e9d](https://viaid.webcasts.com/starthere.jsp?ei=1609324&tp_key=f982141e9d). 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 13737960.

A replay of the webcast and updated slides 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 and for 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, PD-L1-blocking antibody, in patients with platinum-resistant ovarian cancer, with 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 CD3 $\epsilon$ . The binding sites for EpCAM and CD3 $\epsilon$  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 CD3 $\epsilon$  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<sup>®</sup>, 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 716 patents (440 issued, 7 allowed, and 269 pending). 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](http://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, plans to advance our clinical trials for mecbotamab vedotin, BA3011, for ozuriftamab vedotin, BA3021, and for CAB-CTLA-4, BA3071, in multiple indications, whether our clinical trials will support registration; 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 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 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, 2022 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](mailto:rwaldron@bioatla.com)  
858.356.8945

#### **External Contact:**

Bruce Mackle  
LifeSci Advisors, LLC  
[bmackle@lifesciadvisors.com](mailto:bmackle@lifesciadvisors.com)

**BioAtla, Inc.**  
**Unaudited Condensed Statements of Operations and Comprehensive Loss**  
(in thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Operating expenses:		
Research and development expense	\$ 21,697	\$ 16,923
General and administrative expense	7,233	7,423
Total operating expenses	28,930	24,346
Loss from operations	(28,930)	(24,346)
Other income (expense):		
Interest income	1,480	85
Other income (expense)	(10)	7
Total other income (expense)	1,470	92
Consolidated net loss and comprehensive loss	\$ (27,460)	\$ (24,254)

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

	<b>March 31,</b>	<b>December 31,</b>
	<b>2023</b>	<b>2022</b>
Cash and cash equivalents	\$ 192,687	\$ 215,507
Total assets	204,552	225,736
Total current liabilities	26,256	23,131
Total liabilities	48,125	45,397
Total stockholders' equity	156,427	180,339
Total liabilities and stockholders' equity	204,552	225,736