BioAtla Announces FDA Clearance of Investigational New Drug Application for BA3182, a CAB-EpCAMxCAB-CD3 Bispecific T-Cell Engager for the Treatment of Advanced Adenocarcinoma

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- **Following the IND clearance, the Company is advancing into a Phase 1 clinical study**
- **Potentially addressing most common subtypes of adenocarcinoma including colon, lung, breast, pancreas, and prostate**

SAN DIEGO, Feb. 23, 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 that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application to evaluate BA3182 (CAB-EpCAMxCAB-CD3 bispecific T-cell engager) for the treatment of advanced adenocarcinoma. BioAtla plans to initiate and advance a Phase 1 dose-escalation and expansion clinical study in 2023.

The high-level expression of EpCAM in solid tumors has made it an attractive target for antibody molecules to treat epithelial cancers, particularly adenocarcinomas. However, EpCAM is also highly prevalent on normal cells. EpCAM/CD3 bispecific antibodies developed by others have shown beneficial clinical outcomes in cancer patients, but have been hampered by dose limiting toxicities due to wide target distribution in normal tissues and potent T cell activation. *In vitro* studies have shown that our dual CAB bispecific antibody, BA3182, binds to the target proteins, human EpCAM and human CD3, with high specificity and affinity under the characteristic acidic conditions of the tumor microenvironment (TME), while its binding is highly reduced under normal cells' alkaline physiological conditions (pH 7.4). *In vivo* studies with BA3182 indicate that the therapeutic index was improved more than 100-fold relative to non-CAB variants, supporting the potential differentiation of CAB bispecific antibodies versus more traditional bispecific antibodies.

"While we continue to advance our CAB-ADC and CAB immuno-oncology antibodies across multiple tumor types, we are now expanding our pipeline with the recent FDA IND clearance for our potentially first-in-class bispecific antibody, BA3182," said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla. "Our goal is to continue executing and pursuing indications with large unmet medical need that potentially have the highest impact for patients and our shareholders worldwide. We believe our current cash position is sufficient to fund our operations into 2025 through several value generating milestones for our current clinical programs as well as the initiation of the BA3182 clinical trial."

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 Adenocarcinoma

Adenocarcinoma is the most common subtype of carcinoma that may occur almost anywhere in the body, starting in glands that line the insides of the organs, forming in glandular epithelial cells, which secrete mucus, digestive juices, or other fluids. It is often identified by its specific type, such as exocrine cancer in the pancreas, invasive ductal carcinoma in the breast or endometrial cancer in the uterus. Adenocarcinoma is most prevalent in the lung, prostate, breast, pancreas, esophagus, colon/rectum and stomach. Almost all prostate and breast cancers are adenocarcinoma, and about 96% of colorectal and 40% of non-small cell lung cancers are adenocarcinoma (American Cancer Society 2022).

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 704 patents (430 issued, 5 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 prevalent 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; 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 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 February 28, 2022 and in our Quarterly Reports on Form 10-Q filed with the SEC on May 5, 2022, August 9, 2022 and November 4, 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.

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