BioAtla Announces FDA Clearance of Investigational New Drug Application for BA3361, a CAB-Nectin-4 Antibody Drug Conjugate for the Treatment of Multiple Tumors

May 6, 2024 at 8:00 AM EDT

SAN DIEGO, May 06, 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 that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application to evaluate BA3361 (CAB-Nectin-4) antibody drug conjugate (ADC) for the treatment of multiple tumor types.

ADC is a promising treatment modality with broad applicability across multiple tumor indications. The CAB technology is designed to eliminate or reduce both on-target, off-tumor and off-target, off-tumor toxicities. At the AACR Annual Meeting in April 2024, data showed differentiated anti-Nectin-4-ADC via *in vitro* and *in vivo* characterization of its novel next-generation carbohydrate linker system. The NextGen linker system helped eliminate off-target, off-tumor toxicity with substantially improved serum stability and increased hydophilicity thereby improving potency. BioAtla's CAB NextGen anti-Nectin-4-ADC demonstrated: complete tumor regression observed in several cell line derived xenograft models, superior efficacy to an enfortumab vedotin analogue in a patient-derived xenograft pancreatic cancer model, and reduced toxicity through CAB selectivity. BA3361 is the Company's first glycoconjugate CAB-Nectin-4-ADC.

"BioAtla continues to demonstrate differentiated product candidates through the use of the CAB technology with this most recent FDA IND clearance of our first glycoconjugate, CAB-Nectin-4-ADC, BA3361," said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. "We are excited to advance Nectin-4 as a target, particularly since the combination of our CAB technology with the NextGen linker system offers the opportunity to maximize the therapeutic index and expand indications across multiple tumor types."

About BA3361
BA3361, CAB-Nectin4-ADC, is a conditionally and reversibly active antibody drug conjugate directed against Nectin4, a cell-cell adhesion molecule overexpressed in multiple human malignancies. The Nectin4-binding domains of BA3361 have been optimized for binding under tumor microenvironment (TME) conditions and reduced binding under normal physiological conditions. BA3361 is the first molecule containing one of BioAtla's novel NextGen ADC linkers with improved stability and tumor specific payload release. BA3361 showed superior activity in patient-derived pancreatic cancer xenograft models.

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 485 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, 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 2 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 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 our business plans and prospects and 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; plans to form 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 expected R&D 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; 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 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
858.356.8945

External Contact:
Bruce Mackle
LifeSci Advisors, LLC
bmackle@lifesciadvisors.com