



BioAtla Granted FDA Fast Track Designation for Ozuriftamab Vedotin (CAB-ROR2-ADC) for Treatment of Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck

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Ozuriftamab vedotin, the Company's conditionally and reversibly active antibody drug conjugate directed against ROR2, has shown promising clinical activity with a manageable safety profile in treatment-refractory patients with squamous cell carcinoma of the head and neck (SCCHN) in its Phase 2 clinical trial

The Company is on track to meet with the FDA for guidance on a potentially registrational trial in 2H 2024

SAN DIEGO, July 23, 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 granted Fast Track Designation (FTD) to ozuriftamab vedotin, the Company's conditionally and reversibly active ROR2 antibody drug conjugate directed for the treatment of patients with recurrent or metastatic SCCHN with disease progression on or after platinum-based chemotherapy and anti-PD-1/L1 antibody therapy.

"The FDA's decision is an important recognition of the potential of our CAB-ROR2-ADC, ozuriftamab vedotin. There remains a significant unmet need in refractory head and neck cancer where previous treatments have failed and current outcomes are suboptimal with low response rates," said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. "To date, ozuriftamab vedotin has shown promising clinical activity in treatment-refractory SCCHN patients who had a median of 3 prior lines of therapy. In addition, ozuriftamab vedotin continues to have a manageable safety profile with no new safety signals. We look forward to discussing with the FDA plans for a potential registrational trial in the second half of this year."

Fast Track Designation applies to a drug that is intended to treat a serious or life-threatening disease or condition and where the drug has demonstrated the potential to address unmet medical need. It could lead to actions to expedite development and review of the drug, including opportunities for frequent interactions with the FDA review team and potential priority review if supported by the clinical data at the time of a BLA submission.

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, TNBC 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 the treatment of SCCHN patients who have previously progressed on PD-1/L1 therapies with or without platinum chemotherapy.

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 750 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 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 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. BioAtla recently received FDA IND clearance on its next-gen CAB-Nectin4-ADC, BA3361, the Company's first glycoconjugate. 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 the timing of our research and development programs and clinical trials. 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, in our Quarterly Report on Form 10-Q filed with the SEC on May 14, 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.

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