BioAtla Announces FDA Clearance of Investigational New Drug Application For CAB-ROR2-ADC Therapeutic

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CAB-ROR2-ADC to be clinically tested for treatment of several solid tumor cancers

SAN DIEGO, CA - April 16, 2018 - BioAtla, LLC, a global biotechnology company focused on the development of Conditionally Active Biologic (CAB) protein therapeutics, announced today the U.S. Food and Drug Administration (FDA) has cleared BioAtla's Investigational New Drug application (IND) for BA3021, a first-in-class conditionally active ROR2-targeted antibody-drug conjugate (CAB-ROR2-ADC), in patients with solid tumors. Under this IND, the company intends to initiate a first-in-human, open label, multicenter, dose escalation and dose expansion study of CAB-ROR2-ADC in patients with locally advanced or metastatic solid tumors. CAB-ROR2-ADC will be BioAtla's second CAB investigational product to enter clinical trials in the United States with BioAtla initiating patient dosing in February of this year with CAB-AXL-ADC for treatment of solid tumors.

ROR2 is a developmentally restricted receptor tyrosine kinase (RTK) that interacts with Wnt ligands. Although essential for embryonic development, ROR2 expression is rare in normal adult tissues. Many of the activities associated with ROR2 in development have been implicated also in cancer including cell migration and invasiveness. ROR2 has been found to be overexpressed in multiple types of cancer including breast, renal, colorectal, melanoma, pancreatic, non-small cell lung cancer (NSCLC), and gastrointestinal stromal tumor (GIST). In general, ROR2 expression is associated with more aggressive disease states and poorer patient prognosis. Furthermore, recent studies by others indicate that overexpression of either ROR2 or AXL receptor is associated with resistance to anti-PD-1 therapy thereby suggesting immuno-oncology roles for BioAtla's first two clinical stage CAB candidates that target these receptors.

ROR2 is a cell surface Wnt5a receptor that is overexpressed in cancer cells making it an attractive target for therapy. BioAtla applies its proprietary CAB technology to develop its CAB antibody-drug conjugate (ADC) targeting ROR2 with the intent to activate binding to the ROR2 receptor in the tumor microenvironment and deliver the toxic payload only to the cancerous cells.

About Conditionally Active Biologics (CABs)

Conditionally Active Biologic proteins are generated using BioAtla's proprietary protein discovery, evolution and expression technologies. These proteins can be monoclonal antibodies, enzymes and other proteins designed with functions dependent on changes in microphysiological conditions (*e.g.*, pH level, oxidation, temperature, pressure, presence of certain ions, hydrophobicity and combinations thereof) both outside and inside cells.

Studies have shown that cancerous tumors create highly specific conditions at their site that are not present in normal tissue. These cancerous microenvironments are primarily a result of the well understood unique glycolytic metabolism associated with cancer cells, referred to as the Warburg Effect. CAB proteins are designed to deliver their therapeutic payload and/or recruit the immune response in specific and selected locations and conditions within the body and to be active only in the presence of a particular cellular microenvironment. In addition, the activation is designed to be reversible to repeatedly switch â€˜on and off' should the CAB move from a diseased to a normal cellular microenvironment and vice versa. CABs can be developed in a variety of formats including antibodies, antibody drug conjugates (ADCs), bi-specifics, chimeric antigen receptor T-cells (CAR-Ts) and combination therapies.