BioAtla Announces FDA Clearance of IND Application for CAB-AXL-ADC Therapeutic

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

SAN DIEGO, CA - January 24, 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 BA3011, a novel conditionally active AXL-targeted antibody-drug conjugate (CAB-AXL-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-AXL-ADC in patients with locally advanced or metastatic solid tumors. CAB-AXL-ADC will be BioAtla's first CAB investigational product to enter clinical trials in the United States.

The AXL receptor tyrosine kinase is often highly expressed in several cancer types that can lead to poor prognosis. A principal role of AXL appears to be in sustaining a major mechanism of resistance to diverse anticancer therapies. In addition, AXL is a factor in the repression of the innate immune response which may also limit response to treatment including immuno-oncology (IO) therapy. While this makes the AXL receptor an attractive target for tumor therapy, the AXL receptor is also prevalent in normal tissue of several organs in the body. To minimize on-target-off-tumor toxicity of binding to AXL receptors on normal cells, BioAtla applies its proprietary CAB technology to develop its CAB antibody-drug conjugate (ADC) targeting AXL with the intent to activate binding to the AXL receptor only in the tumor microenvironment and deliver the toxic payload 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.