

Evaxion Biotech announces dosing of first patient in the Phase 1/2a study NeoPepVac of a personalized neoepitope immunotherapy (EVX-01) in combination with PD-1/PD-L1 checkpoint inhibitors in solid tumors

- *EVX-01 is a personalized peptide immunotherapy using artificial intelligence (AI), targeting neoepitopes in melanoma, non-small cell lung cancer (NSCLC) and bladder cancer*
- *EVX-01 combined with PD-1/PD-L1 blockade represents a novel combination approach in immuno-oncology*
- *First Evaxion clinical program in the new field of cancer immunotherapy targeting neoepitopes*
- *Initial clinical data expected in first half of 2020*

Copenhagen, Denmark, April 3, 2019 - Evaxion Biotech, a clinical-stage biotechnology company specializing in the development of innovative AI-driven immunotherapies to improve the lives of patients with cancer and infectious diseases, announced today the dosing of the first patient in a Phase 1/2a first-in-human clinical trial NeoPepVac of its lead cancer immunotherapy candidate, EVX-01, in combination with anti-PD-1/PD-L1 therapy. EVX-01, a novel personalized cancer neoepitope immunotherapy based on Evaxion's PIONEER artificial intelligence (AI) technology is being developed for the treatment of patients with melanoma, non-small cell lung cancer (NSCLC) and bladder cancer.

As a novel immunotherapy, EVX-01 is designed to engage the immune system to mount a targeted response against neoepitope-expressing solid tumors. Evaxion believes that its state-of-the-art neoepitope detection technology PIONEER in combination with the improved cytokine activation profile observed in preclinical studies of EVX-01 could offer a potential efficacy advantage with reduced toxicities compared to other neoepitope cancer immunotherapies. Moreover, there is a shorter turnaround time (7 weeks) in manufacturing EVX-01 compared to other personalized neoepitope immunotherapies.

"Today's news represents an important milestone for cancer patients and for Evaxion," said Dr. Lars Staal Wegner, CEO for Evaxion. "There is a strong unmet medical need for novel immunotherapies to treat patients with relapsed or refractory solid tumors. Current therapies, including checkpoint inhibitors, which is the standard of care for these patients, are active only in a fraction of patients, and patients are still confronted with high relapse rates."

"We are pleased to have started the first clinical study for EVX-01," commented Dr. Thomas Bogenrieder, Chief Medical Officer of Evaxion. "Despite significant recent advances in cancer immunotherapy, immune escape of tumor cells remains a major challenge. We believe that EVX-01 has a high potential for cancer patients in multiple indications and could play an important role in checkpoint inhibitor combination strategies for patients who are non-responsive, have a poor response or who have stopped responding to anti-PD-1/PD-L1 immunotherapies. Recent clinical data have demonstrated that neoepitopes are validated targets for cancer immunotherapy. We are particularly excited to begin clinical evaluation of EVX-01 as our preclinical data suggest that it possesses important attributes and could offer benefits compared to current investigational

therapies. Most importantly, we believe this program has the potential to change the treatment of cancer and help patients.”

“EVX-01 is our first personalized neoepitope immunotherapy candidate developed based on Evaxion’s next-generation PIONEER platform to enter the clinic,” continued Dr. Staal Wegner. “Our next-generation PIONEER platform has been optimized to identify neoepitopes in cancer patients to achieve enhanced biological activity and an improved therapeutic index. The recent clinical data for neoepitope immunotherapies looks very promising, and we are eager to see if the advantages shown in preclinical studies with EVX-01 will be confirmed in the clinic. We anticipate reporting initial clinical data from the trial in the first half of 2020.

“We expect that this study will generate important insights about the utility of personalized neoepitope immunotherapies among patients with melanoma, NSCLC or bladder cancer, for whom we still need new effective treatment options,” said the sponsor of the clinical trial, Professor Inge-Marie Svane, M.D., Ph.D., Center for Cancer Immune Therapy (CCIT), Copenhagen University, Hospital Herlev. “This research furthers the field of cancer immunotherapy and has the potential to advance treatment options for patients with multiple cancer types, including patients with otherwise poor response to checkpoint inhibitors.”

The NeoPepVac consortium is a part of Evaxion’s’ strategic collaboration with CCIT Copenhagen University, DTU Health Tech and the Center for Vaccine Research at Statens Serum Institute (SSI). The goal of the collaboration is to discover, develop and deliver novel, disease-altering oncology therapies based on Evaxion’s artificial intelligence research platform PIONEER. This program has been supported by the Innovation Fund Denmark.

About the Study

This open-label Phase 1/2a clinical trial will evaluate the safety, tolerability, immune response markers, and overall response rates achieved with NeoPepVac in combination with anti-PD-1/L1 inhibitor treatment in up to 25 patients across three groups: cutaneous melanoma, NSCLC and bladder cancer. Please refer to www.clinialtrials.gov for additional clinical trial details.

About Neoepitopes and Cancer

The connection between cancer and neoepitopes has been the central focus for scientists at Evaxion, who were amongst the first to acknowledge the important role of neoepitopes in cancer immunology and as novel therapeutic targets in cancer. Recent insights revealed the potential of targeting neoepitopes with personalized immunotherapies in solid tumor malignancies. Evaxion believes that inhibition of these mutated proteins with a personalized immunotherapy may lead to clinical benefit for cancer patients and offers the potential to treat multiple cancer types that are otherwise poorly responsive to checkpoint inhibitors.

About Evaxion Biotech

Apart from infectious diseases, Evaxion Biotech is focused on discovering and developing novel drugs to treat cancer, through scientific leadership in the field of neoepitopes. In addition to an active research and discovery pipeline across these two therapeutic areas, Evaxion has multiple first-in-class lead product candidates in the fields of cancer immunotherapy and infectious disease

vaccines. All Evaxion programs focus on genetically identified antigens, leveraging our knowledge of antigens, immunology and genomics. For more information, please visit our website at www.evaxion-biotech.com.

Forward-Looking Statements

This release, like many written and oral communications presented by Evaxion Biotech, and our authorized officers, may contain certain forward-looking statements regarding our prospective performance and strategies within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of said safe harbor provisions. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of the Company, are generally identified by use of words "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "seek," "strive," "try," or future or conditional verbs such as "could," "may," "should," "will," "would," or similar expressions. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Except as required by applicable law or regulation, Evaxion undertakes no obligation to update these forward-looking statements to reflect events or circumstances that occur after the date on which such statements were made.