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Evaxion's AI technology identifies cancer vaccine targets associated with longer progression-free survival of melanoma patients in the EVX-01 Phase 1 clinical trial

- *The clinical trial of the personalized cancer vaccine EVX-01 met its primary endpoints of safety and tolerability*
- *Positive clinical responses were reported in 8 out of 12 EVX-01 treated patients*
- *High-quality neoantigens, predicted by AI technology, were associated with longer progression-free survival*
- *Strong vaccine-specific immune responses were induced in all 12 EVX-01 treated patients*
- *Higher EVX-01 dose induced a stronger immune response and was associated with improved clinical outcome*

COPENHAGEN, Denmark, June 03, 2023 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX) ("Evaxion" or the "Company"), a clinical-stage biotechnology company specializing in the development of AI-powered immunotherapies, today presented promising clinical data from its EVX-01 Phase 1 dose escalation trial in metastatic melanoma at the 2023 ASCO annual meeting in Chicago, Illinois.

The Phase 1 trial successfully met primary endpoints for safety and tolerability of EVX-01 in metastatic melanoma patients and demonstrated positive clinical responses in 8 out of 12 (67%) treated patients. In addition, Evaxion's proprietary AI technology PIONEER™ was able to identify high-quality cancer vaccine targets, so-called neoantigens, associated with longer progression-free survival.

"We are excited that our AI technology could effectively identify vaccine neoantigens associated with better clinical responses and longer progression-free survival. And the data suggest a treatment effect, with response rates nearly double of those observed in historical data for checkpoint inhibitors. Our findings in this study position us well to prospectively identify patients who will benefit from personalized cancer immunotherapy for our upcoming trials, potentially making the benefit for patients even greater," said Per Norlén, Chief Executive Officer of Evaxion.

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The study demonstrated the ability of the PIONEER™ platform to identify vaccine targets that are associated with improved patient outcomes. Stratification based on PIONEER™ scores outperformed tumor mutational burden as a predictive biomarker, with patients having high-quality neoantigens showing better treatment responses and longer progression-free survival.

The evaluation of treatment-related immune responses revealed strong neoantigen T-cell responses in all 12 patients, mediated by activated CD4+ T cells in all cases and CD8+ T cells in 7 out of 12 patients. Further, immune response magnitude correlated with the vaccination dose.

“The positive association between clinical outcome and prevalence of immunogenic cancer neoantigens validates the PIONEER™ platform for its use for personalized cancer vaccines and emphasizes the importance of a robust AI system for designing neoantigen vaccines. Moreover, the dose-dependent increase in responses has been instrumental for Phase 2 dose selection in the ongoing clinical trial. We have great expectations on the upcoming interim Phase 2 results that are planned to be presented later this year,” Per Norlén continues.

About the Phase 1 Study with EVX-01

The open-label, single-arm, single-center Phase 1 study, titled “Personalized Neo-antigen Vaccine in Advanced Solid Tumors (NeoPepVac)” (ClinicalTrials.gov Identifier: [NCT03715985](https://clinicaltrials.gov/ct2/show/study/NCT03715985)), was conducted in collaboration with DTU, SSI, the center for genomic medicine at Rigshospitalet and CCIT-DK and aimed to assess the safety and efficacy of EVX-01 vaccine in combination with anti-PD1 (pembrolizumab or Nivolumab) in patients with metastatic melanoma. The design consisted of multiple 15-27mer peptides comprising one or more patient-specific neoantigens formulated with the novel liposomal adjuvant CAF®09b to potentiate immune responses. The primary objective was to determine the safety and tolerability of the combination of EVX-01 and a checkpoint inhibitor. Additional objectives were to evaluate manufacturing feasibility, immune responses, and clinical efficacy.

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About Evaxion Biotech

Evaxion Biotech A/S is a clinical-stage biotech company focused on harnessing the power of artificial intelligence to decode the human immune system and develop immunotherapies for cancer, bacterial diseases, and viral infections. Through its proprietary AI platform, PIONEER™, Evaxion aims to revolutionize cancer treatment by identifying unique and immunogenic neoantigens and designing individualized therapies. The Company is committed to transforming the lives of cancer patients with unmet clinical needs by providing innovative and targeted treatment options. For more information about Evaxion Biotech and its groundbreaking personalized cancer immunotherapies, please visit www.evaxion-biotech.com.

Forward-looking statement

This announcement contains forward-looking statements 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. The words "target," "believe," "expect," "hope," "aim," "intend," "may," "might," "anticipate," "contemplate," "continue," "estimate," "plan," "potential," "predict," "project," "will," "can have," "likely," "should," "would," "could," and other words and terms of similar meaning identify forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including, but not limited to, risks related to: our financial condition and need for additional capital; our development work; cost and success of our product development activities and preclinical and clinical trials; commercializing any approved pharmaceutical product developed using our AI platform technology, including the rate and degree of market acceptance of our product candidates; our dependence on third parties including for conduct of clinical testing and product manufacture; our inability to enter into partnerships; government regulation; protection of our intellectual property rights; employee matters and managing growth; our ADSs and ordinary shares, the impact of international economic, political, legal, compliance, social and business factors, including inflation, and the effects on our business from the worldwide COVID-19 pandemic and the ongoing conflict in the region surrounding Ukraine and Russia; and other uncertainties affecting our business operations and financial condition. For a further discussion of these risks, please refer to the risk factors included in

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our most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. We do not assume any obligation to update any forward-looking statements except as required by law.

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