

EVAXION

Evaxion announces promising results from Phase 1/2a clinical trial of personalized DNA cancer immunotherapy EVX-02

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COPENHAGEN, Denmark, Nov. 17, 2022 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX) ("Evaxion" or the "Company"), a clinical-stage biotechnology company specializing in the development of AI-driven immunotherapies, today announced promising clinical data from the Phase 1/2a first-in-human study of its DNA-based cancer immunotherapy, EVX-02.

In the clinical study, EVX-02 is given in combination with a checkpoint inhibitor and targets cancer mutations, neoantigens, in patients with resected melanoma. The Company reported encouraging interim safety and immunogenicity data from the Phase 1/2a study of its personalized DNA-based immunotherapy, EVX-02. The results are summarized below.

"We are thrilled to announce promising interim data from the first eight patients in our Phase 1/2a study of EVX-02. We believe that these results serve as validation of our DNA technology for personalized cancer immunotherapy. All patients demonstrated a specific T-cell immune response induced by the treatment, confirming the potential capabilities of our AI platform technology. And importantly, the treatment appeared to be well tolerated in all patients, with only very mild adverse events (AEs) observed," said CEO Per Norlén.

Personalized cancer immunotherapy, like EVX-02, is particularly challenging to produce because a new and unique drug is manufactured for each patient.

"This is a tremendous achievement. Our team has successfully completed this complex process, from biopsy, through genome sequencing, a selection of the most promising cancer targets through our AI platform technology, to manufacturing, quality testing, and drug product production and delivery. And they succeeded with every single step for each patient," says Mr. Norlén.

"The promising EVX-02 data, demonstrating both proof of mechanism and an encouraging safety profile, give us exactly what we need for our upcoming clinical trial of EVX-03 and our next-generation DNA technology."

Interim results in summary:

- Safety: Treatment appeared to be well tolerated in all patients, with only very mild adverse events (AEs) observed in relation to EVX-02 treatment.
- EVX-02 induced CD4+ and CD8+ specific T-cell responses in all patients, providing proof of mechanism for our DNA-delivery technology, in that the delivered EVX-02-DNA gave rise to immune reactions to its encoded neoantigen peptides.
- The T-cell responses were robust and long-lasting.

A full clinical trial report for the EVX-02 Phase 1 study is expected in the second quarter of 2023.

About Evaxion

Evaxion Biotech A/S is a clinical-stage biotech company developing AI-powered immunotherapies. A proprietary and scalable AI technology is used to decode the human immune system to discover and develop novel immunotherapies for cancer, bacterial diseases, and viral infections. Evaxion has a broad pipeline of novel product candidates, including patient-specific cancer immunotherapies. It is located in Hørsholm, Denmark, with 70 employees.

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Source: Evaxion Biotech

Forward-looking statement

This announcement contains forward-looking statements that involve substantial risks and uncertainties. All statements, besides those of historical facts, included in this announcement regarding the Company's future operations, plans and objectives are forward-looking. Although the Company believes its expectations are based on reasonable assumptions, all statements other than statements of historical fact included in this announcement about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by, or including words such as "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 or the negative thereof. 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 associated with the Company's financial condition and need for additional

capital; risks associated with the Company's development work; cost and success of the Company's product development activities and preclinical and clinical trials; risks related to commercializing any approved pharmaceutical product developed using the Company's AI platform technology, including the rate and degree of market acceptance of the Company's product candidates; risks related to the Company's dependence on third parties including for conduct of clinical testing and product manufacture; risks associated with the Company's inability to enter into partnerships; risks related to government regulation; risks associated with protection of the Company's intellectual property rights; risks related to employee matters and managing growth; risks related to the Company's ADSs and ordinary shares, risks associated with the pandemic caused by the coronavirus known as COVID-19 and the emergence and prevalence of COVID-19 variants, such as the Delta and Omicron variant and certain related variants such as the Omicron BA.4 and BA.5 variants, risks associated with the invasion of the Ukraine by Russia and other risks and uncertainties affecting the Company's business operations and financial condition.

Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results, performance, or achievements to be materially different from the expected results, performance, or achievements expressed or implied by such forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the Company's business in general, see the risks described in the "Risk Factors" section included in the Company's Annual Report on Form 20-F filed on March 31, 2022 and the Company's current and future reports filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC). Any forward-looking statements contained in this announcement speak only as of the date hereof, and except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

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Source: Evaxion Biotech