EVAXION

Evaxion announces promising clinical data for DNA-based personalized cancer immunotherapy EVX-02: Phase 1/2a trial met both primary and secondary endpoints

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- All 10 patients with late stage melanoma who completed EVX-02 treatment demonstrated robust and treatment-specific immune responses and were relapse-free at their last assessment
- Results further validate predictive potential of proprietary AI technology and pave the way for advancement of EVX-03, a next-generation DNA-based personalized cancer immunotherapy, into the clinic in Q4

COPENHAGEN, Denmark, April 18, 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 Phase 1/2a first-in-human study of its DNA-based personalized cancer immunotherapy, EVX-02 in combination with the checkpoint inhibitor nivolumab. Data were presented in the Late Breaking Research: Clinical Research 2 session at the 2023 AACR (American Association for Cancer Research) meeting in Orlando, Florida.

The study, in patients with resected melanoma, showed that:

- All 10 patients who received the full dosing schedule of 8 immunizations with EVX-02 were relapse-free at their last assessment
- Of these 10 patients, 9 completed the full study and were relapse-free at the 12-month end of study visit. One patient was prematurely terminated due to non-EVX-02 related adverse events (AEs), and was relapse-free at the last visit at 9 months
- The combination of EVX-02 and nivolumab was well tolerated and only mild EVX-02-associated AEs were observed
- Robust and long-lasting neoantigen-specific T-cell immune responses were confirmed in all EVX-02 completers
- The induced T-cell immune responses involved both CD4+ and CD8+ T cells

"We are extremely happy to share the positive clinical data from our Phase 1/2a EVX-02 study at AACR. We met both our primary endpoints on safety, tolerability and immunogenicity and our secondary endpoint on clinical efficacy. With all 10 patients who completed the EVX-02 treatment being relapse-free during the trial and with robust and treatment-specific immune responses, we see clear signs of a protective cancer vaccination effect," said Per Norlén, Chief Executive Officer of Evaxion. "The EVX-02 data affirm our ability to select the right neoantigens, matched to the cancer of each patient, and provide further validation of our AI platform PIONEER™. They also support our plan to fast track our next-generation DNA-based personalized cancer immunotherapy, EVX-03, to the clinic in Q4."

About the Phase 1/2a Study with EVX-02

The open-label, single-arm, multi-center Phase 1/2a study (NCT04455503) was designed to evaluate the combination of EVX-02 plus nivolumab in patients who had undergone complete surgical resection of late stage melanoma and were at high risk for recurrence. The primary objectives of the 12-month study were to assess the safety, tolerability and immunogenicity of EVX-02 plus nivolumab. In addition, the study was intended to evaluate relapse free survival. Evaxion reported initial, interim safety and immunogenicity data from the first 8 patients in the study in November 2022.

About Evaxion

Evaxion Biotech A/S is a clinical-stage biotech company developing AI-powered immunotherapies. Evaxion's proprietary and scalable AI technologies decode the human immune system to discover and develop novel immunotherapies for cancer, bacterial diseases, and viral infections. Evaxion has a broad pipeline of product candidates, including three personalized cancer immunotherapies. The company is located in Hørsholm, Denmark, and is listed on the Nasdaq New York stock exchange. For more information, please visit: www.evaxion-biotech.com.

Source: Evaxion Biotech

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 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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