

## Evaxion reports convincing one-year data from phase 2 trial on AI-designed personalized cancer vaccine EVX-01

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- 11 out of 16 patients had objective clinical responses, equaling a 69% Overall Response Rate
- 15 out of the 16 patients had a reduction of their tumors (target lesions)
- 79% of EVX-01s vaccine targets triggered a targeted immune response, which compares very favorably to what is seen with other approaches
- A positive correlation was observed between the AI-Immunology™ platform predictions and neoantigen immune response (p=0.00013)
- EVX-01 as a novel potential melanoma treatment holds a significant commercial potential for Evaxion
- Data will be discussed at a webinar with key opinion leader Professor Georgina V. Long on September 18, 2024

COPENHAGEN, Denmark, Sept. 16, 2024 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX) ("Evaxion"), a clinical-stage TechBio company specializing in developing AI-Immunology™ powered vaccines, announces positive one-year data from the ongoing phase 2 trial with its lead asset EVX-01, an AI-designed personalized cancer vaccine.

"We are thrilled to present this groundbreaking data, which underscores the significant therapeutic potential of EVX-01. Among several promising individual data points, the 69% Overall Response Rate (ORR) is particularly impressive and encouraging. Building on an already strong data package for EVX-01, these new findings strengthen our confidence that we can meaningfully improve treatment options for advanced melanoma," says Birgitte Rønø, CSO of Evaxion.

"The clinical findings are another validation of our AI-Immunology™ platform as a leading AI technology for fast and effective vaccine target discovery and design and clearly positions us as a leader in the field of AI immunology. The observed reduction in tumors in 15 out of 16 patients is offering great hope for patients with melanoma. We are looking very much forward to engaging with stakeholders to present the compelling clinical profile of EVX-01 as a transformative personalized cancer vaccine," says Christian Kanstrup, CEO of Evaxion.

The data stems from a one-year interim analysis of the ongoing phase 2 trial investigating EVX-01 in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in patients with advanced melanoma (skin cancer). The data was presented during the weekend at a poster session at the European Society for Medical Oncology (ESMO) Congress 2024 in Barcelona, Spain.

Unique profile of EVX-01 supported by both clinical efficacy and immune data

The data demonstrates 69% ORR, reduction in tumor target lesions in 15 out of 16 patients, an immunogenicity rate of 79%, and a positive correlation between Evaxion's AI-Immunology™ platform predictions and immune responses induced by the individual neoantigens in the EVX-01 vaccine (p=0.00013). Neoantigens are newly formed antigens generated from cancer-specific mutations. As a neoantigen vaccine, EVX-01 aims at triggering the patient's immune system to target these specific antigens and thereby eradicate the cancer cells.

The 69% ORR is calculated based on 11 out of 16 patients in the trial having objective clinical responses. This rate may increase as more data are collected but will not decrease. Final results are expected in the third quarter of 2025.

Further to the encouraging clinical data, the immunogenicity data from the trial are also impressive, demonstrating that 79% of EVX-01's neoantigens triggered a targeted immune response. This immunogenicity rate stands out as unprecedented compared to historical observations and compares very favorably to what is seen with other approaches. It also underlines and validates the precision of the AI-Immunology™ platform in identifying neoantigens which leads to detectable signals in patients.

The new data also confirms the strong predictive capabilities of AI-Immunology™ with a positive correlation between its predictions and the neoantigen immune response detected in the patients with a p-value of p=0.00013. In other words, the data confirms that the neoantigens identified by the platform as the most relevant vaccine targets are also the ones that trigger specific immune responses in patients.

Significant commercial potential

The global burden from melanoma is estimated to increase to 510,000 new cases and 96,000 deaths by 2040 (Arnold et al., JAMA Dermatology 2022), and the global market for melanoma treatments is estimated to grow to \$7.4 billion by 2029 (GlobalData).

Considering the prevalence of the disease and the size of the market, the development of EVX-01 as a novel potential melanoma treatment holds a significant commercial potential for Evaxion. As EVX-01 is also thought to have the potential to treat several other solid tumor cancers, the total commercial opportunity could be further enhanced by expanding into other indications.

Webinar on September 18

Evaxion will be hosting an online webinar featuring key opinion leader and the trial's principal investigator, Professor Georgina V. Long, on September 18, 2024, at 19.00 CEST/13.00 EDT. The webinar can be attended through registration via [this link](#).

In the webinar, Professor Long will present the data from the one-year interim analysis and discuss challenges in the medical treatment of advanced

melanoma. In the end, a Q&A session will be held, and participants are encouraged to present questions.

#### About EVX-01

EVX-01 is a personalized peptide-based cancer vaccine intended for first-line treatment of multiple advanced solid cancers. It is Evaxion's lead clinical asset.

EVX-01 is a personalized therapy designed with our AI-Immunology™ platform and is tailored to target the unique tumor profile and immune characteristics of each patient. It engages the patient's immune system to fight off cancer by mounting a targeted response against tumors.

In the completed Phase 1/2a clinical trial (NCT03715985), assessing EVX-01 in combination with a PD-1 inhibitor, eight of twelve metastatic melanoma patients (67%) had objective clinical responses with two complete and six partial responses.

In addition, vaccine-induced T cells were detected in all patients and a significant correlation between clinical response and the AI-Immunology™ predictions was observed, underlining the predictive power of the platform.

#### About EVX-01 phase 2 clinical trial

The Phase 2 clinical study (NCT05309421) is a self-sponsored open-label, single-arm, multi-center trial carried out in collaboration with leading principal investigators and research centers from Italy and Australia. The trial aims to evaluate the efficacy and safety of EVX-01 vaccination in combination with MSD's anti-PD1 therapy KEYTRUDA® (pembrolizumab) in treatment-naive patients with metastatic or unresectable malignant stage III or IV melanoma. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. Merck Sharp & Dohme LLC supplies KEYTRUDA® (pembrolizumab) for the trial.

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#### About EVAXION

Evaxion Biotech A/S is a pioneering TechBio company based upon its AI platform, AI-Immunology™. Evaxion's proprietary and scalable AI prediction models harness the power of artificial intelligence to decode the human immune system and develop novel immunotherapies for cancer, bacterial diseases, and viral infections. Based upon AI-Immunology™, Evaxion has developed a clinical-stage oncology pipeline of novel personalized vaccines and a preclinical infectious disease pipeline in bacterial and viral diseases with high unmet medical needs. Evaxion is committed to transforming patients' lives by providing innovative and targeted treatment options. For more information about Evaxion and its groundbreaking AI-Immunology™ platform and vaccine pipeline, please [visit our website](#).

#### 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 ongoing COVID-19 pandemic and the ongoing conflict in the region surrounding Ukraine and Russia and the Middle East; 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](http://www.sec.gov). We do not assume any obligation to update any forward-looking statements except as required by law.