Evaxion reports 69% Overall Response Rate in its phase 2 trial on lead cancer vaccine candidate EVX-01

September 9, 2024

- Topline data from a one-year interim analysis of the ongoing phase 2 trial show that 11 out of 16 patients had objective clinical responses, equaling a 69% Overall Response Rate
- 15 out of the 16 patients had reduction of their tumors (target lesions)
- The complete one-year dataset will be presented at the ESMO congress this week and discussed at a webinar with key opinion leader Professor Georgina V. Long on September 18, 2024

COPENHAGEN, Denmark, Sept. 09, 2024 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX) ("Evaxion"), a clinical-stage TechBio company specializing in developing AI-Immunology™ powered vaccines, announces new exciting clinical phase 2 data for its lead compound EVX-01. The data show that 11 out of 16 patients had objective clinical responses, equaling a 69% Overall Response Rate (ORR). 15 out of the 16 patients had reduction of their tumors (target lesions).

This topline data is part of a one-year interim analysis of the ongoing phase 2 trial assessing 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 complete one-year clinical data will be presented at a poster session at the European Society for Medical Oncology (ESMO) Congress 2024, taking place in Barcelona, Spain, from September 13-17, 2024.

"We are very excited about these data, which strongly support both the clinical profile of EVX-01 as a promising personalized cancer treatment and the unique predictive capabilities of our AI-Immunology™ platform. To present phase 2 efficacy data for an AI-designed vaccine is a major milestone for Evaxion. Huge unmet medical needs remain in the field of melanoma, and we believe that EVX-01 could potentially be an improved treatment option for patients. We look forward to presenting the complete one-year dataset at ESMO, discussing the data with potential partners and advancing the phase 2 trial towards its completion next year," says Christian Kanstrup, CEO of Evaxion.

Evaxion's innovative approach to develop personalized cancer vaccines builds on its AI-Immunology™ platform. The vaccines are designed to target the unique genetic makeup of an individual's tumor and are tailored to the patients' immune system, potentially enhancing the efficacy of treatment and improving patient outcomes.

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 EST. 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.

ESMO presentation details:

Abstract Title:	Phase 2 study of AI-designed personalized neoantigen cancer vaccine, EVX-01, in combination with pembrolizumab in advanced melanoma
Abstract#:	1084P
Poster#:	2904
Track:	Melanoma and other skin tumours
Location:	Hall 6
Date/Time:	September 14 at 12:00 – 13:00 CEST
Presenter:	Dr. Paola Queirolo, Director, Medical Oncology of Melanoma, Sarcoma and Rare Tumors, European Institue of Oncology, Milan, Italy

Link to abstract on the ESMO website.

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.

About melanoma

Melanoma accounts for approximately 1 in 5 of the 1.5 million new skin cancer cases estimated globally in 2020 with approximately 325,000 cases and 57,000 deaths. 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). The global market for melanoma treatments is estimated to grow to $7.4 billion by 2029 (GlobalData).

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. We do not assume any obligation to update any forward-looking statements except as required by law.

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