Evaxion completes dosing in phase 2 trial with personalized cancer vaccine EVX-01

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- Trial remains on track for completion and data readout in the second half of 2025

COPENHAGEN, Denmark, January 15, 2025 - Evaxion Biotech A/S (NASDAQ: EVAX) ("Evaxion"), a clinical-stage TechBio company specializing in developing AI-Immunology™ powered vaccines, has now completed the dosing of all 16 patients in its phase 2 trial with the company's lead asset EVX-01. Designed with Evaxion's AI-Immunology™ platform, EVX-01 is a personalized cancer vaccine being developed as a treatment of advanced melanoma (skin cancer).

Dosing has been completed according to trial protocol and timelines, meaning the trial remains on track for completion and data readout in the second half of 2025. Coincidently, the first patient has now completed the trial and has had last visit according to the protocol. Patients will continue to be monitored and data collected.

"We are happy to report completion of the dosing in this important trial, demonstrating our strong capabilities in trial execution. Now we focus on carrying the trial through to completion and we are eagerly anticipating the full clinical data readout later this year. Based on the impressive data generated so far, we see that EVX-01 could potentially become a new and effective treatment option for advanced melanoma. With more than 300,000 new melanoma cases each year and significant medical needs, this offers great commercial potential for Evaxion", says Christian Kanstrup, CEO of Evaxion.

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

The phase 2 trial investigates 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). Each patient enrolled in the trial has received a unique vaccine designed and manufactured based on their individual biology.

Convincing one-year phase 2 data

Convincing interim one-year data from the trial was presented at the European Society for Medical Oncology (ESMO) Congress in September 2024. Data demonstrated a 69% Overall Response Rate, reduction in tumor target lesions in 15 out of 16 patients, and a positive correlation between the AI-Immunology™ platform predictions and immune responses induced by the individual neoantigens in the EVX-01 vaccine (p=0.00013). Further, 79% of EVX-01's vaccine targets triggered a targeted immune response, which compares very favorably to what is seen with other approaches.

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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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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 other significant geopolitical and macro-economic events; 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.