EVAXION

Evaxion Announces Phase 2 Clinical Trial Update: First Patient Completed Dosing with Personalized Cancer Vaccine EVX-01

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- Significant Phase 2 clinical trial progress obtained with first patient finalizing EVX-01 vaccine dosing
- Favorable safety profile confirmed
- Trial on track for one-year clinical efficacy readout in Q3 2024

COPENHAGEN, Denmark, April 17, 2024 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX) ("Evaxion" or the "Company"), a clinical-stage TechBio company specializing in developing AI-Immunology™ powered vaccines, announces that the first patient in its EVX-01 Phase 2 trial in metastatic melanoma received the last vaccine dose in combination with KEYTRUDA® (NCT05309421).

The Company initiated its Phase 2 clinical study in September 2022 to assess the efficacy, safety and ability to induce a tumor-specific immune response of the EVX-01 cancer vaccine in metastatic melanoma patients. The EVX-01 vaccine was designed using Evaxion's proprietary AI-Immunology™ platform and is an individualized therapy matching the unique tumor profile and characteristics of the patient's immune system. Each patient enrolled in the trial receives a unique vaccine designed and manufactured based on their individual biology. Patients are administered ten EVX-01 doses over a period of 78 weeks in combination with the anti-PD-1 therapy, KEYTRUDA® (pembrolizumab).

Birgitte Rønø, CSO of Evaxion, commented, "With the progress made in the Phase 2 study, we are one step closer to fulfilling our mission of saving and improving lives with AI-Immunology™. We eagerly anticipate sharing the one-year clinical readout in Q3 this year and look forward to being one step closer to market with a novel personalized cancer vaccine."

Professor Adnan Khattak at One Clinical Research, Hollywood Private Hospital, Western Australia, expresses enthusiasm, stating, "We are now entering into the era of personalized cancer therapies, where we adopt a tailored approach against an individual patient's tumor. In other words, we are treating each patient with the right drug. As a physician, I firmly believe this is the future."

At the end of 2023, Evaxion reported initial EVX-01 Phase 2 data confirming the favorable safety profile and promising immunological data as observed in the previously successful Phase 1 clinical trial. To learn more, please read the related press release.

About EVX-01 Phase 2 Clinical Trial

EVX-01 is Evaxion's lead clinical asset and constitutes a peptide-based personalized cancer vaccine. The Phase 2 clinical study is a self-sponsored open-label, single-arm, multi-center trial carried out in collaboration with Merck Sharp & Dohme LLC that, together with leading principal investigators and research centers from Italy and Australia, aims to evaluate the efficacy and safety of EVX-01 vaccination in combination with anti-PD1 therapy KEYTRUDA® (pembrolizumab) in treatment-naive patients with metastatic or unresectable malignant stage III or IV melanoma. More information can be accessed under clinical trial ID NCT05309421.

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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