EVAXION

Evaxion receives approval from FDA to proceed with the clinical Phase 2b study for EVX-01

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COPENHAGEN, Denmark, Jan. 03, 2023 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX) ("Evaxion" or the "Company"), a clinical-stage biotechnology company specializing in the development of AI-driven immunotherapies, today announced that the U.S. Food and Drug Administration ("FDA") determined that the Company may proceed with its Phase 2b clinical trial of EVX-01.

In November 2022, the Company submitted an Investigational New Drug Application ("IND") along with a Fast Track designation application to the FDA for a Phase 2b clinical trial of EVX-01 in combination with KEYTRUDA® for the treatment of patients with metastatic melanoma. On December 22, 2022, the FDA issued approval for the Company to proceed with its Phase 2b trial. The Company anticipates a response to the Fast Track designation submission in the first quarter of 2023.

"Receiving a green light from the FDA is a tremendous boost for our personalized cancer vaccine program. EVX-01 is already actively enrolling patients in Australia, and the FDA approval expands our ability to move forward quickly with our lead program in malignant melanoma. Moreover, the FDA is a universally recognized national authority, and its endorsement is an important step towards demonstrating a clinically meaningful benefit of our first personalized cancer vaccine," says Erik Heegaard, Chief Medical Officer at Evaxion.

The Phase 2b study will be conducted at clinical sites across the United States, Europe, and Australia. It is carried out in collaboration with Merck, supplying its PD-1 inhibitor KEYTRUDA®. The trial was first initiated in Australia with the enrollment of the first patient in September 2022.

Read about EVX-01 Ph2b on clinicaltrials.gov: NCT05309421.

About Evaxion

Evaxion Biotech A/S is a clinical-stage biotech company developing AI-powered immunotherapies. With our proprietary and scalable AI technology, we decode the human immune system to discover and develop novel immunotherapies for cancer, bacterial diseases, and viral infections. Evaxion has a broad pipeline of novel product candidates, including three personalized cancer immunotherapies. It is located in Hørsholm, Denmark, with 70 employees.

Source: Evaxion Biotech

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Forward-Looking Statements

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.