EVAXION

Evaxion receives FDA fast-track designation for personalized cancer immunotherapy

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COPENHAGEN, Denmark, Jan. 19, 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") has granted fast track designation for the Company's personalized cancer therapy, EVX-01, in combination with KEYTRUDA ®.

In December 2022, Evaxion received FDA approval to proceed with its Phase 2b clinical trial, where EVX-01 is given in combination with KEYTRUDA® to patients with metastatic melanoma. On January 17, 2023, Evaxion furthermore received fast track designation for the vaccine candidate. The fast track is designed to expedite the FDA's review of innovative, new drugs that demonstrate the potential to address an unmet medical need.

"We are extremely pleased that our cancer vaccine candidate EVX-01 has received the FDA fast track designation, as it enables a potentially faster approval of the vaccine. This is first and foremost to the benefit of the patients. And it is a great validation of our AI platform, PIONEER, and our drug development candidate," says Per Norlén, CEO at Evaxion.

EVX-01 is a peptide-based cancer immunotherapy and is Evaxion's most advanced clinical asset. Under the program, a unique drug is generated for each patient based on gene analysis of their tumors and on matching with their immune system. This process is made possible by the Company's proprietary AI platform, PIONEER.

The ongoing Phase 2b study is 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 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 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.