

EVAXION

Important Milestone Reached for Evaxion Biotech's EVX-01 Personalized Cancer Therapy

September 21, 2022

COPENHAGEN, Denmark, Sept. 21, 2022 (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, reached an important milestone announcing today that it had enrolled its first patient in the global phase 2b clinical trial of EVX-01, the Company's personalized cancer therapy for the treatment of melanoma.

In the company's first phase 2b clinical trial, Evaxion is evaluating the efficacy and safety of EVX-01 in adults with metastatic melanoma. The trial is being conducted globally at clinical sites across the US, Europe, and Australia in collaboration with Merck & Co., Inc., which is supplying the trial with its PD-1 inhibitor, KEYTRUDA®.

Patients enrolled in the phase 2b clinical trial will receive standard of care treatment along with KEYTRUDA® in combination with EVX-01. Evaxion is responsible for the conduct of the trial and Merck will supply the required KEYTRUDA®. Evaxion and Merck will continue to collaborate as the data mature.

Erik Heegaard, Evaxion's Chief Medical Officer, said:

"We are extremely proud to take EVX-01 into the next clinical development phase, enrolling our first patient in the clinic. We believe that this will help to support our efforts in developing new and more efficacious treatments for patients suffering from malignant melanoma. With this phase 2b trial, we are addressing a major unmet medical need in an indication that has become a multi-billion-dollar market. Together with our collaborators at Merck, we hope to further validate the promising data generated in our phase 1/2a study, which we believe may potentially pave the way for much needed improvement in the treatment landscape for melanoma and possibly other cancers."

Background:

- EVX-01 is a novel personalized cancer immunotherapy based on Evaxion's proprietary PIONEER™ AI technology, for the treatment of patients with melanoma.
- Data from the Phase 1/2a clinical trial of EVX-01 has shown that 67% of nine patients benefitted from EVX-01 in combination with a PD-1 inhibitor (KEYTRUDA®) for the treatment of metastatic melanoma, compared to the historical data of only 40% benefiting from a PD-1 inhibitor alone
- 22% of the patients in the Phase 1/2a clinical trial achieved a complete response (full recovery) with EVX-01 in combination with a PD-1 inhibitor (KEYTRUDA®).
- The first patient in the Phase 2b clinical trial has now been enrolled
- The Company anticipates interim topline data readout in H2 of 2023
- For further information, please refer to [clinicaltrials.gov: KEYNOTE – D36 NCT05309421](https://clinicaltrials.gov/KEYNOTE-D36-NCT05309421)

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

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, and currently has 70 employees.

For more information

Evaxion Biotech A/S	LifeSci Advisors LLC
Erik Heegaard	Corey Davis, Ph.D.
Chief Medical Officer	Managing Director
ehe@evaxion-biotech.com	cdavis@lifesciadvisors.com
+45 20810282	+1 (212) 915 2577

Forward-looking statement

This announcement contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this announcement regarding the Company's future operations, plans and objectives are forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, all statements other than statements of historical fact included in this announcement about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by, or including words such as "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 or the negative thereof. 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 associated with the Company's financial condition and need for additional capital; risks related to the Company's development work; cost and success of the Company's product development activities and

preclinical and clinical trials; risks related to commercializing any approved pharmaceutical product developed using the Company's AI platform technology, including the rate and degree of market acceptance of the Company's product candidates; risks related to the Company's dependence on third parties including for conduct of clinical testing and product supply and manufacture; risks associated with the Company's inability to enter into partnerships; risks related to government regulation; risks associated with protection of the Company's intellectual property rights; risks related to employee matters and managing growth; risks related to the Company's ADSs and ordinary shares, risks associated with the pandemic caused by the coronavirus known as COVID-19 and the emergence and prevalence of COVID-19 variants, such as Delta and Omicron, and specific related variants such as the Omicron BA.4 and BA.5 variants, risks associated with the hostilities between Ukraine and Russia and other risks and uncertainties affecting the Company's business operations and financial condition.

Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results, performance, or achievements to be materially different from the expected results, performance, or achievements expressed or implied by such forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the Company's business in general, see the risks described in the "Risk Factors" section included in the Company's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 31, 2022 and the Company's current and future reports filed with, or furnished to the SEC. Any forward-looking statements contained in this announcement speak only as of the date hereof, and except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

EVAXION AI-Powered
Immunotherapies

Source: Evaxion Biotech