

EVAXION

Evaxion Biotech Receives Regulatory Clearance to Initiate Phase 2 Trial of EVX-01 in Combination with KEYTRUDA® for Treatment of Melanoma

January 18, 2022

COPENHAGEN, Denmark, Jan. 18, 2022 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX), a clinical-stage biotechnology company specializing in the development of AI-driven immunotherapies to improve the lives of patients with cancer and infectious diseases, announced today it has received clearance from the Australia Therapeutic Goods Administration to initiate a Phase 2b trial of its patient specific cancer immunotherapy EVX-01 in combination with Merck & Co., Inc.'s (known as MSD outside the United States and Canada) anti-PD-1 therapy KEYTRUDA® (pembrolizumab).

The open label, single arm trial will evaluate the efficacy and safety of EVX-01 in combination with KEYTRUDA® in approximately 100 checkpoint inhibitor treatment naïve adults with unresectable or metastatic melanoma, with overall response as the primary endpoint. The study is expected to be initiated in Q2. Evaxion will be responsible for the conduct of the study and Merck & Co., Inc. will supply all of the necessary KEYTRUDA® and will continue to collaborate as the data mature.

Lars Wegner, CEO of Evaxion, said: "Australian clearance for our Phase 2b trial of our lead product EVX-01 is a significant step forward for Evaxion and our exciting pipeline of immunotherapies. Data from the Phase 1/2a trial have shown that EVX-01 may be able to dramatically improve the treatment landscape in melanoma and possibly other cancers and we are excited to continue the clinical progress of our lead drug candidate EVX-01 in collaboration with Merck. This new Phase 2b trial, combining EVX-01 and KEYTRUDA®, addresses a significant medical need and a potential multibillion dollar market. There could be potential further benefits from combining EVX-01 with checkpoints inhibitors such as KEYTRUDA®, and so this study may enable expansion into many other types of cancers, addressing a market of well over \$100 billion."

An ongoing Phase 1/2a trial is investigating EVX-01, a novel patient specific cancer neopeptide immunotherapy based on Evaxion's proprietary PIONEER™ AI technology, for the treatment of patients with melanoma. Data from this trial has shown that 67% of the nine patients benefited from EVX-01 in combination with anti-PD-1 for the treatment of metastatic melanoma, compared to the historical data of only 40% benefiting from the checkpoint inhibitor alone. 22% of the patients in the trial achieved a complete response with EVX-01 in combination with anti-PD-1.

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

About Evaxion

Evaxion Biotech A/S is a clinical-stage AI-immunology™ platform company decoding the human immune system to discover and develop novel immunotherapies to treat cancer, bacterial diseases and viral infections. Based on its proprietary and scalable AI-immunology core technology, Evaxion is developing a broad pipeline of novel product candidates which currently includes three patient-specific cancer immunotherapies, two of which are in Phase 1/2a clinical development. In addition, Evaxion is advancing a portfolio of vaccines to prevent bacterial and viral infections currently in preclinical development.

For more information

Corey Davis, Ph.D.

LifeSci Advisors

cdavis@lifesciadvisors.com

+1 (212) 915 2577

Source: Evaxion Biotech

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 associated with 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 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 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 Form 20-F for the year ended December 31, 2020 and the Company's other reports filed with, or submitted to, the U.S. Securities and Exchange Commission (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.



Source: Evaxion Biotech