

EVAXION

Evaxion Biotech Reports Data from Phase 1/2a Trials of EVX-01 and EVX-02

July 8, 2021

- New clinical data demonstrates antitumor effect of EVX-01 in combination with anti-PD1 treatment
- Objective Response Rate (ORR) of 67% with EVX-01 + anti-PD1 treatment in nine metastatic melanoma patients, including 22% Complete Response (CR) and 44% Partial Response (PR)
- Clinical trial data supports the proprietary AI-Immunology platform, PIONEER, with regard to: neoepitope prediction, *de novo* T-cell activation and clinical response in cancer patients
- Phase 2 trial of EVX-01 in melanoma, planned to start in December 2021
- First patients in Phase 1/2a trial of EVX-02 showed T-cell activation, with further data to be generated with aim of initiating Phase 2 trial in Q2 2022
- Conference call and webcast this morning July 8, 2021 at 8:00 AM EDT

COPENHAGEN, Denmark, July 08, 2021 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX), a clinical-stage biotech company specializing in the development of AI-driven immunotherapies to improve the lives of patients with cancer and infectious diseases, announced today results from both its Phase 1/2a trial of cancer immunotherapy EVX-01 in metastatic melanoma and interim Phase 1/2a trial of cancer immunotherapy EVX-02 in adjuvant melanoma.

Data from the trial of EVX-01, a novel patient-specific cancer neoepitope immunotherapy based on Evaxion's PIONEER AI technology in combination with a PD-1 checkpoint inhibitor, showed a safety profile with only Grade 1 and 2 adverse events observed.

Combined therapy with EVX-01 demonstrated an objective response rate of 67% across all nine patients compared with historical data of 40% with anti-PD1 treatment alone¹. The study also demonstrated a complete response rate of 22%, compared with a historical 7%¹ with anti-PD1 treatment alone, and a partial response rate of 44%, versus 33% compared with anti-PD1 treatment alone¹. Among the four patients on the highest two doses, there was an objective response rate of 75%. Three patients with Stable Disease for 10, 8 and 9 months on anti-PD1 treatment alone, achieved CR, CR and PR respectively following EVX-01 administration and subsequent activation of a neoepitope specific *de novo* T-cell response.

Lars Wegner, CEO of Evaxion, said: "We are very excited about the Phase 1/2a data for EVX-01, which shows encouraging results for our AI-developed immunotherapy in metastatic melanoma and appears to be well tolerated with only Grade 1 and 2 adverse events such as fatigue and fever all of which were resolved with treatment. The complete elimination of all tumors we see in the two patients stable for 8-10 months on checkpoint inhibitor treatment has further increased our belief in the benefit our neoepitope-based therapies can bring to patients. In addition, the tumor reduction in patients correlates with neoepitope specific T-cell activation and PIONEER predictions. The data demonstrate the potential of our PIONEER platform and its ability to identify patient specific cancer neoepitopes. Importantly, the objective response rate demonstrates that EVX-01 may be able to improve the treatment landscape in melanoma and potentially other cancers. Furthermore, the first results from our Phase 1/2a trial with EVX-02 demonstrate its potential for treatment of melanoma. Based on the data from these two studies, we expect to initiate a Phase 2 trial with EVX-01 by the end of the year and a Phase 2 trial with EVX-02 in Q2 2022."

Professor Inge Marie Svane, Head of the Danish Centre for Cancer Immunotherapy and Principal Investigator of the EVX-01 study, said: "These Phase 1/2a data demonstrate the feasibility of the combination of EVX-01 with anti-PD1 therapy with substantial reduction of tumor burden in some patients. It is particularly interesting to see that two patients improved their response to anti-PD1 therapy further to complete response following addition of EVX-01. This could be good news for patients and I look forward to contributing to the further development of this novel therapy."

About the EVX-01 Phase 1/2a clinical trial in metastatic melanoma

In the Phase 1/2a trial, nine patients with metastatic melanoma were injected biweekly with EVX-01, three times intraperitoneal and three times intramuscular plus, with pembrolizumab every three weeks or nivolumab every four weeks. Patients were dosed at three different levels of EVX-01, 500 µg, 1,000 µg and 2,000 µg.

The study also revealed encouraging biomarker information supporting EVX-01's mechanism of action. There was broad T-cell activation in all patients, with 76.2% of the administered neoepitopes inducing reactive T cells, while 84.8% of EVX-01 induced reactive T cells were *de novo* responses. Patient cases established a direct link between EVX-01 activated T cells and antitumor effect and duration of response. The data further demonstrated a link between neoepitopes identified by the PIONEER platform and clinical response.

The results also showed that Evaxion's novel proprietary AI-Immunogenetic Drug Response Platform (AI-DeeP™), which provides immuno-genetic profiling of individual patients based on biological rationale for drug response, can predict the response to therapy with precision and sensitivity.

We believe that the data support progressing the development of EVX-01 into a subsequent randomized Phase 2b trial, which we expect to initiate in December 2021. We also intend to present the data at an upcoming medical society meeting in first half of 2022.

Phase 1/2a results with EVX-02 in adjuvant melanoma

This is an open label, multi-center study assessing the safety, tolerability, pharmacodynamics, and potential efficacy of EVX-02 in combination with checkpoint inhibitor in patients who have had a complete resection of Stage IIIB/IIIC/IIID or Stage IV melanoma and are at high risk of recurrence. The study is taking place at five clinical centers in Australia.

Data from the first patients in the trial showed T-cell activation, even in assays which had not been prestimulated. Based on this readout, Evaxion will continue to generate more data from the trial with the aim of initiating a Phase 2 trial with EVX-02 in an adjuvant setting in the second quarter of 2022.

1) Robert *et al.* 2015. Pembrolizumab versus Ipilimumab in Advanced Melanoma. *N. Engl. J. Med.* 372: 2521–32.

Webcast and Conference Call

To discuss today's data announcement Evaxion will host a webcast and conference call today, July 8, 2021 at 8:00 a.m. EDT.

To dial-in for the conference call, please use the following details:

US: 877-407-0792

International: +1-201-689-8263

Conference ID: 13720456

Webcast: <http://public.viavid.com/index.php?id=145224>

The webcast recording will be available from 8th of July 2021 at: [Webcast Archive](#)

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, and vaccines against 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

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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 end December 31, 2020 and the Company's current and future 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