

Status update from Alzinova

Alzinova AB (publ) (ticker:ALZ), a Swedish biopharma company focused on the development of treatments for Alzheimer's disease, is working at a rapid pace and provides here a status update on where the business is at the moment. The work is mainly focused around four different parts: the ongoing extension part of the phase 1b study, the ongoing high-dose cohort of the phase 1b study, preparatory work for planned phase 2 studies, and work to find an ideal partner, with financial strength, that can drive the work all the way to commercialization.

Alzinova's main goal is to develop a vaccine as a long-term treatment for Alzheimer's disease. To achieve this goal, the vaccine candidate ALZ-101 is being developed. ALZ-101 has undergone preclinical studies and is now in phase 1 clinical development. The study is divided into several parts:

- The first part of the study has evaluated two different dose strengths. The strong results from the first part presented at the end of 2023/beginning of 2024 show that the vaccine is safe and that patients treated also developed antibodies, i.e. the patient's immune system was activated. This means that the results indicates that the vaccine works. The study also showed that patients who received a higher dose produced higher levels of antibodies. The company also looked at certain substances in the body called biomarkers, as measuring these can show whether the medicine is working. The results show that these biomarkers have improved in the spinal fluid of patients who have been treated with ALZ-101, suggesting that the vaccine seems to have a positive effect.
- The second part of the study, the extension part, evaluates the safety of the vaccine treatment and the amount of antibodies over a longer period of time.
- The third and final part of the phase 1b study, the high dose cohort, is being done with the purpose of investigating a higher dose of ALZ-101 following the earlier results indicating that a higher dose produces increased antibody levels.

All patients have been dosed in the extension part of the phase 1b study

In the ongoing extension part of the phase 1b study, all patients received their final dose in early April 2024. In total, all patients have thus been treated on four occasions during a 16-week period, followed by a 52 week follow-up. This means that a 42-week follow-up period is now underway and will end in the third quarter of 2024. Alzinova intends to analyze and present the week 42 data during the fourth quarter of 2024 before the final follow-up visits of the extension part of the study is fully completed.

The extension part of the study will provide information on long-term safety, how well the treatment is tolerated, the body's immune response, as well as possible changes in biomarkers and cognitive functions over a longer period of time. All in all, this is important information for the company to design the upcoming phase 2 study.



All patients have been dosed in the high dose cohort of the phase 1b study

In the ongoing high-dose cohort, all patients have now been dosed with at least 2 doses of ALZ-101. In total, patients will be treated on four occasions over a 16-week period, followed by a four-week follow-up period that will end Q4 2024. Alzinova intends to present data from this high-dose cohort in the first quarter of 2025.

The main purpose of the high-dose cohort is to evaluate a higher dose of the vaccine candidate ALZ-101 ahead of a future phase 2 clinical study. By evaluating a higher dose, the company can both strengthen the knowledge of the vaccine candidate and optimize the conditions and study design for the phase 2 study.

Upcoming phase 2 studies

Alzinova intends to run the work from clinical phase 2 studies onwards through a partner. The process of finding the right partner is ongoing. As previously announced, the company has engaged with a renowned US Adviser, covering life sciences consulting, M&A and investment banking, to assist the company in identifying and subsequently signing a partner agreement. In short, they help clients that are looking for business deals, such as license agreements and partnerships, to find an optimal partner. The goal is to secure a strategic partnership to support the clinical development and commercialization of ALZ-101.

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Please note that this is an English translation of a press release written in Swedish by Alzinova AB (publ), in the event of any inaccuracies, the Swedish version applies.

Attachments

Status update from Alzinova