PRESS RELEASE
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Alzinova provides market update with future sales forecast – strengthened position for phase 2

Alzinova AB (ALZ) hereby provides an update to the market, highlighting several key milestones that mark a successful first half of 2025 and establish a solid foundation for the company's continued progress. The company has completed its clinical Phase 1b study with positive results, secured the drug substance for the upcoming Phase 2 study, carried out a successful rights issue, and intensified business development efforts through global partnership dialogues. As a result, Alzinova is well-positioned for the next clinical phase in the development of its vaccine candidate ALZ-101 targeting Alzheimer's disease. In addition to operational progress, Alzinova also presents sales forecasts based on internal market estimates, projecting a peak sales potential of over USD 5.4 billion and total sales exceeding USD 62.5 billion over the drug's estimated lifespan. Furthermore, the company outlines an estimated market value for ALZ-101, based on its sales projections and the probability of achieving market approval, with a risk-adjusted net present value (eNPV) ranging from USD 130–200 million with a partnership established before Phase 2, and from USD 780–1,100 million with a partnership established after Phase 2. Finally, the company reports that its simulations estimate the probability of market approval at 15 percent prior to initiating Phase 2, and 50 percent following its completion.

Scientific results

During the first half of the year, Alzinova achieved several important milestones and continues to progress towards market:

- The clinical Phase 1b study of ALZ-101 has now been completed, with objectives met regarding safety, tolerability, and immunogenicity, while data also show clear signs of clinical stability among treated patients.
- A critical demonstration of CNS exposure has also been obtained through detectable antibody levels in cerebrospinal fluid, corresponding to at least 0.3 percent of plasma levels. This result is consistent with levels observed during treatment with monoclonal antibodies, further strengthening ALZ-101's profile as a potential disease-modifying therapy for Alzheimer's disease.
- Additional support for this potential comes from the biomarker neurofilament light (NFL), where a trend toward lower levels in treated patients aligns with the observed cognitive outcomes and suggests a possible slowing of the neurodegenerative process.
- New clinical findings indicate that healthy elderly individuals naturally have high levels of protective antibodies against toxic amyloid-β oligomers, whereas these levels are significantly lower in Alzheimer's patients. Treatment with ALZ-101 increased these

antibody levels in patients to levels comparable to healthy controls, reinforcing the hypothesis that the vaccine may correct an immunological deficiency associated with the disease.

In summary, the strong results from the Phase 1b study, with both primary and secondary endpoints met, together with compelling findings from post-hoc analyses, have confirmed the potential of ALZ-101 as a disease-modifying therapy for Alzheimer's disease, reducing the risk and thereby enhancing the value of the company's assets.

Operational progress

- During the spring, Alzinova received the drug substance for the upcoming Phase 2 study, manufactured in accordance with GMP standards by PolyPeptide Laboratories in Strasbourg. This delivery represents a key milestone, enabling the production of the final drug product. The partnership with PolyPeptide is being further deepened to optimize manufacturing processes ahead of the next clinical phase and future commercialization.

- During the summer, the GMP-compliant drug product is also scheduled for release, which means that the company will have clinical trial material ready for the forthcoming Phase 2 study.

- Worldwide Clinical Trials (Worldwide) was recently appointed as Alzinova's clinical research partner (CRO) for the planned Phase 2 study with ALZ-101. Worldwide is a global CRO with over 40 years of experience in clinical trials and a particular focus on neuroscience. The company has conducted numerous Alzheimer's disease trials and has a proven track record of delivering clinical results that have supported regulatory approvals of disease-modifying treatments for Alzheimer's. Partnering with Worldwide strengthens Alzinova's ability to conduct a high-quality and efficient study, from patient recruitment to regulatory follow-up, and ensures that the Phase 2 program is conducted in accordance with international quality standards.

Financial information

- To complete preparations for the Phase 2 study, a rights issue was carried out during the second quarter, raising approximately SEK 30.3 million before issuance costs, following a subscription rate of 85 percent. The proceeds provide Alzinova with the financial capacity to initiate the Phase 2 study as planned in the second half of 2025, while also enabling the company to evaluate various financing and partnership opportunities. As part of these efforts, Alzinova recently participated in the BIO International Convention in Boston in mid-June, where the company held discussions with potential international partners regarding development and commercialization strategies. The growing external interest in ALZ-101 reinforces the company's view that it is in a strategically advantageous position, both clinically and commercially.

- During the spring, Alzinova also entered into a collaboration with Rx Securities to further increase awareness of both the company and its vaccine candidate ALZ-101 among institutional investors. This partnership expands Alzinova's analyst coverage, which already includes established relationships with DNB Carnegie and Redeye.

During the reporting period, all three independent analyst firms, DNB Carnegie, Redeye, and Rx Securities, published updated analyses of the company, focusing primarily on the drug candidate ALZ-101. The combined valuation assumptions in these analyses indicate a valuation range of approximately USD 50 to 90 million. The analysts' models are based on Alzinova's current stage of development, as well as the clinical profile and market potential of ALZ-101 in the Alzheimer's field. Moreover, the analysts forecast peak sales in the range of USD 3.2 to 9 billion following market approval, which aligns with the company's own simulations projecting peak sales of over USD 5.4 billion and total sales exceeding USD 62.5 billion over the product's expected lifetime. The sales forecasts are based on conservative assumptions regarding market share and include only the regions of Europe, the United States, Japan, and China. Furthermore, the forecasts account solely for therapeutic use of ALZ-101, excluding potential revenues from its use as a prophylactic vaccine, as well as any future revenues from the company's other drug candidate, the monoclonal antibody ALZ-201.

As previously communicated, the company's primary goal is to secure a partnership with Big Pharma prior to initiating the Phase 2 study. However, Alzinova also sees the possibility of independently conducting the Phase 2 study, which could deliver significant shareholder value if a partnership instead is established after its completion. The company's internal simulations estimate a risk-adjusted net present value (eNPV) of ALZ-101 in the range of USD 130–200 million with a partnership established before Phase 2, and between USD 780–1,100 million with a partnership formed after a successful Phase 2 study, representing a valuation multiple of 5.5x to 6x. The probability of achieving market approval has been estimated at 15 percent before the start of Phase 2, and 50 percent after its completion.

For further information, please contact:
Tord Labuda, CEO
E-mail: info@alzinova.com

About Alzinova AB
Alzinova AB is a Swedish biopharmaceutical company in clinical development specializing in the treatment of Alzheimer's disease, where the starting point is to attack toxic amyloid-beta oligomers. The lead candidate ALZ-101 is a therapeutic vaccine against Alzheimer's disease. Alzinova's patented AβCC peptide technology makes it possible to develop disease-modifying treatments that target the toxic amyloid-beta oligomers that are central to the onset and development of the disease with great accuracy. From a global perspective, Alzheimer's disease is one of the most common and devastating neurological diseases, with around 40 million affected today. Based on the same technology, the company is also developing the antibody ALZ-201, which is currently in preclinical development, and the goal is to further expand the pipeline. The company's Certified Adviser on Nasdaq First North Growth Market is Mangold Fondkommission AB. For more information about Alzinova, please visit: **www.alzinova.com**

This information is information that Alzinova is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-06-23 07:20 CEST.

Attachments

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