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ScandiBio Therapeutics Enters Phase III With Mitochondrial-Focused Alzheimer's Treatment

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Operating largely under the radar, ScandiBio Therapeutics is now taking its biggest step yet – a Phase III study enrolling more than 600 Alzheimer's patients. The trial, which aims to restore the brain's energy production, marks the start of one of the most comprehensive clinical programs to date targeting mitochondrial dysfunction. BioStock contacted CEO Olof Nord to discuss the company's innovative approach and the goal of presenting Phase III data as early as next year.

While the fact that the privately held company is initiating an international Phase III trial may raise a few eyebrows, ScandiBio's progress has been deliberately low-key. Its scientific foundation has been built quietly but with a clear vision – to combat Alzheimer's disease by restoring the brain's energy balance rather than targeting its presumed causes.

Mitochondria as a new treatment target

Most current research and approved Alzheimer’s treatments focus on toxic beta-amyloid plaques in the brain, aiming to slow disease progression and limit cognitive and functional decline. ScandiBio instead seeks to address the metabolic dysfunction that leads to memory loss and cognitive impairment.

Mitochondria – the cell’s power plants – play a central role in energy production, particularly in energy-intensive organs such as the brain. In Alzheimer’s disease, their efficiency declines, leading to energy deficits, increased oxidative stress, and gradual neuronal death.

By stimulating mitochondrial activity and increasing levels of NAD^+ and glutathione, ScandiBio hopes to help preserve brain function. If successful, the goal is to provide healthcare with a complementary therapy to amyloid-targeted drugs and broaden the treatment arsenal against Alzheimer’s.

Clinical trial with great potential

The ongoing Phase III trial is being conducted across nine hospitals in Turkey. It is double-blind and placebo-controlled and includes patients with mild, moderate, and severe Alzheimer’s symptoms.

A total of 676 patients will receive treatment for 26 weeks with twice-daily doses of the company’s drug candidate CMA (Combined Metabolic Activators). The primary endpoint is change in the Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-Cog) from basline to end of treatment.

Over 60 patients have already been enrolled, and the study is expected to be completed in the second half of 2026.

A three-step approach to boost mitochondria

The drug candidate CMA is based on a three-step strategy to reactivate the mitochondria's energy production. The theory that is now being tested is that the combination of four natural substances – L-carnitine, nicotinamide, L-serine and N-acetylcysteine – together will strengthen the cells' metabolism and protect them against stress. L-carnitine transports fatty acids to the mitochondria where they are converted into energy, while the other substances strengthen energy production and protect cells from oxidative stress.

CMA is based on a three-stage strategy to reactivate mitochondrial energy production. The hypothesis being tested is that a combination of four natural compounds – L-carnitine, nicotinamide, L-serine, and N-acetylcysteine – together will strengthen cellular metabolism and protect against stress. L-carnitine transports fatty acids into mitochondria where they are converted into energy, while the other compounds enhance energy production and protect cells from oxidative damage.

Together, these three steps form a synergistic cascade that both boosts energy generation and reduces cellular stress. Previous preclinical and clinical studies have shown that this same combination can improve mitochondrial function, restore metabolic balance, and enhance cognitive performance. Beyond drug development, ScandiBio has also created a dietary supplement based on the same scientific principles. The product, Mitochondria Boost, developed in collaboration with UK-based Phenome Longevity – where Dr Adil Mardinoglu is also involved – contains the same four ingredients and is intended to support mitochondrial function in healthy individuals.

Leading expertise in neurodegeneration

ScandiBio Therapeutics was founded by researchers from KTH Royal Institute of Technology, Karolinska Institutet, the Sahlgrenska Academy, and King's College London, with its scientific base at the Science for Life Laboratory (SciLifeLab) in Stockholm. The research is led by Dr Adil Mardinoglu and Professor Mathias Uhlén in collaboration with Professor Jan Boren at the Sahlgrenska Academy. Professor Uhlén, a pioneer in biotechnology and precision medicine, founded SciLifeLab and leads the Human Protein Atlas project. The board also includes Alzheimer's researcher Professor Henrik Zetterberg, affiliated with the University of Gothenburg and the UK Dementia Research Institute in London.

CEO comments

BioStock contacted CEO Olof Nord to discuss the launch of the study, the potential of CMA, and ScandiBio Therapeutics' next milestones.

Your Phase III study is one of the largest of its kind. What does this mean for ScandiBio's position and for future Alzheimer's treatments?

– After ten years of intensive development work, it's a fantastic feeling to finally start the decisive clinical trial.

CMA targets mitochondrial dysfunction rather than Alzheimer's primary causes such as beta-amyloid. Based on your Phase II results, how can this strategy impact cognition and quality of life?

– The treatment aims to improve cognition – particularly memory – and thereby significantly enhance the quality of life for both patients and their families.

You position CMA as a complement to antibody-based drugs such as Leqembi. How do you view the potential for combination therapies going forward?

– Alzheimer's is a complex disease that should be attacked from several angles. Since our therapy does not address the underlying cause of dementia, it is highly attractive to combine our cognition-enhancing treatment with biological drugs that target the amyloid plaques found in Alzheimer's patients. One possible scenario is to first remove the plaques using antibodies and then strengthen mitochondrial energy production simultaneously or afterward with CMA.

What are the main challenges in such a large program – for example, patient recruitment and coordination – and how do you collaborate with Veranex and Aurevia to ensure data quality?

– Recruiting more than 600 patients is of course a challenge, particularly since many require assistance with transport and logistics. At the same time, there is a large patient pool and a significant lack of treatment alternatives. Collaborations with Veranex and Aurevia are key since they bring extensive experience in clinical trials and ensure compliance with regulatory requirements.

Your AI-based modeling of cell metabolism has been central to development. How has it optimized the Phase III strategy and deepened understanding of CMA's mechanism of action?

– We modeled energy metabolism at the cellular level and then tested various components experimentally, followed by animal models. The clinical trials have since confirmed the predictions from the cell modeling.

The study is being conducted in Turkey at nine hospitals across five cities. Why was Turkey chosen as the main location, and how do local partners such as Viscoran and MyPharma support the implementation?

– The clinical quality of hospitals in Turkey is very high, and there is a large patient base for such trials. Our local partners have been crucial, as they have extensive experience in pharmaceutical manufacturing and strict adherence to Good Manufacturing Practice (GMP) standards.

How is the Phase III trial financed, and what is the market potential if results are positive?

– The study is financed through investments from Navigare Ventures AB and the company's founders.

– Depending on the outcome, CMA could be used alongside amyloid-clearing therapies, sequentially afterward, or as a standalone treatment. If CMA demonstrates clinical efficacy with a good safety profile at a significantly lower cost, we see strong potential for health-economic benefits and improved patient access. The market potential is substantial given the vast unmet need.

How do you view the market potential for Mitochondria Boost among healthy individuals?

– Our immediate focus is the Alzheimer's clinical trial launched in September. However, we believe healthy individuals can also benefit from strengthened energy metabolism. The supplement will initially be launched in the UK, where we see high potential, although we plan a gradual market expansion.

You are currently unlisted. Are there plans to go public in the longer term?

– Remaining private has been a major advantage, allowing us to act swiftly and advance through several clinical stages at record speed – something that would have been more difficult, though not impossible, as a listed company. If the Phase III results are positive, however, we will need to scale up quickly, and a stock-market listing could become relevant.

Finally, what are the key milestones for 2026, and how are you preparing for the next step if the results confirm your expectations?

– The top priority is, of course, to complete the Phase III study that began in September while preparing the company for its next stage of growth.