

NovaGo Therapeutics AG

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Promobility therapeutics

Novel regenerative treatments for CNS disorders and cerebral stroke

Biotech start-up company NovaGo is developing human antibodies that stimulate nerve repair and regeneration following a stroke. The company's lead candidate anti-Nogo-A antibody (NG004) is ready for phase 1 trials, and it is looking for partners to develop it through the clinic.

Stroke is the leading cause of adult disability in the developed world, affecting approximately 33 million patients worldwide and costing more than €40 billion per year in direct and indirect costs in the EU alone. Following a stroke, rapid re-establishment of blood flow can reduce tissue and neuron injury, but there is no pharmacotherapy available that can regenerate damaged regions of the brain; the mainstay of stroke treatment is rehabilitation therapy, which typically results in only modest improvements or recovery of function, leaving more than half of stroke patients severely and permanently disabled. As the global incidence of stroke is increasing at the same time as death from stroke is declining, stroke is now a disease of chronically disabled survivors, many of whom lose their independence and are forced to live in nursing homes.

NovaGo Therapeutics, a biotech start-up company that develops human antibodies that stimulate nerve repair and regeneration, is set to address this large unmet medical need. The company's co-founder and president, Martin E. Schwab, previously discovered that neurite growth inhibitors prevent repair and regeneration in the central nervous system (CNS). Although needed for proper CNS development and maintenance, they obstruct the regenerative process following stroke or injury, limiting recovery of function. Schwab identified Nogo-A as a key inhibitor of axonal growth. Since then he has founded NovaGo Therapeutics to pursue the development of regenerative therapies for CNS disorders. A strategic partnership with biopharmaceutical company Neurimmune enabled the discovery of specifically targeted human-derived antibodies that block Nogo-A.

By inhibiting Nogo-A, NovaGo's lead anti-Nogo-A antibody (NG004) induces neurite outgrowth—not only near the injured site but also in contralateral or other areas of the brain. The neuronal sprouting, together with rehabilitation exercise, enables significantly more recovery of function than rehab alone (Fig. 1). "Unlike a neuroprotectant, our recombinant human monoclonal antibody allows neurons to make new connections," explained Eduardo Vianna, CEO. "This promotes the central nervous system's regenerative healing process and neurological recovery and should allow stroke patients to recover much more function."

Preclinical studies in rodent and non-human primate models demonstrate that anti-Nogo-A therapy is highly effective in enhancing nerve fiber repair and the formation of new fiber connections.

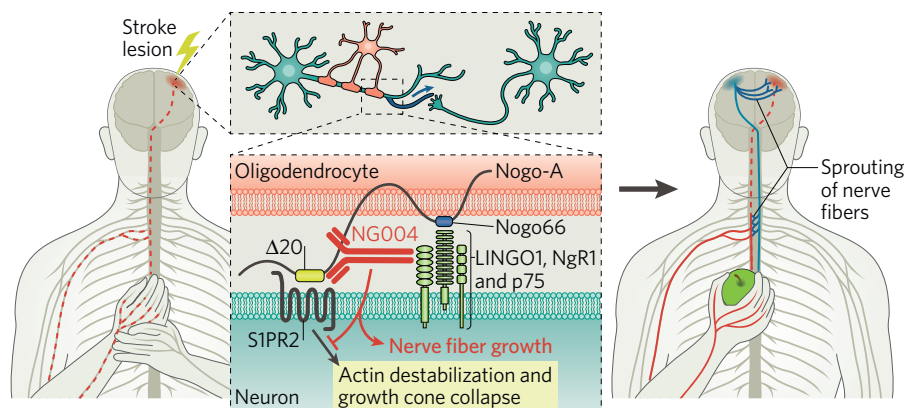


Fig. 1 | NovaGo's anti-Nogo-A therapy for stroke. The recombinant human monoclonal antibody NG004 induces neurite outgrowth by blocking the binding of Nogo-A to the Nogo-A receptor complex, preventing its activation (centre box). This allows neurons to make new connections, thereby promoting the neurological regenerative healing process, which in turn leads to a higher degree of functional recovery (right). Regeneration is observed near the injured site and in contralateral areas of the brain. This illustration is a prediction of how NG004 could work in humans based on data obtained from current animal models.

After a cerebral stroke, animals given the antibody for 2 weeks followed by 4 weeks of rehabilitation exercises recover 70–85% of function compared with only 40% for control animals receiving rehab alone. "Our anti-Nogo-A therapy boosts the sprouting of new nerve fibers, and the newly formed circuits are stabilized by intensive training," said Vianna. "Our results have overturned the dogma in medicine that injuries of the brain and spinal cord will not heal and cannot be repaired."

Furthermore, the time window for administering the anti-Nogo-A therapy extends from days to weeks or even months after a stroke, enabling treatment of chronic strokes, months after the acute infarct.

Phase 1 trials are scheduled to start by the middle of 2021. A trial in patients with spinal cord injury is already ongoing and has shown that anti-Nogo-A therapies are safe and tolerable. However, high patient heterogeneity in stroke research presents a challenge, as recovery for each patient will depend on the type, size and location of the resulting lesion, their age, concurrent disorders and so on. Therefore, end points will include recovery of motor functions and quality of life assessment using stroke-specific scales. "Clinically, any improvement in nerve fiber regeneration and neural circuit repair is expected to have a strong impact on patients' outcomes and could dramatically enhance their quality of life," said Vianna.

Clinical studies partners

NovaGo's founding and management team has a proven track record in research and drug development, and maintains international networks across academia and industry, including close collaborations with the University of Zurich and the University Hospital in Zurich, Switzerland, where the company has its headquarters. NovaGo has started a series B investment round and is looking for suitable investors willing to participate as partners to support clinical studies of anti-Nogo-A through proof of concept to phase 2. "We are looking for investors who have an understanding of stroke and are willing to partner with us on this journey," said Vianna. "Our first-in-class regenerative therapy for stroke has a unique mechanism of action that leads to a large degree of functional recovery that could be life changing for sufferers of this debilitating and disabling condition."

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