Noveome Biotherapeutics, Inc.
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ST266—a next-generation anti-inflammatory and neuroprotective platform biologic

Noveome Biotherapeutics, Inc. is developing a new class of biologic consisting of the secretome of a novel population of cells derived from the amnion. The biological factors secreted by these cells have unique anti-inflammatory and neuroprotective effects. Presently, the company is looking for partners to drive clinical drug development of its lead product, ST266, in ophthalmological indications.

Noveome Biotherapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing next-generation biologics for the promotion and restoration of cellular integrity of diseased or damaged tissues.

ST266 is a first-of-its-kind, multi-targeted, non-cellular platform biologic with the potential to improve patients' outcomes across a range of challenging diseases and conditions in ophthalmology, neurology, dermatology and others. Many of these conditions currently have no or limited therapeutic options, in part because they are often too complex to be treated with traditional 'one-drug, one-target' therapies.

The components of ST266 are secreted by a novel population of cells generated by a proprietary method of culturing select amnion-derived epithelial cells collected from full-term placentas normally discarded after birth. The cells produce many of the biological factors found in amniotic fluid that may be responsible for the remarkable healing capabilities and lack of scarring observed following in-utero fetal surgery.

The company is evaluating ST266 in multiple indications including ophthalmological conditions such as optic neuritis, glaucoma and persistent corneal defects. Noveome uses targeted intranasal delivery of ST266 to bypass the blood–brain barrier, clearing a major hurdle to reach the optic nerve directly for treatment (**Fig. 1**). The company has an ongoing phase 1 trial to assess the safety of intranasal ST266 and an ongoing phase 2 trial in which ST266 is applied topically to treat persistent corneal defects.

Noveome is now looking for potential corporate partners interested in the clinical development and eventual commercialization of ST266 for optic neuritis and glaucoma.

According to Larry Brown, CSO and executive vice president of R&D at Noveome, "ST266 provides a potentially revolutionary new way of treating ophthalmic conditions by targeting the optic nerve directly rather than just managing risk factors such as elevated ocular pressure. We are first focusing on optic neuritis to prove the concept, but we believe the greatest opportunity will be in the treatment of glaucoma."

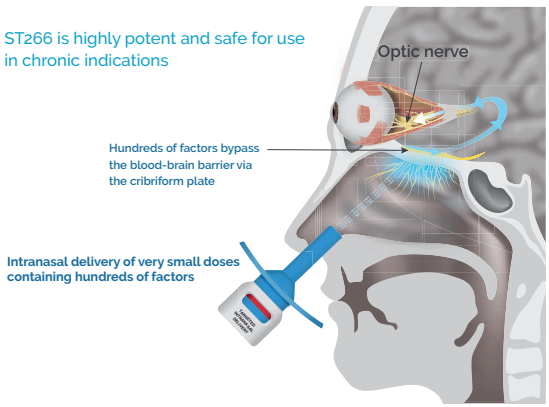

Fig. 1 | Next-generation multifactorial biologic for optic nerve and brain conditions. The non-cellular, multi-target platform biologic, ST266, stimulates anti-inflammatory and neuroprotective pathways. ST266 is delivered intranasally directly to the optic nerve and the brain, thereby bypassing the blood–brain barrier.

ST266—groundbreaking potential

Normal tissue healing is a complex process that requires a combination of growth factors, cytokines and extracellular matrix components. In the 1970s, scarless, regenerative wound healing was first observed in the fetal environment, and this phenomenon was attributed to growth factors and cytokines secreted by the amnion cell layer of the placenta.

Noveome was founded to translate this observation into a novel therapeutic solution. The company has developed a proprietary culture method to create amnion-derived multipotent progenitor (AMP) cells as a primary source of the complex matrix of secreted biological factors—the secretome.

The anti-inflammatory, vision recovery, and retinal ganglion cell and myelin preservation capabilities of ST266 have been demonstrated in an animal model of optic neuritis[1] and an optic nerve crush traumatic injury model[2]. Lot-to-lot reproducibility of ST266 is ensured by the measurement and conformance to specifications for a representative subset of factors in the secretome.

Noveome uses noninvasive intranasal delivery to enable delivery of ST266 to the olfactory nerve and brain and thus target the neuroprotective effects of ST266 to the central nervous system. In preclinical studies with rodents and non-human primates, the highest concentrations of ST266 were observed in the optic nerve tissues, leading Noveome to focus initially on ophthalmic indications. Backed by positive good laboratory practice (GLP), safety and toxicology studies using the intranasal device to deliver ST266, Noveome submitted an investigational new drug (IND) application to the US FDA in August 2019 and obtained a 'safe to proceed' evaluation from the agency, and patient dosing has been initiated.

"ST266 should be of great interest to companies operating in the glaucoma space who are looking at ways in which to treat the optic nerve directly," said Brown.

A broad collaborative spectrum

ST266 is being developed for several indications. Beyond identifying corporate partners for the development and commercialization of ST266 for optic neuritis and glaucoma, Noveome is also exploring the use of ST266 for other indications such as post-cataract surgery complications, chronic traumatic encephalopathy, necrotizing enterocolitis and emphysema. For these other applications, Noveome is seeking partners to drive further development.

"Noveome's primary focus now is on intranasal delivery of ST266 and its potential to treat conditions such as optic neuritis and glaucoma," said Brown. "But we are also looking for partners who might be interested in the preclinical development of other applications of ST266 that might allow us to address other pressing global health challenges."

1. Khan, R. S. *Sci. Rep.* **7**, 41768 (2017).
2. Grinblat, G. A. *Invest. Ophthalmol. Vis. Sci.* **59**, 2370–2477 (2018).

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