Dry AMD: SeaBeLife achieves highly promising preclinical efficacy results for SBL03, without injections into eye

SBL03 was formulated as an ophthalmic gel for non-invasive topical delivery. Its unique ability to infiltrate eye tissues effectively and protect retina from degeneration was demonstrated at a preclinical stage

Treatment directly targets retinal cell necrosis and is positioned as a groundbreaking alternative to intravitreal injections, currently available only in the US

With SBL03, SeaBeLife becomes the only company to develop topical treatment for retinal cell necrosis in geographic atrophy (GA), offering unprecedented hope to the five million people worldwide affected by advanced, debilitating form of dry AMD

Roscoff, France, January 29, 2025 – SeaBeLife, a biotechnology company developing innovative drug candidates intended to block cellular necrosis, today announces significant *in vivo* results for its SBL03 drug candidate, an innovative ophthalmic gel to combat necrotic retinal cell death in geographic atrophy (GA), an advanced form of dry AMD (age-related macular degeneration). These data can be regarded as a major step forward on a high-stakes journey to provide a solution for the millions of patients faced with irreversible sight loss, for whom there is no available treatment in Europe.

The primary aim of the study was to evaluate the efficacy of the SBL03 drug candidate in an *in vivo* preclinical model of induced retinal degeneration. It involved confirming the therapeutic potential of SBL03 in the treatment of geographic atrophy, a severe form of age-related macular degeneration (dry AMD) using a groundbreaking, non-invasive, well-tolerated solution.

SBL03 is a dual inhibitor of regulated necrotic cell death. It is formulated as an ophthalmic gel for topical delivery in the form of eyedrops and is therefore non-invasive. This solution would prevent patients from experiencing sight loss associated with retinal degeneration, by directly targeting the cells affected by the disease, whatever its origin.

The efficacy of SBL03, an ophthalmic gel formulation, was evaluated using a preclinical animal model reproducing the key clinical characteristics of geographic atrophy seen in patients. These include degeneration of the retinal pigment epithelium, resulting in progressive, irreversible loss of the photoreceptor cells responsible for sight.

After retinal degeneration was induced, the preclinical models were treated with repeated topical instillations of SBL03 over several days. The therapeutic effects were evaluated using functional and structural analysis *in vivo* (electroretinography – ERG; optical coherence tomography – OCT; fundus autofluorescence – FAF), along with post-mortem quantitative histological testing.

The data highlights the ability of SBL03 to infiltrate the different parts of the eye and reach its target tissue, the retina, in adequate concentration. Analysis found that the SBL03-treated eyes show significant protection of the structural and functional integrity of the retina. The various parameters examined were correlated and show that repeated topical ocular treatment with SBL03 has a protective effect against retinal degeneration compared with placebo.

"The preclinical results achieved with SBL03 are highly promising and open up new opportunities in the treatment of degenerative retinal disorders. The combination of targeted action and topical delivery makes it a particularly promising solution for preserving patients' sight and therefore their quality of life," said Prof. Jean-François Korobelnik, professor of ophthalmology at the Bordeaux University Hospital, France.

"Compared with current treatments, available only in the US, including intravitreal injections, the topical method of delivery used for SBL03 could considerably improve patient comfort and adherence for this chronic disorder, which requires life-long treatment. It would provide a promising alternative that could transform the care of patients who currently lack a satisfactory or well-tolerated treatment option," said Morgane Rousselot, PhD, CEO and co-founder of SeaBeLife. "With the series A funding round that we're preparing for at the moment, we will be able to continue the development of SBL03 in treating this disorder which affects millions of people worldwide."

To date, SeaBeLife is the only company to develop a therapeutic solution with topical delivery that contains a regulated necrotic cell death inhibitor to treat geographic atrophy. This positions SBL03 as a breakthrough innovation. SeaBeLife plans to ramp up the development of SBL03 by introducing a standard production process. Regulatory preclinical studies are expected to start in 2025, with the aim of conducting an initial clinical trial in humans in 2026.

Geographic atrophy is a severe, advanced form of dry (or atrophic) AMD which is characterized by progressive, irreversible sight loss. The disorder results from the destruction of the photoreceptors and the cells in the retinal pigment epithelium; it affects five million people worldwide. Owing to population aging, this figure is expected to reach ten million by 2040. In both Europe and the United States, it is the leading cause of blindness in patients aged over 50. Currently, there is no medication or treatment available in Europe for dry AMD.

About SeaBeLife

SeaBeLife uses its innovative platform technology to develop small molecules that simultaneously target two different regulated cell death pathways – necroptosis and ferroptosis. With these molecules, it aims to find much-needed solutions for the treatment of rare, acute and chronic diseases. Its main programs include SBL01 for the treatment of severe acute hepatitis and SBL03 for the treatment of dry age-related macular degeneration.
SeaBeLife's novel approach is unique in that it targets both necroptosis and ferroptosis simultaneously. There is currently no such dual inhibitor of regulated necrosis available on the market. The ability to target both cell death pathways simultaneously opens up new treatment options for a wide range of acute and chronic conditions. All the company's research and use cases in this area are protected, with some patents already granted in the US and Europe.
Founded in 2019 and based in Roscoff in Brittany, France, SeaBeLife is led by CEO and co-founder Morgane Rousselot, who holds a PhD in biochemistry from Sorbonne University/the French National Center for Scientific Research (CNRS)/Roscoff Marine Station. The company's activities are based on the research work of Stéphane Bach, PhD, CNRS research engineer and scientific lead at the Roscoff screening platform, Marie-Thérèse Dimanche-Boitrel, research director at IRSET (the French institute for research in environmental and occupational health), and Claire Delehouzé, PhD in biology, co-founder and CTO at SeaBeLife.
SeaBeLife currently employs eight people and since its creation has raised €5.5M ($5.86M) in private equity and grants. In 2023, the company raised €1.2M ($1.28M) in financing. In 2024 it was among the winners of the i-Nov innovation competition. The company also benefits from the support of numerous partners, including SATT Ouest Valorisation, Biotech Santé Bretagne, Bpifrance and the regional council of Brittany.
www.seabelife.com

Media and analyst contact
Andrew Lloyd and Associates
Céline Gonzalez / Saffiyah Khalique
UK +44 1273 952 481
US +1 203 724 5950