



SeaBeLife receives Orphan Drug Designation (ODD) from EMA for treatment of acute liver failure

Orphan designation shows recognition of therapeutic potential of drug candidate SBL01 targeting two regulated cell death pathways

European Medicines Agency's (EMA) granting of ODD status is key milestone for SeaBeLife and its innovative approach in treating severe disorders

Roscoff, France, September 3, 2024 – SeaBeLife, a biotechnology company developing drug candidates intended to block cellular necrosis, today announces the granting of an Orphan Drug Designation (ODD) by the European Medicines Agency (EMA) for its drug candidate SBL01 in the treatment of acute liver failure.

Acute liver failure (ALF) is a life-threatening disease which occurs when the liver suddenly loses its ability to function in a person without a pre-existing liver disorder, resulting in encephalopathy (brain dysfunction) and coagulopathy (bleeding disorder). ALF often affects young people and carries a high morbidity and mortality rate (85% when transplantation is not feasible).

In the EU, the population of patients with ALF is estimated to be between 1.3 and 3.1 in 10,000¹. This meets the EMA's orphan designation threshold, which is targeted at conditions that affect no more than 5 in 10,000 people. With this ODD, SeaBeLife will be able to benefit from regulatory and financial incentives, including protocol assistance, reduced fees and market exclusivity for ten years upon approval.

According to the EMA's committee for orphan medicinal products: "[SeaBeLife] has provided non-clinical data in a model of acute liver failure showing reduced hepatotoxicity and improved survival when SBL01 was used in combination with the currently authorized product in the applied for condition, as compared to the authorized product alone. The committee considered that this constitutes a clinically relevant advantage."

"We are thrilled to receive the orphan drug designation from European authorities. This is an important recognition of our strong preclinical research dataset. It reinforces our determination to push ahead with our approach in treating acute liver diseases and serious ophthalmologic disorders," said Morgane Rousselot, CEO and co-founder of SeaBeLife. "This achievement comes at a time when we are actively preparing a Series A fundraising with venture capital funds, institutional funds and family offices."

SBL01 is a first-in-class small molecule 'dual inhibitor of both necroptosis and ferroptosis'. Regulated cell death, such as necroptosis and ferroptosis, are key processes in acute liver failure where cells degenerate abruptly. The company's molecule is capable of specifically inhibiting the induction cascade of these two cell death mechanisms and thereby enabling cellular protection and restoration of liver function.

¹ The incidence data is derived from a large epidemiological study, run over a one-year period in a population of 124,511 people (Mei-Sheng Duh et al, 1999).

About regulated cell death and SeaBeLife's technology

When a cell dies, there are several modes in which it can do so. In the case of certain pathologies, a phenomenon called necroptosis occurs, which is a form of regulated necrosis. Unfortunately, necroptosis results in inflammation, which damages surrounding tissue. SeaBeLife's molecules have a unique property that make them particularly effective in fighting necroptosis; they also block another specific mode of regulated cell death, ferroptosis, making them double action inhibitors.

In recent scientific literature, researchers have demonstrated that [this dual action is essential to the inhibition of regulated necrosis](#) in treating certain complex pathologies. The synergy between necroptosis and ferroptosis triggers cell death and rapid organ degeneration.

SeaBeLife's approach – based on dual action molecules that simultaneously target two different pathological cell death pathways – is unique in tackling the complex crosstalk between them, unlike other treatments that tend to target a single pathway. As a result, SeaBeLife's treatment options are more likely to prove effective and reduce the chance of resistance in patients.

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