Press Release
September 30, 2022

A major breakthrough innovation for organ transplants

The biotechnology company HEMARINA obtains the CE mark for its HEMO2life® technology

Thanks to the CE marking obtained for its additive to organ preservation solutions HEMO2life®[1], HEMARINA, a company from Brittany, France and pioneer in the field of marine biotechnologies, provides patients and surgeons with a major innovation. HEMO2life® revolutionizes the preservation of grafts awaiting transplantation without modifying clinical protocols and with a demonstrated effect on the survival of post-transplant patients. This CE marking is a major achievement for HEMARINA and its teams and will allow them to market the first oxygen carrier in the world for the preservation of kidney grafts.

The European Union recognizes the first universal oxygen carrier.

HEMARINA has just obtained the CE marking for HEMO2life®[2], a pioneer oxygenation solution[3]. The CE marking attests the conformity of the HEMO2life® medical device to the essential requirements of safety and clinical benefit set by EU regulation, and allows its marketing in Europe. **HEMO2life® technology is a pioneer in optimizing renal graft preservation time and quality to accelerate post-transplant function recovery (DGF: Delay Graft Function).** The improvement of these essential parameters means **a clear improvement of patient survival**. This technology will now be a key option for every procedure in the European Union and in countries where the CE mark is recognized. HEMO2life® is turning transplantation from an emergency procedure to programmed medicine.

To preserve an organ is to save a life!

HEMARINA's founder, Dr. Franck Zal, has been conducting research on the exceptional properties of the extracellular hemoglobin of the arenicolous worm for more than 15 years**. 250 times smaller than human hemoglobin, this hemoglobin is able to transport 40 times more oxygen.**
Several clinical studies and 4-year follow-up of transplanted patients have been conducted, in particular by Professors Le Meur (Brest University Hospital) and Barrou (AP-HP), which allow today the following demonstration for a patient transplanted with HEMO2life®:

- **A 98.3% survival rate after 4 years,** compared to a 86% survival rate under conventional preservation conditions.
- **A decrease of ischemia-reperfusion damage allowing an accelerated recovery of the graft** after transplantation: decrease of the DGF marker of 7% (HEMO2life® arm) vs 26% (Control arm).
- **A decrease in the use of Belatacept® over a 4-year period,** an immunosuppressant used in case of graft rejection event (0% HEMO2life® arm vs 11% Control arm).

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[1] *Under MDR 2017/745 reglementation.*
[2] *Class III medical device from its M101 technology platform.*
[3] *With the approval of the notified body BSI n°2797 (British Standard Institution).*

With HEMO2life® HEMARINA is bringing a tangible solution to a major public health issue related to acute renal failure. **In France, more than 20,000 patients were waiting for a kidney transplant as of March 17, 2022, while less than 6,000 transplants are performed each year.** In recent years, this innovation has notably enabled the success of two face transplants performed by Professor Laurent Lantieri, from the AP-HP HEGP and the Percy Military Hospital, in 2018 and 2022.

Achieving a collective adventure.

From fundamental research to the operating room, HEMO2life® is today the first oxygen carrier in the world to obtain a marketing authorization rewarding the work of a committed team: *"This certification rewards several years of hard work by a team of experts whose work is equal to this success. They have never given up and have made it possible to turn a somewhat crazy dream of treating patients with sea worm hemoglobin into a unique, world-leading, health company,"* says Franck Zal.

With offices in Morlaix, Boston and soon in Montreal and New Delhi, HEMARINA adopts the model of the largest American biotechs, and has now become the French herald of great biomedical innovation. With access to the market for its flagship solution, HEMARINA is entering a new era in its global development: *"We have all the assets to become one of the next French "unicorn". It's making us proud but it has never been a reward in itself: the driving force behind our work is the number of lives saved thanks to a technology developed by French fundamental research,"* adds the founder.

This first approval demonstrates the relevance of HEMARINA M-101's platform in the oxygenation of human cells. It will be followed by many other innovations under development, allowing the company to serenely feed its pipeline protected by some sixty patents.

ABOUT HEMARINA

HEMARINA is a company created in 2007 by Dr. Franck ZAL and based in Morlaix (Finistère, France). The company is specialized in the development of universal therapeutic oxygen carriers of marine origin. HEMARINA has a technical and commercial subsidiary in Boston (HEMARINA Inc.) and a production subsidiary for its raw material on the Island of Noirmoutier FMN (Vendée, France). HEMARINA is developing several disruptive therapeutic innovations based on its technology platform to fight anemia (lack of red blood cells) and ischemia (blood circulation problems).

Its founder, Dr. Franck Zal, has gained international recognition through his original approach based on the observation of marine organisms and biomimicry. The scientific work carried out by Franck Zal for more than 20 years has enabled him to develop a unique expertise in the field of respiratory pigments belonging to marine invertebrates.

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