



## PRESS RELEASE

### **Brest University Hospital and HEMARINA present positive new advances from the initial clinical trial of HEMO<sub>2</sub>life<sup>®</sup> at the American Transplant Congress in Seattle**

- Significant improvement in graft function

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**Morlaix, Brest (France), 6 June 2018 – Brest University Hospital and HEMARINA announced at a poster<sup>1</sup> session at the American Transplant Congress (American Transplant Congress "ATC")<sup>2</sup>, the leading global organ transplant congress, the interim 3-month results from the OxyOp<sup>3</sup> study, presented by Professor Yannick Le Meur, the trial's principal investigator. This study, conducted at six French transplant centres, followed, for one year, patients who had received a kidney that had been preserved in a solution containing the HEMO<sub>2</sub>life<sup>®</sup> additive.**

Brest University Hospital and HEMARINA had already published initial very positive results on the safety in use of HEMO<sub>2</sub>life<sup>®</sup> in November 2017 ([click here](#) for more details), namely:

- No product-related graft loss, according to the Independent Data Safety Monitoring Board (IDSMB),
- No death at 3 months,
- No major adverse event related to HEMO<sub>2</sub>life<sup>®</sup>,
- No immunological, allergic or pro-thrombotic effects,
- Promising preliminary efficacy data.

**The new results presented confirm this major medical innovation in kidney transplants.** In terms of efficacy, two major results should be noted:

- Fewer patients who received a kidney preserved with HEMO<sub>2</sub>life<sup>®</sup> suffered from Delayed Graft Function (DGF): 6.98% vs 26.19%. This marker, the DGF, is predictive of the long-term success of the transplant,
- Another blood parameter, like serum creatinine, which indicates a defect in the elimination of organ waste in the blood, also marked the difference between the two patient groups; patients whose kidneys had been preserved with HEMO<sub>2</sub>life<sup>®</sup> reached target levels of serum creatinine in an average of 7 days, compared with an average of 13 days in the other patient group. Moreover, this parameter is usually studied to assess the success of a kidney transplant.



**Professor Yannick Le Meur, Nephrologist, University Professor, Head of Department at Brest University Hospital**, stated *"HEMARINA's technology is extremely promising: its use by the surgical teams is simple and can easily be integrated into current practices. It should make the teams' work easier by giving them more time to prepare transplants. I am therefore very pleased to present the results of this world first to the entire scientific community gathered at the ATC and to be able to share them with colleagues worldwide"*.

**Dr Franck Zal, co-founder and CEO of HEMARINA** added: *"We are delighted with the results obtained. HEMO<sub>2</sub>life<sup>®</sup> enables delayed graft function to be reduced by almost two-thirds. This criterion is a predictor of the long-term survival of the transplant and unambiguously demonstrates excellent preservation of the graft compared with existing clinical techniques. We are fully committed to bringing this medical device onto the market. We expect HEMO<sub>2</sub>life<sup>®</sup> to very rapidly become the benchmark in graft preservation. These clinical results contribute to strengthening our technological platform. A transplant is so precious that we should give it every chance of success. We owe it to the donors, the receivers, and their respective families"*.

<sup>1</sup> **Poster:** reference D48 presented on Tuesday 5 June 18:00 – 19:00, Hall 4 EF

<sup>2</sup> **ATC:** global congress for Health professionals who are interested in the clinical and research aspects of organ transplantation. It brings together 5,000 participants and exhibitors

<sup>3</sup> **OxyOp:** evaluation of a marine OXYgen carrier, HEMO<sub>2</sub>life<sup>®</sup>, for hypOthermic kidney graft preservation before transplantation (first human clinical study of a marine oxygen carrier).

### **References:**

Congress website: <https://atcmeeting.org/>

Programme: [https://atcmeeting.org/sites/default/files/docs/2018/atc2018\\_cti\\_program\\_4-30-18.pdf](https://atcmeeting.org/sites/default/files/docs/2018/atc2018_cti_program_4-30-18.pdf)

### **About the OxyOp study (NCT02652520)**

The multicentre OxyOp clinical study has been designed to assess the safety in use and obtain preliminary efficacy data on the HEMO<sub>2</sub>life<sup>®</sup> product, used as an additive in a graft preservation solution. The study has been financed by a public-private partnership: public funds from a French government grant (Clinical Research Hospital Programme, PHRC) and private funds provided by Hemarina. 60 patients received transplants in six reference transplant centres in France using kidneys that had been preserved in hypothermic conditions (machine perfusion and static) supplemented by HEMO<sub>2</sub>life<sup>®</sup>. The principal aim of the trial was the security in use of HEMO<sub>2</sub>life<sup>®</sup> as an additive to existing preservation solutions. The secondary aims were renal function parameters, biomarkers and the histological profiles of the transplanted organs. Further information on the OxyOp trial can be found at <https://www.clinicaltrials.gov/>

### **Study timeline:**

- ANSM authorisation to conduct the study - October 2015
- Start of enrolment - February 2016
- End of monitoring of last patient included - February 2018
- Presentation of interim 3-month results of all patients - June 2018
- Presentation of final results - not yet available

### **About kidney transplants**

Kidney transplant is currently the only treatment for end-stage renal disease. It enables patients whose kidneys have been destroyed by disease to have a near-normal life expectancy and quality of life. A transplant lasts for an average of around fifteen years. In 2016, there were 3,615 kidney transplants in France, however during this time, 5,181 patients were added to the waiting list. The majority of grafts come from donors who are brain dead, and in recent years the profile of donors has changed: they are now older and more frequently have a history of heart disease. Transplantation is accordingly now faced with a dual challenge: enabling the highest number of patients to receive transplants while the number of donors is insufficient and increasing the lifespan of grafts that are more fragile and more susceptible to ischemia-reperfusion injuries (ISI) [Source: *Medical and Scientific Report on Removal of Grafts in France by the Agence de la Biomédecine (Biomedicine Agency) 2016*].



### **About Hemarina**

Hemarina is a biotechnology company founded in 2007 and headquartered in Morlaix, Finistère, France. The company specializes in the development of universal marine oxygen carriers. Hemarina has a technical & commercial affiliate in Boston (Hemarina Inc.) and a production subsidiary for its raw materials located on the island of Noirmoutier (France), as well as offices in Paris.

Hemarina has identified three medical applications and one industrial application:

- An additive to organ preservation solutions: HEMO<sub>2</sub>life®
- A therapeutic oxygen carrier: HEMOXYCarrier®
- An oxygenating dressing: HEMHealing®
- An input for industrial bioproduction: HEMOXCell®/HEMBoost®

For more information, visit our website: [www.hemarina.com](http://www.hemarina.com)

### **About Brest University Hospital**

Research is one of the three missions of Brest University Hospital, inseparable from care and education. Its aims are the acquisition of new knowledge and also, with regard to translational research, to facilitate patient access to the most innovative treatments and contribute to improving their care. This research is based on certified research units, significant clinical research activity driven by clinical activity and medical technology hubs, which have been supported since 2011 by the Multidisciplinary Research Institute. The University Hospital research activity has grown steadily with a current portfolio of 764 studies including 78 interventional trials that have been undertaken under its supervision.

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