



PRESS RELEASE

Brest University Hospital and HEMARINA announce positive Top-line results from first clinical trial of HEMO₂life[®] in kidney preservation before human transplantation.

- OxyOp trial represents the first use in human of the marine oxygen carrier HEMO₂life[®]. HEMO₂life[®] was added in preservation solution in order to reduce ischemia reperfusion injuries due to hypoxia during the preservation of the graft.
- 3 month analysis of the multicenter study OxyOp* started in October 2015 shows an excellent safety profile for HEMO₂life[®] and promising preliminary efficacy data in regard to existing standard of care in kidney transplantation.
- HEMO₂life[®] confirms its potential as a breakthrough oxygen-carrier innovation used as a universal additive to existing organ preservation solutions in static or dynamic (perfusion machine) environment.

Morlaix, Brest (France), Tuesday, November 14, 2017: Brest University Hospital and Hemarina announced today that the first ever clinical study (OxyOp) with an oxygen carrier (HEMO₂life[®]) in human transplantation met its primary endpoint of demonstrating safety of HEMO₂life[®] used as additive to existing hypothermic organ preservation methods.

Three months after the transplantation, preliminary data analysed over 60 patients in six French reference transplant centers showed the following Top line results:

- No graft loss related to product, according to IDSMB, Independent Data Safety Monitoring Board
- No death at 3 months
- No major adverse event related to HEMO₂life[®]
- No immunological, allergic or pro-thrombotic effects
- Promising preliminary efficacy data

“Organ transplantation remains the last resort for a certain number of otherwise incurable medical conditions. Despite recent improvement in the field, organ preservation and ischemia-reperfusion injuries (IRI) associated with it remain an essential factor responsible for primary and long-term dysfunction after transplantation” said Prof. Benoit Barrou, Head of the Kidney Transplantation Program, Department of Urology, Nephrology and Renal Transplantation, Groupe Hospitalier Pitié Salpêtrière, Paris, France. *“New interventions should be developed to enhance the quality of grafts at the end of preservation not only to reduce the consequence of IRI but also to expand the number of available transplantable grafts, thus reducing the worldwide organ shortage.”*

Based on the results of the OxyOp study, the company intends to apply for a CE marking of HEMO₂life[®] as additive to existing preservation solutions (before solid organ transplantation), in order to make this innovation available to patients and clinicians.

“We are delighted with the 3 months results seen in OxyOp study, the first clinical trial with HEMO₂life[®]. Data issued from 60 patients receiving a kidney preserved with the addition of HEMO₂life[®] show an excellent safety profile for HEMO₂life[®] in regard to both grafts and patients. We continue of course to follow our patients to ensure that the results observed today will translate into significant benefits in the long term.” said Professor



Yannick Le Meur, head of Nephrology and Kidney Transplantation Department at Brest University Hospital and investigator coordinator of the study.

"We want to thank the patients, family members and clinicians who participated in the OxyOp trial. This landmark study confirms the promising results seen in many preclinical studies so far and represents the first step of a new era in organ preservation. We are working intensively to make this product commercially available and to provide an effective tool to fight against the organ shortage and better meet the need of the patients registered on the waiting lists. Hemarina remains committed to its credo: to save lives by bringing its technology to patients worldwide" said Dr. Franck Zal, co-founder and CEO, Hemarina. "We look forward to further analysing the detailed results from OxyOp study and submitting them for presentation to a major medical meeting."

**OxyOp : Evaluation of a marine OXYgen carrier, HEMO₂life[®], for hypOthermic kidney graft Preservation before transplantation*

About OxyOp trial (NCT02652520)

The multicenter clinical study OxyOp was designed to evaluate the safety and get preliminary efficacy data on HEMO₂life[®] used as an additive in graft preservation solution. The study was financed by a public-private partnership: a national French grant (Programme hospitalier de recherche clinique PHRC) involving public funds and Hemarina's private funds. 60 patients were transplanted in six French reference transplant centers with kidneys preserved in hypothermic conditions (static and perfusion machine) with supplementation with HEMO₂life[®]. The primary objective of the trial was the safety of using HEMO₂life[®] as an additive to current preservation solutions. Secondary endpoints were parameters of renal function, biomarkers and histological patterns of the transplanted organs. For more information on the OxyOp trial, go to www.clinicaltrials.gov.

About kidney transplant

Kidney transplantation is the elective treatment for End Stage Renal Disease. It allows patients, whose kidneys have been altered by the disease, to prolong life expectancy and to enjoy a near normal quality of life. The average running time of a transplant is about thirteen years. During the year 2016, 3615 patients received a kidney transplant in France, but in the same time 5181 patients were registered on the waiting list. The vast majority of grafts are retrieved from brain-death donors and in recent years the profile of donors has changed including older donors with more comorbidities. Thus, the transplantation community is now facing a double challenge: firstly to enable the largest number of patients to receive a transplant, and secondly to increase the viability of grafts while they are more sensitive to IRI [Source: 2016 Report of the French Biomedicine Agency].

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 site located on the island of Noirmoutier (France) so as offices in Paris.

Hemarina identified four applications which are highly creative for short-medium term value including three medical applications and one industrial application:

- A therapeutic oxygen carrier: HEMOXYCarrier[®]
- An additive to organ preservation solutions: HEMO₂life[®]
- An oxygenating dressing: HEMHealing[®]
- An input for industrial bioproduction: HEMOXCell[®] / HEMBoost[®]

For more information, visit our website: www.hemarina.com

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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, which are a very important clinical research activity driven by clinical activity and medical technology poles. They have been supported since 2011 by the Multidisciplinary Research Institute. The CHRU research activity has grown steadily with a current portfolio of 764 studies including 78 interventional trials which were undertaken under its supervision.

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