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Press Release

Organ transplantation: ALS achieved CE Certification for PERLA®, The new class of solution – PPS – and launches a randomized comparative clinical trial (RCT)

- **ALS has received CE marking approval for PERLA®, the First-In-Class Preservation and Protection Solution for liver and kidney , designed to protect the graft from retrieval to transplantation.**
- **With PERLA®, ALS introduces a New Class of Preservation and Protection Solutions (PPS), designed to actively protect the graft against ischemia-reperfusion injury, moving beyond traditional Cold Storage Solutions (CSS).**
- **Launch of a randomized comparative clinical trial including approximately 500 patients across Europe, a study of unprecedented scale in the field of solutions for more than 30 years.**

April 28th 2026: ALS achieved CE certification for PERLA®, The new Class of Preservation and Protection Solution (PPS) developed to protect the graft throughout its journey, from organ retrieval to transplantation.

At the same time, the company is launching a randomized comparative clinical trial to evaluate PERLA® versus current solutions in the market (CSS).

Preservation: a critical step in transplantation

Each organ transplant involves a particularly sensitive phase: the period between graft retrieval and implantation into the recipient. This phase, which can last several hours, is known as ischemia (lack of oxygen) followed by reperfusion (restoration of blood flow upon implantation).

During this time, the organ must be **stored**, **preserved** and **protected** under conditions that maximize functional recovery, a key determinant of both graft survival and patient quality of life.

Today, transplantation remains a life-saving treatment for patients with end-stage organ failure. Globally, more than 170,000 organ transplants are performed each year, according to the Global Observatory on Donation and Transplantation. However, this meets only a fraction of medical needs, with approximately one transplant performed for every four patients on waiting lists.

The kidney is the most frequently transplanted organ worldwide, followed by the liver, heart and lungs.

Despite these advances, transplantation still faces major challenges: organ shortages and increasing reliance on so-called “extended criteria donors”, whose organs are more sensible. **Today, more than 60% of donors are over 60 years old, whereas donors were significantly**

younger when current preservation solutions were originally developed. As a result, ischemia-reperfusion injury has a much greater impact on today's grafts.

Historically, solutions used in transplantation belong to the category of **Cold Storage Solutions (CSS)**. Their purpose is to slow down graft metabolism by storing organs at low temperature, thereby limiting degradation during transport and ischemia-reperfusion phases.

While this approach has extended preservation time, it mainly targets metabolic slowdown and does not adequately address the biological mechanisms involved in ischemia-reperfusion injury.

In this context, **a new paradigm is emerging: not only ensuring storage and preservation, but also actively protecting the graft against ischemia-reperfusion injury throughout the transplantation process.**

PERLA : a solution designed to preserve and protect the graft

Developed by ALS, PERLA® is part of a **Preservation and Protection Solution (PPS) approach**, acting on the biological mechanisms involved in transplantation-related injuries. It relies on protective molecules that actively mitigate ischemia-reperfusion damage.

Beyond simple storage, PERLA® is designed to limit cellular injury associated with ischemia-reperfusion, which occurs when blood supply is interrupted and then restored during transplantation.

The solution is used:

- during organ **flushing** at the donor site,
- throughout the **preservation phase** prior to transplantation,
- while actively c**ontributing to graft protection**.

PERLA®'s formulation combines, through drug repurposing, three pharmacological agents: trimetazidine, carvedilol and tacrolimus. Several studies have shown that these agents help protect cells against the deleterious effects of ischemia-reperfusion.

This approach aims to preserve cellular integrity and support functional recovery of the graft after transplantation.

Strong scientific expertise

PERLA® is built on the scientific expertise of ALS's team, led by Silvina Ramella, a globally recognized expert with more than 30 years of experience in organ preservation and protection.

Silvina Ramella previously contributed to the development of preservation solutions widely used in transplantation centers.

With PERLA®, ALS continues its work to improve graft protection and optimize transplantation outcomes.

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Launch of a comparative clinical trial

Following CE marking, ALS is launching a randomized comparative clinical trial to evaluate PERLA® under real-life clinical conditions.

The study will compare PERLA® with currently used cold storage solutions (CSS).

Randomized comparative studies in this field are rare, and no large-scale study of this magnitude has been conducted in more than 30 years, despite significant changes in donor profiles and graft characteristics.

The objective is to generate clinical data assessing PERLA®'s ability to protect the graft and support functional recovery after transplantation, compared to existing solutions.

Presentation at the ILTS international congress

ALS will exhibit at the International Liver Transplantation Society (ILTS) congress in Geneva.

This will be an opportunity for transplant specialists to better understand the benefits of PERLA®.

This major scientific event is a key moment for the transplantation community, particularly in liver transplantation.

About ALS

ALS – Advanced Life Solutions - is a French company specializing in the development, industrialization and commercialization of medical devices dedicated to organ protection in transplantation. From its inception, ALS has pursued a global deployment strategy.

ALS was founded by Silvina Ramella and Thierry Asmar.

Silvina Ramella is a scientist with more than 30 years of experience in organ preservation, having contributed to the development of the latest generation of preservation solutions in Europe.

Thierry Asmar has more than 30 years of experience in executive leadership in France and internationally.