Publication of positive results for hypothermic machine preservation of donor livers

New technology shows potential to improve quality and availability of livers for transplantation

Lifeline Scientific (AIM: LSIC), the transplantation technology company, welcomes the publication in the American Journal of Transplantation of the clinical study (Study): “Hypothermic Machine Preservation Facilitates Successful Transplantation of “Orphan” Extended Criteria Donor Livers.”

The Study was led by Dr. James Guarrera and colleagues at New York-Presbyterian Hospital/Columbia University Medical Center. Results show that this novel system of hypothermic machine preservation (‘HMP’) of the liver has meaningful clinical utility with the potential to increase the number of donor livers suitable for transplantation and help close the wide gap between organ supply and demand. Use of this technology also demonstrated a significant reduction in hospital stay for patients and most notably, successful recovery of livers from older and sicker donors, long considered too risky for transplant.

Informed by the clinical success of the Company’s global market leading LifePort® Kidney Transporter, the liver HMP system continuously pumps Vasosol®, the Company’s specially formulated proprietary cold preservation solution, through the liver. By comparison, today’s standard practice for preservation is static cold storage (SCS), a process in which organs are maintained in a cool box filled with ice.

In the Study, HMP intervention led to better transplant outcomes than traditional static cold storage. The HMP transplant recipients experienced higher one-year survival rates, shorter hospital stays and fewer long-term complications. Even more impressive, the HMP livers were considered “orphan livers,” which means the organs were rejected by every transplant center in the United Network for Organ Sharing (UNOS) region where originally offered.

Dr. Guarrera, surgical director of adult liver transplantation at New York-Presbyterian Hospital/Columbia University Medical Center, and an associate professor of surgery at Columbia University College of Physicians and Surgeons, said: “This new technology should allow a significant expansion in the number of potential livers recovered, making transplant available to many more people. The Study results showed that better transplant outcomes were achieved versus conventional ice-box static cold storage, thus improving the overall liver transplant process. As well, these so called ‘orphan’ livers were very likely to be discarded. We knew that if we could successfully recover them for transplant, it would allow more patients access to a lifesaving transplant.”

Worldwide, tens of thousands of patients with end-stage liver disease are on official waiting lists for a lifesaving transplant. In the US and EU each year, it is estimated that more than 5,000 liver transplant candidates die waiting for a transplant. In every country where transplantation is performed, there is a significant disparity between the number of patients on waiting lists and the availability of donor organs.

Employing an early prototype of Lifeline’s LifePort Liver Transporter coupled with the Company’s proprietary preservation solution, Vasosol, Dr. Guarrera and his team compared two groups of patients receiving isolated primary liver transplantation. 31 liver transplant patients in the intervention arm received HMP-preserved livers from older and sicker deceased donors, known as extended criteria donors, while 30 liver transplant patients in the control arm received SCS-preserved extended criteria donor livers that were matched for donor age, recipient age, cold ischemic time, donor risk index and Model for End-Stage Liver Disease (MELD), score.
During the 12-month post-transplantation follow-up, there were significantly fewer biliary complications in the HMP group versus SCS (4 vs. 13, respectively; \( p = 0.016 \)), and lower early allograft dysfunction rates (19% vs. 30%, respectively). In addition, mean hospital stay was significantly shorter in the HMP group (13.6 vs. 21.1 days, respectively; \( p=0.001 \)). The HMP-preserved livers also had lower levels of blood markers of liver and kidney injury than the SCS-preserved livers, suggesting less donor organ injury during preservation.

These newly published results support data from Columbia University Medical Center’s first clinical feasibility study using this technology, which showed 50 percent fewer patients receiving HMP perfused livers had biliary complications, that early allograft dysfunction was seen in 25 percent of SCS livers compared with 5 percent of HMP, and that patients receiving HMP perfused livers had a significantly lower length of hospital stay than patients with SCS livers.

**David Kravitz, CEO of Lifeline Scientific, commented:** “This is very promising news and we congratulate Dr. Guerrera and his colleagues for their pioneering work advancing our community’s understanding of the benefits of hypothermic machine perfusion in liver transplantation. This second Study appears to further demonstrate fundamental clinical safety and efficacy of HMP in liver transplantation. Most significantly, we are encouraged by the potential major impact this technology could have for helping the tens of thousands of end-stage liver disease patients waiting for a life saving liver transplant. Any advancement that helps enable the availability of more organs and improved post-transplant outcomes is a blessing for patients and a very important contribution to our field of medicine.”


**For further information:**

**Lifeline Scientific, Inc.**

David Kravitz, CEO
Lisa Kieres, CFO

**Panmure Gordon (UK) Limited**

Freddy Crossley (Corporate Finance)
Maisie Atkinson (Corporate Broking)

**Walbrook**

Paul McManus
Mike Wort

**About Lifeline Scientific Inc.**

Lifeline Scientific, Inc. is a Chicago-based global medical technology company with regional offices in Brussels and Sao Paulo. The Company’s focus is the development of innovative products that improve transplant outcomes and lower the overall costs of transplantation. Its lead product, LifePort Kidney Transporter, is the global market-leading medical device for hypothermic machine preservation of donor kidneys. LifePorts and novel solutions designed for preservation of other organs are in development, with LifePort Liver Transporter next in line for commercial launch. For more information please visit [www.lifeline-scientific.com](http://www.lifeline-scientific.com)

**About LifePort Kidney Transporter**

Created with the challenges of organ recovery and transport in mind, LifePort Kidney Transporter is a proprietary medical device designed to help improve kidney preservation, evaluation and transport prior to transplantation. It has been widely studied in clinical trials throughout the world and is the standard of care for machine preservation of kidneys. Employed by surgeons in over 165 leading transplant programmes in 27
countries, LifePorts have successfully preserved over 47,000 kidneys indicated for clinical transplant. For more information please visit www.organ-recovery.com

**About LifePort Liver Transporter**
LifePort Liver Transporter is modeled upon the clinically proven technology platform of LifePort Kidney Transporter and the early HMP prototype used by Dr Guarrera and colleagues at New York-Presbyterian Hospital/Columbia University Medical Center. LifePort Liver Transporter and the Company’s proprietary machine preservation solution, Vasosol, are in the process of US and European regulatory registrations. The system is designed to help improve outcomes in liver transplantation by enabling the clinical use of hypothermic machine perfusion, and has been developed in consultation with clinical and research teams specializing in liver transplantation at Columbia University Medical Center and the University of Chicago. The system employs a rugged, streamlined ergonomic design for ease of use and transportability from donor bedside to recipient operating room. For more information please visit: http://www.organ-recovery.com/pipeline.php