Evaluate Vantage

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Event – Xvivo tech aims to breathe new life into transplants

Elizabeth Cairns

Systems to keep organs alive so they can be transported to their recipients are old news. An advisory panel to the US FDA is now to evaluate a more notable technology: one that not only preserves the function of donated lungs, but actually improves it.

The FDA's Gastroenterology & Urology Devices Panel will meet on March 20 to review the Xvivo Perfusion System (XPS) developed by Sweden's Xvivo Perfusion. The device is used to pass a liquid of Xvivo's own devising through excised donor lungs initially deemed unsuitable for transplant, with the intention of preserving and even improving the function of the donated lungs.

Xvivo is seeking a humanitarian device exemption (HDE) for the system, highlighting its innovative nature and the unmet need it is intended to address. HDEs are designed to be awarded to devices intended for conditions that affect fewer than 4,000 individuals in the US each year. A lower burden of proof of efficacy is required compared with a PMA, though the company must show that the probable benefit to health outweighs any risk posed by the device, and that no other device that can perform the same function already exists.

The company also hopes to obtain CE mark approval for the perfusion system this year.

Novel

The adcom will evaluate data from the pivotal US study, Novel, in which 42 patients received transplanted lungs that had been placed on the XPS and perfused with Xvivo's Steen Solution. This is a buffered fluid including human albumin intended to protect the endothelium from excessive leucocyte interaction, already approved in the US. The patients in the treatment arm were matched with 42 control patients who underwent conventional transplantation.

During the Xvivo procedure, the system was primed with 2,000ml of Steen Solution. After a hour, 500ml of circulated perfusate was removed and replenished with 500ml of fresh solution. After that, 250ml of perfusate was exchanged every hour. The primary endpoint is mortality at 30 days post-transplant.

Xvivo says that interim results from the trial indicate that initially rejected lungs could be made to perform as well as lungs that were deemed good enough for transplant. The company says that worldwide, more than 240 patients have received lungs that would have otherwise remained unused.

Currently, only about 15% of donated lungs are transplanted each year. At a site in Toronto where the Xvivo system is used, 40% of donated lungs have been found suitable for transplant. Since listing on the Nasdaq OMX First North exchange in October 2012, the company's shares have increased 78%; the company's investors have clearly kept faith. Now the FDA's experts must be likewise convinced.

Trial name	Trial ID
Novel	NCT01365429

To contact the writer of this story email Elizabeth Cairns in London at elizabethc@epvantage.com or follow @LizEPVantage on Twitter

Evaluate APAC
+81-(0)80-1164-4754