Press Release
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Gothenburg

First third of STEEN Solution™ study in USA completed.

The fourth of the total of twelve patients included in the USA study for STEEN Solution™, and which enables sales approval in the important USA market, has now received a transplant. The first transplantation was carried out in September and four transplantations have thus now been carried out at four centres. A fifth centre, Duke University, has been included in the study, and it is anticipated that they will be able to start within approximately one month there.

A study is being carried out at present in the USA, comprising 12 patients who are being given transplants after treatment of donor lungs using STEEN Solution™. Five well-reputed lung transplant centres in Baltimore, New York, Boston, Denver and Durham are participating. The study has been devised in consultation with the FDA and complements the previously published Canadian study on 22 patients.

Sales approval in the USA is expected if the study obtains results that correspond to those obtained in the study carried out in Canada. Approval would mean that STEEN Solution™ could begin to be used clinically in the USA, which would then open up a large market, as approximately half of all lung transplants in the world are done in the USA.

The STEEN Solution™ method involves a fluid (STEEN Solution™) being pumped at body temperature through the organ's blood vessels, whereupon the organ is given the chance to recover and is tested for function. The study includes lungs that were initially assessed not to be sufficietntly functional for use in transplantation. Using the STEEN Solution™ method the number of organs available for transplantation can thereby be increased and fatalities and the time on the waiting list reduced.

"After having met and overcome more bureaucratic problems than we had expected to start the study, we have now relatively quickly got through a third of the study, which is a big step towards sales approval in the USA," says Magnus Nilsson, CEO.

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VITROLIFE AB (publ)

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Vitrolife is a global biotechnology/medical device Group that works with developing, manufacturing and selling advanced products and systems for the preparation, cultivation and storage of human cells, tissue and organs. The company has business activities within three product areas: Fertility, Transplantation and Stem Cell Cultivation. The Fertility product area works with nutrient solutions (media), cryopreservation products and advanced consumable instruments such as needles and pipettes, for the treatment of human infertility. The Transplantation product area works with solutions and systems to evaluate and maintain organs outside the body in order to select usable organs and keep them in optimal condition while waiting for transplantation. The Stem Cell Cultivation product area works with media and instruments to enable the use and handling of stem cells for therapeutic purposes.
Vitrolife today has approximately 220 employees and its products are sold in more than 85 markets. The company is headquartered in Gothenburg, Sweden, and there are subsidiaries in USA, Australia, France, Italy, United Kingdom and Japan. Production facilities are located in Sweden and the USA. The Vitrolife share is listed on NASDAQ OMX Stockholm, Small Cap.