Press release
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Gothenburg

Application for market approval of STEEN Solution™ in the USA has been submitted to the FDA

Vitrolife has submitted an application to the American Food and Drug Administration (FDA) regarding market approval of STEEN Solution™, a product used for cleansing and evaluation of lungs outside the body (ex vivo) before transplantation.

The application was based on successful results from the clinical trial that Vitrolife is conducting in the USA with STEEN Solution™**.** This new innovative method has been shown to enable that those lungs that previously had been deemed not usable, were usable after performing perfusion with STEEN Solution™ when the organ was taken out of the donor's body. The use of STEEN Solution™ has therefore the potential to significantly increase the number of lungs available for transplantation, something that could be lifesaving for many patients since there today is a lack of available organs to transplant.

"The submission of the application to the FDA for market approval is a milestone in the clinical and commercial development of Vitrolife's unique and innovative STEEN Solution™" says Magnus Nilsson, head of Vitrolife's subsidiary Xvivo Perfusion AB that focus on developing and commercializing products for organ transplantation.

If the application is approved by the FDA, it is estimated that sales in the USA can commence in the end of 2012 whereafter Xvivo Perfusion AB can start marketing STEEN Solution™ and other products related to the clinical use of STEEN Solution™ that the company has developed.

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Gothenburg, Sweden
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Vitrolife is a global biotechnology/medical device Group that has business activities within the areas of fertility and transplantation. 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. There is also business to enable the use and handling of stem cells for therapeutic purposes. 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.

Vitrolife today has approximately 220 employees and its products are sold in almost 90 markets. The company is headquartered in Gothenburg, Sweden, and there are offices in USA, Australia, France, Italy, United Kingdom, China and Japan. The Vitrolife share is listed on NASDAQ OMX Stockholm, Small Cap.

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