Press release
April 18, 2012
Gothenburg

All patients included in the clinical study on STEEN Solution™ in the USA

In the clinical study that was begun during 2011 on STEEN Solution™ with the aim of forming a basis for sales approval in the USA, a total of 13 patients have now received transplants. The required number of patients, which was 12, has thereby been included in the study. "Even if some work remains and it is difficult to assess how the FDA will reply it is now reasonable to assume that this is a big step closer to sales approval in the most important market in the world," says Dr Magnus Nilsson, who is responsible for Vitrolife's transplantation area.

Since autumn 2011 Vitrolife has run a clinical study on STEEN Solution™ in the USA with the aim of forming a basis for an application for sales approval in the USA. At least 12 patients were to receive transplants using organs that initially were assessed to be unusable. These organs have then been perfused with STEEN Solution™ at body temperature, which means that fluid is pumped through the blood vessels of the organ in the same way as blood in the body. After a few hours treatment the organ has been evaluated regarding clinical usability and then been approved.

The patients will be compared with the same number of control patients who at the same hospitals during the same period of time have undergone transplantation using conventionally acquired and assessed organs. It still remains to include a couple of control patients, after which the collected data in the study will be analysed and compiled. Vitrolife estimates that an application for market approval can be submitted to the U.S. Food and Drug Administration (FDA) for scrutiny during the second quarter. If the FDA approves the application it is estimated that sales in the USA will be able to begin during the second half of 2012.

Vitrolife plans to apply for Humanitarian Device Exemption (HDE), which means a quicker application procedure and which can be granted to products of crucial importance when the indication for use is relatively limited. HDE approval means that the company may sell the product under controlled forms. The clinical study is continuing with the aim of including a larger number of patients in order to strengthen documentation of the advantages of using STEEN Solution™, which is important in the marketing of the new treatment method. Vitrolife also intends on a later occasion, the timing of which depends on the assessment of the FDA, to use these more extensive data to apply for full approval, so-called Premarket Approval (PMA).

Vitrolife's product STEEN Solution™ is part of a method where, after an organ has been taken out from the donor, a fluid (STEEN Solution™) is pumped at body temperature through its blood vessels, whereby the organ has the opportunity to recover and can also be tested for function. Using the STEEN Solution™ method the number of organs available for transplantation can be significantly increased. So far approximately 150 lung transplants have been performed using the method, which today is approved in Europe and Australia.

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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.

This is a translation of the Swedish version of the press release. When in doubt, the Swedish wording prevails.