Press Release
July 6, 2006
Kungsbacka, Sweden

Unique product approval obtained

Vitrolife is the first company to have nutrient solutions used in in vitro fertilization and containing human protein reviewed by the EMEA (the European Medicines Agency) and has obtained European approval (CE marking) for these. "We are in the forefront in this field regarding authority approval of fertility products. In the light of the EU Commission's new directive, which requires clinics to use CE marked media, we hope that this will give us considerable competitive advantages," says Vitrolife's CEO Magnus Nilsson.

The products that have now been CE marked are all of Vitrolife's media containing protein. Vitrolife's GIII media series without protein has previously been approved. It was the first complete media system on the market to be CE marked. The products that have now been approved, with the designation GIII-plus, are pre-mixed and thereby easier to use for clinics. Of the GIII series' total sales, just over 40 percent are today constituted by the Plus products.

The approval means that all of Vitrolife's media and instrument products are now CE marked. Vitrolife is the only company in the fertility market to have achieved this. The company hereby obtains further competitive advantages in the European countries where the products have already been introduced and it will be easier to introduce the products in new markets with local rules and regulations. Based on available official statistics, the European market is the largest market for in vitro fertilization in the world and it represents over 50 percent of the 600,000 treatments that are carried out each year.

The process of obtaining approval for products containing blood derivates is considerably longer and requires more documentation than for other products. This is due to the fact that they shall then be reviewed by Europe's central pharmaceutical authority, the EMEA. The process takes one to two years rather than in other cases 3 months.

"An increasing number of clinics today require CE marked media. In the EU Commission's new directive 2006/17/EC, fertility clinics are required to use CE marked products as from the autumn. How this will be complied with and inspected remains to be seen. Vitrolife has put a good deal of effort into this question and will continue to push it, in order to increase patient safety and to stop dubious competition," says Vitrolife's CEO Magnus Nilsson.

Vitrolife has also recently obtained certification in accordance with ISO13485:2003 and ISO9001:2000 for all the companies in the Group.

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Magnus Nilsson
CEO

Queries should be addressed to:
Magnus Nilsson, CEO, phone +46 31 721 80 00 or +46 708 22 80 61.
Anna Ahlberg, CFO, phone +46 31 721 80 13 or +46 708 22 80 13.

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 Cell Therapy. The Fertility product area works with nutrient solutions (media) and advanced one-time instruments such as needles and pipettes, for the treatment of human infertility. The Transplantation product area works with solutions and systems to maintain tissue in optimal condition outside the body for the required time while waiting for transplantation. The Cell Therapy product area works with media to enable the use of stem cells for therapeutic purposes.

Vitrolife today has approximately 110 employees and the company's products are sold in more than 80 markets. The head office is in Kungsbacka, Sweden, and there are subsidiaries outside Gothenburg, Sweden and in Denver, USA. The Vitrolife share is listed on the O-list of the Stockholm Stock Exchange.