



PRESS RELEASE

Uppsala March 21, 2011

Solesta™ improves fecal incontinence - results published in The Lancet

First Randomized-Controlled Trial of Solesta™ Comparing Active and Sham Treatments to Show Efficacy and Safety

Q-Med, together with its partner Oceana Therapeutics today announced the publication of results from a randomized-controlled clinical trial of Solesta that involved 206 patients aged 18 to 75 from the United States and Europe with fecal incontinence. This study, published in The Lancet, of the injection of bulking agent, NASHA™ DX, a dextranomer suspended in stabilized hyaluronic acid, into the anal sphincter in patients with fecal incontinence, met primary and secondary endpoints and demonstrated efficacy and safety. The trial was sponsored by Q-Med AB and Oceana Therapeutics.

Solesta, has been under development as a minimally invasive treatment for patients with fecal incontinence who have failed conservative therapy. Fecal incontinence is the loss of ability to control passage of feces. It is estimated to affect about two percent of the population and seven percent of the population over age 65 years. Current treatment options are mainly medical treatments or surgery. Solesta can be administered in an outpatient setting without the need for anesthesia.

In June 2009, Oceana Therapeutics obtained the exclusive worldwide marketing rights to Solesta and has since collaborated on controlled studies of the product's effectiveness and safety. In April 2010, the Premarketing Approval Application (PMA) was submitted to the U.S. Food and Drug Administration (FDA) and in December 2010, the FDA's Gastroenterology and Urology Devices Panel recommended approval of Solesta as a treatment for fecal incontinence.

"Solesta represents an important new option for patients with fecal incontinence and can serve as an intermediary step between conservative therapies such as diet control, antidiarrheal medication and more aggressive intervention such as surgery," commented Dr. Cindy Wong, Chief Medical Officer at Q-Med.

The pivotal study, representing the main body of clinical evidence in the PMA submission, involved 206 patients (136 Solesta, 70 Sham). The study consisted of a 6-month double-blinded phase followed by an open label phase in which patients originally randomized to Sham treatment were offered Solesta. The primary efficacy objective of the study required: 1) demonstrating a statistically significant Solesta effect after 6 months of treatment; 2) meeting a pre-defined threshold for clinical significance; and 3) showing durability of the Solesta benefit up to 12 months after treatment. All three of these endpoints were met and Solesta was found to be safe with few serious adverse effects.

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The information in this press release is such as that which Q-Med is required to disclose in accordance with the Swedish Securities Market Act and/or the Financial Instruments Trading Act. The information was submitted for disclosure at 15.20 on March 21, 2011.

Q-Med AB is a medical device company that develops, manufactures, markets, and sells high quality medical implants for esthetic and medical use. The majority of the products are based on the company's patented technology, **NASHA™**, for the production of stabilized non-animal hyaluronic acid. The product portfolio today contains: **Restylane®** for filling lines and folds, contouring and creating volume in the face, **Macrolane™** for body contouring, **Durolane™** for the treatment of osteoarthritis of the hip and knee joints, **Deflux®** for the treatment of vesicoureteral reflux, VUR, (a malformation of the urinary bladder) in children, and **Solesta™** for the treatment of fecal incontinence. Sales are made through the company's own subsidiaries or distributors in over 70 countries. Q-Med has about 650 coworkers, with almost 400 at the company's head office and production facility in Uppsala, Sweden. Q-Med AB is listed in the Mid Cap segment of the NASDAQ OMX Nordic.

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