

Q-Med AB and Oceana Therapeutics achieve key milestone with the submission of a Premarketing Application for FDA approval of Solesta[®]

Q-Med AB and Oceana Therapeutics, based in USA, today announced the filing of a Premarket Approval (PMA) application with the U.S. Food and Drug Administration (FDA) for Solesta[®]. Solesta is a new alternative for the treatment of fecal incontinence which affects about 2 percent of the population.

The PMA application contains a substantial amount of clinical data to show the safety and effectiveness of Solesta[®]. The pivotal multi-center, randomized, Sham (placebo) controlled study represents the main body of clinical evidence in the PMA submission. The study met all primary endpoints. These endpoints were pre-specified in a study protocol approved by the FDA. Treatment effect was associated with an improvement in quality of life.

Solesta has been under development as a minimally invasive treatment for patients suffering from fecal incontinence who have failed conservative therapy. Solesta is an injectable gel administered in an outpatient setting without the need for anesthesia. Through a transaction finalized in June, 2009, Oceana Therapeutics obtained the exclusive world wide marketing rights to Solesta from Q-Med AB.

Q-Med's President & CEO, Bengt Ågerup, "After many years of dedication we have succeeded in developing a new treatment to help patients with a socially debilitating condition and we are very pleased to partner with Oceana in achieving this important step towards bringing Solesta into the U.S. market. Solesta, which utilizes our NASHA[™] technology, is a potentially significant product and we share in Oceana's enthusiasm regarding the product's growth prospects."

Cindy Wong, Q-Med's Chief Medical Officer, said "Solesta treatment has been shown to be safe and effective in patients with fecal incontinence. Improvement in quality of life was also shown in the studies. There is clearly a need for a new treatment option and this is reinforced by the interests shown by the investigators and the patients who participated in the studies. Their commitment has been essential in the clinical development of Solesta."



John T. Spitznagel, Oceana's Chairman & CEO, said "This represents a major milestone in the growth of our company. It is a testimony to the dedication, experience and excellence of the Oceana team and reflects the strength of our close working relationship with Q-Med."

Fecal incontinence 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.

For more information from Oceana Therapeutics please visit: www.oceanathera.com

Queries should be addressed to:

Bengt Ågerup, President and CEO

Tel: +46 70 974 9025

Cindy Wong, Chief Medical Officer

Tel: +46 733 871450

Per Langö, Senior Director Corporate Development and Strategy

Tel: +46 733 871521

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 today 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.

Q-Med AB (publ), Seminariegatan 21, SE-752 28 Uppsala, Sweden. Corporate identity number 556258-6882.
Tel: +46 18 474 90 00. Fax: +46 18 474 90 01. E-mail: info@q-med.com. Web: www.q-med.com.