

PRESS RELEASE  
Uppsala  
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## **Q-Med and Smith & Nephew takes Durolane™ PMA in USA to next stage**

Q-Med has together with its global partner Smith & Nephew agreed to the next stage in the approval process for the US launch of Durolane™ Single Injection, Stabilized Hyaluronic Acid.

Representatives from Q-Med AB, Sweden, and Smith & Nephew met August 19<sup>th</sup> with the FDA's Orthopaedic and Rehabilitation Devices Advisory Committee to discuss clinical evidence for the use of Durolane™ in the treatment of knee pain caused by osteoarthritis ("OA").

The FDA Advisory Committee did not recommend Durolane™ for immediate approval, requesting further information as part of the Premarket Approval ("PMA") process for the product. Q-Med plans to work with Smith & Nephew and the FDA to provide the data required.

Smith & Nephew and Q-Med have an exclusive relationship for the global development and commercialization of Durolane. It is already marketed in 20 countries, including Canada, and has been used to treat the symptoms of OA in more than 350,000 patients worldwide.

Q-Med's CEO and founder Bengt Ågerup said, "We are continuing the clinical development of Durolane in collaboration with Smith & Nephew to provide satisfactory clinical evidence of Durolane's performance. We remain committed to our goal of providing U.S. physicians and patients access to a non-animal single injection product."

Mark Augusti, President of Smith & Nephew Biologics & Spine, said: "We are committed to expanding our range of HA therapies in the United States. Use of our multi-injection SUPARTZ® Joint Fluid Therapy as a treatment for knee OA continues to increase and we are exploring its potential for other indications."

Ken Reali, SVP and General Manager of Biologics & Spine, added: "Our meeting with the Advisory Committee on single injection Durolane provided some very useful and valuable feedback on our Premarket Approval application. We intend to work with our Q-Med partners and the FDA to initiate the next steps in making this highly successful global product available to U.S. patients."

Smith & Nephew and Q-Med have an exclusive partnership for the global development and commercialization of Durolane. It is already marketed in 32 countries, including Canada, and has been used to treat the symptoms of OA in more than 350,000 patients worldwide.

Editors Notes:

1. Durolane™ is produced using the unique NASHA™ technology, a patented process for the production of stabilized hyaluronic acid. Durolane™ is a transparent gel which contains high levels of HA (Hyaluronic Acid). HA is a naturally occurring molecule that provides lubrication and cushioning in a normal joint. Durolane is injected into knee joints affected by osteoarthritis to relieve pain, restore lubrication and cushioning.
2. Durolane™ is currently marketed in some 32 countries, including Canada, Europe, Scandinavia, the Middle East, the Far East and South America. Outside the United States, it is approved for the treatment of osteoarthritis of the hip and knee.
3. SUPARTZ® is a registered trademark of Seikagaku Corp.

**About Smith & Nephew** - Smith & Nephew is a global medical technology business, specializing in Orthopaedics, including Reconstruction, Trauma and Clinical Therapies; Endoscopy and Advanced Wound Management. Smith & Nephew is a global leader in arthroscopy and advanced wound management and is one of the leading global orthopaedics companies. Smith & Nephew is dedicated to helping improve people's lives. The Company prides itself on the strength of its relationships with its surgeons and professional healthcare customers, with whom its name is synonymous with high standards of performance, innovation and trust. The Company operates in 32 countries around the world. Annual sales in 2008 were \$3.8 billion.

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**Q-Med AB** is a medical device company. The company develops, manufactures, markets, and sells primarily medical implants. 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 approximately 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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