Uppsala, Sweden
April 17, 2012

Q-Med, a Galderma division, provides update on the use of Macrolane for breast augmentation

Dear Doctor and valued Macrolane customer:

Macrolane is a safe and well-tolerated injectable product used to enhance body contour and correct soft tissue defects. Introduced in 2008, it has improved quality of life for thousands of patients across various indications ranging from HIV-related lipoatrophy to breast augmentation. A safety reporting system has been in place since launch and no safety concerns have been identified.

However, because of the ongoing and unresolved debate relating to radiology examination of breasts treated with injectable products, Q-Med has decided to discontinue Macrolane for breast augmentation until further notice.

No safety concerns have been identified with Macrolane

Because no safety concerns have been identified, women who have undergone breast augmentation with Macrolane do not need to take any actions other than to attend their follow-up consultations as scheduled after injection.

Breast augmentation and screening procedures

As with any breast prostheses, it is important that patients inform the healthcare professional conducting their breast examination of the date of their last Macrolane treatment prior to the assessment. The currently validated approach to conducting breast screening in women who have received Macrolane treatment is summarised on page 2 of this letter.

Furthermore, Q-Med continues to invest in research to confirm screening protocols for women who have received Macrolane for breast augmentation, as described on page 2 of this letter.

Macrolane remains available for use in other approved indications

Q-Med will continue to promote Macrolane for body contouring procedures and soft tissue defects. Q-Med is also pursuing a number of potential new uses for Macrolane-like gels.

Further information

Q-Med will follow up this letter with a personal contact to discuss any concerns that you may have with respect to the decision, your patients or your clinic. Q-Med will also make available a patient leaflet to address potential concerns from your patients who have received Macrolane. We will also update the Macrolane website (www.macrolane.com) with any further developments in this situation.

We wish to thank you for your support for Macrolane, and we look forward to our continued relationship.

Regards

[Signature]

Name

Position

Addressing the interference of breast augmentation with mammography

All breast augmentation procedures can interfere in the reading of mammograms. This is well-recognised and is typically addressed by using additional standard assessment techniques or radiology investigations. To use ultrasound as an adjunct to mammography is not unusual, particularly in women with dense breast for whom the sensitivity of screening mammography may be reduced.

Macrolane can interfere with reading of mammography. The current Macrolane product information provides very clear information about this. Q-Med supports international recommendations on the importance of baseline examination prior to breast augmentation. After breast enhancement, digital mammography is the preferred method of obtaining adequate information for screening purposes. Supplemental ultrasound may also be employed. This sequence of investigations has been proposed by expert radiologists.

Confirming best practices in breast screening for women treated with Macrolane

A 24-month follow-up study was recently conducted in Sweden and France to evaluate any potential difficulties with the interpretation of digital mammography image(s) or ultrasonography and the value of this combination of radiology investigations. The preliminary results of this study suggest that an adequate examination can be performed using those techniques. Q-Med will make the 24-month follow-up data available as soon as possible to facilitate optimal clinical follow-up of women treated with Macrolane.