FOR IMMEDIATE RELEASE

Aquamid - a long lasting soft hydrogel targeting facial volume restoration and contouring

SOEBORG, Denmark, January 25, 2012 - Although they are often considered as identical, currently marketed Polyacrylamide Hydrogels significantly differ from each other in composition, manufacturing processes, injection technique as well as the clinical documentation. These differences determine the safety and efficacy of each of the hydrogels. In a comparison prepared by Dr. Rhoda Narins and Richard Schmidt\(^1\), Aquamid stands out in its safety and efficacy profile among the cohort of hydrogels on the market.

“It is highly important that both physicians and patients understand the differences between various products in the market, especially in light of the recent discussions that the PIP implants raised,” says Dr Narins. “This will allow them to be confident of their treatment choices, and of the support and responsibility of the product manufacturers.”

The comparison study shows how the performance and safety profiles of the marketed polyacrylamide hydrogels depend on many factors such as the unique chemical and physical characteristics, manufacturing process and control, injection technique, and interaction with surrounding tissue. Aquamid is manufactured at a GMP-compliant manufacturing facility under tightly-controlled product specifications. Compared to other products, Aquamid contains very low polymer content (2.5%) reducing the amount of foreign body to the absolute minimum. In addition, the hydrogel is highly purified to ensure its safety

“With Aquamid’s unique mode of action the hydrogel becomes vascularized, enabling immune system access, thus ensuring that the implant becomes an integral part of the host tissue,” explains Dr. Chris Inglefield. “This process, together with the constant water exchange between the tissue and the implant, prevents the risk of encapsulation, which may result in undesired adverse reactions. Aquamid has become an important part of my aesthetic business. Many of my patients are now asking me for a volumizer that is instant, looks natural, and provides long lasting results. Aquamid fits these criteria very well.”

The marketed products also differ significantly in clinical documentation. Aquamid has proven to have an excellent safety profile in a 5-year follow-up study for aesthetic indications, conducted in 15 sites in Europe\(^2\), a 5-year follow-up study for facial lipoatrophy\(^3\), as well as a 24-months follow-up safety study in

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Unlike other Hydrogels that are intended for long-term use, Aquamid benefits from an extensive clinical documentation, covering more than 5,000 patients and 10 years’ market experience, which shows an incidence of complications of less than 0.1%. The US pivotal study has compared Aquamid and Restylane – the golden standard of biodegradable fillers – and found Aquamid to have an excellent safety profile, similar to Restylane. Moreover, those results haven’t changed in the additional 12 months follow-up period and at the 24 months end-point. This clinical experience goes far beyond that of any other permanent filler. To date more than a quarter of a million people have successfully been treated with Aquamid.

Contura is a responsible company committed to patient safety. The company actively sponsors research intended to minimize and mitigate risks associated with dermal fillers in general, and with Aquamid specifically. “We are proud of the extensive clinical documentation of Aquamid safety and effectiveness,” says Michael Peytz, CEO of Contura International, “and are confident that Aquamid is an excellent choice for physicians and consumers looking for lasting volumizing results such as reshaping or restoring facial features.”

Contura has implemented a comprehensive product development program for Aquamid, and is the only polyacrylamide manufacturer to have performed a pivotal clinical study in the U.S. and to be pursuing PMA approval. Patient safety is a primary focus for Contura and we strive to provide safe products and mitigate their potential risk to the extent possible.

About Aquamid

The Aquamid range of safe injectable volume fillers delivers reliable long-lasting replacement of lost volume, for the correction of wrinkles and for augmentation and sculpting of facial features.

Aquamid and Aquamid Reconstruction are based on Contura’s proprietary hydrogel, composed of 97.5% water and 2.5% cross-linked polyacrylamide. The hydrogel is homogeneous containing no micro particles. Unlike particle-based fillers, the Aquamid product range does not rely on an intended foreign body reaction to achieve the desired augmentation. Therefore, the filling effect is immediate and predictable. Aquamid and Aquamid Reconstruction are used mainly for treating nasolabial folds, lip augmentation, cheek contouring and nose enhancement, and for treating facial lipoatrophy.

Aquamid was approved in Europe in 2001 for facial augmentation and Aquamid Reconstruction in 2003 for facial augmentation and minor body contouring. The products are available in 40 countries in Europe, Asia, the Middle East, and Latin America. Data from the US pivotal trial has supported a PMA application with the FDA.


About Contura International

Contura International is an innovative medical technology company that develops, manufactures and markets injectable hydrogels and related devices. Contura’s products – Aquamid for facial contouring, and Bulkamid® for the treatment of female urinary incontinence are manufactured using the company’s patented polyacrylamide hydrogel technology.

Aquamid products are sold through a network of local distributors in several countries in Europe, Asia, the Middle East and South America. Ethicon Inc., a Johnson & Johnson company, holds the exclusive worldwide distribution rights for Bulkamid.

Contura’s products are developed, and manufactured in Denmark in compliance with the European and US regulatory requirements for medical devices.

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