

Contura files Bulkamid PMA

Contura A/S (“Contura”), a wholly owned subsidiary of Speciality European Pharma Limited (“SEP”), is pleased to announce that on 30 July 2017 it filed a Premarket Approval (“PMA”) application with the Federal Drug Administration (“FDA”) in the United States for the approval of Bulkamid®.

Bulkamid® is Contura’s proprietary medical device for the treatment of stress urinary incontinence (“SUI”). The product is currently marketed in more than 25 countries throughout the world. In 2014 the pivotal North American study for the product was published, reporting on the efficacy and safety of Bulkamid® for the treatment of female stress incontinence in a randomised, prospective, multicentre North American study. This North American study forms the basis of Contura’s PMA.

Commenting on the filing, Patrick Banks, Director of Contura, said:

“Since Contura’s acquisition by SEP in 2013 it has been the intention of the company to file a PMA in the United States. The completion of the pivotal North American study for the product provided the necessary data for the filing, but it was not until the completion of the management buyout of SEP in May 2016 that the company was provided with the necessary financial resources. We are excited by the opportunity this filing provides. The United States market is by far the largest market in the world for SUI products. With the current controversy surrounding the use of slings and meshes for SUI treatment, particularly in the United States, and the emerging data supporting Bulkamid’s more prominent use, we believe Bulkamid® is well positioned to be offered as the first line treatment of choice for SUI.”

About Bulkamid®

Bulkamid® is a homogenous hydrophilic hydrogel used in the treatment of female stress urinary incontinence. The product was granted CE approval in 2003 and is currently sold in more than 25 countries worldwide. Bulkamid® is delivered to the patient under endoscopic control using the Bulkamid® Urethral Bulking System.

About SEP

SEP is the parent company of a European group which specialises in the distribution and sale of healthcare products, both pharmaceuticals and medical devices, focused primarily upon the fields of urology and urogynaecology. Its lead products are:

Bulkamid®
Aquamid®





CONTURA A/S
Sydmarken 23
2860 Søborg

Tel.: +45 81100900
Fax: +45 81100901
info@contura.com
www.contura.com

VAT Registration No. 27 05 77 16

Mitem[®]
Regurin[®] XL
Cystistat[®]

SEP was founded in 2006 and built an experienced and accomplished management team. In 2013, SEP acquired Contura A/S, a Danish company based in Copenhagen. Contura A/S had two marketed products at the time of its acquisition by SEP, Bulkamid[®] and Aquamid[®]. It also had a number of development programmes focused upon additional uses of its hydrogel technology. In 2016, SEP was acquired by its management team in conjunction with new investors. SEP has established a sales and marketing infrastructure in the leading European markets, either through its own sales force or through distribution partners. SEP has offices in the UK, Denmark, Germany, France and Italy.

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For further information please contact:

SEP
Patrick Banks, Chief Executive Officer

Tel: +44 (0)20 7421 7400

