

## **Contura signs clinical research agreement to initiate a randomised controlled trial of Bulkamid against Tension-free Vaginal Tape**

Contura A/S (“Contura”), a wholly owned subsidiary of Speciality European Pharma Limited (“SEP”) is pleased to announce that on 2 September 2015 it entered into a clinical research agreement (the “Research Agreement”) with Clinical Research Institute at Helsinki University Central Hospital (“HUCH”) in Finland.

Under the terms of the Research Agreement, HUCH will conduct a randomised controlled trial (“RCT”) to compare the effectiveness and safety outcomes of patients with stress urinary incontinence (“SUI”) treated with Bulkamid® to those treated with Tension-free Vaginal Tape (“TVT”). Over 200 patients will be randomised in the study and followed for a period of five years. More details on the study can be found at <https://clinicaltrials.gov/ct2/show/NCT02538991>.

### **Commenting on the Research Agreement, Rakesh Tailor, Director of Contura, said:**

“Numerous studies have been completed over the past decade, such as the North American RCT and the EU multi-centred 2 year study, confirming the effectiveness and safety profile of Bulkamid®, as well as its durability over many years. More recently though, there have been a number of centres that have published data demonstrating Bulkamid’s promising use as a first line treatment for women with SUI. It was therefore important to confirm these results in a prospective RCT against TVT, the current gold standard treatment for SUI, in what is an investigator initiated trial. The use of TVT’s for SUI is coming under increasing scrutiny with an adverse safety profile emerging from all over the world. Contura is committed to generating high quality data for Bulkamid® and supporting this independent study will generate valuable insight to guide decisions about treatment options for women with SUI. There is a clear need for a new, safe, first line treatment for SUI and Contura is hopeful that Bulkamid® will be that treatment.”

### **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 20 countries worldwide. Bulkamid® is delivered to the patient under endoscopic control using the Bulkamid® Urethral Bulking System.





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### **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<sup>®</sup>  
Aquamid<sup>®</sup>  
Mitem<sup>®</sup>  
Regurin<sup>®</sup> XL  
Cystistat<sup>®</sup>

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<sup>®</sup> and Aquamid<sup>®</sup>. It also had a number of development programmes focused upon additional uses of its hydrogel technology. 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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