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SEP signs clinical research agreement with Central Manchester University Hospitals NHS Foundation Trust for the study of Bulkamid as a first line treatment for stress urinary incontinence

Speciality European Pharma Limited ("SEP") is pleased to announce that on 17 February 2017 it entered into a clinical research agreement (the "Research Agreement") with Central Manchester University Hospitals NHS Foundation Trust ("CMFT") in the United Kingdom.

Under the terms of the Research Agreement, CMFT will conduct a prospective cohort study (the "Latitude Study") of Bulkamid®, SEP's proprietary medical device for the treatment of Stress Urinary Incontinence ("SUI"). The purpose of the Study is to assess Bulkamid® when used first line in patients with SUI. The Latitude Study will be conducted at multiple centres across the north of England. Over 200 patients will be recruited and followed for a period of five years.

Commenting on the Study, Rakesh Tailor, Chief Operating Officer of SEP, said:

"Supporting the Latitude Study confirms our ongoing commitment to generating high quality independent data for Bulkamid, as it follows our support for the randomised controlled trial of Bulkamid® versus the mid-urethral sling in Helsinki, Finland. The Latitude Study will evaluate the effectiveness of Bulkamid® as a primary treatment in women with SUI, with further objectives including the evaluation of the proportion of women who would choose Bulkamid® as a first line treatment when given the option, and the proportion of Bulkamid® patients needing to subsequently go on to having a mid-urethral sling. There is a safety concern emerging with the prominently used slings for SUI all over the world and it is important to show Bulkamid's effect as a first line treatment. This study is particularly important as it contemplates a stepwise hierarchical treatment approach to treatment. For example, in orthopaedics, patients with osteoarthritis are initially offered physiotherapy. Only when this has been unsuccessful are patients offered intra-articular injections, arthroscopic washouts and finally a joint replacement. In confirming its effectiveness as a first line treatment, if the Latitude Study further shows no detrimental impact on a subsequent sling and its preference by women with SUI, then it suggests that Bulkamid® should be offered as part of a hierarchical treatment pathway for women with SUI before the mid-urethral sling."

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®
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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