Bulkamid®: one year anniversary of FDA approval in the United States

January 28, 2021: Following the FDA approval of Bulkamid in the US for the treatment of stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) in adult women on January 28 2020, Contura is pleased to share that the product has become a mainstay treatment for SUI in many key institutions, with thousands of patients having receiving Bulkamid in 2020 across the US.

Bulkamid has demonstrated impressive results across clinical trials and clinical practice. Most notably, it was the pivotal North American study reporting on the efficacy and safety of Bulkamid for the treatment of SUI in women which formed the basis of its approval by the FDA.[1] Bulkamid is filling a clear unmet need for women suffering from SUI in the US.

Commenting on the impact the launch has already had on the lives of patients in the US, Rakesh Tailor, Chief Operating Officer of Contura said: "***We are aware that, given the invasiveness or unreliability of the current options, there is often a reluctance from patients to accept treatment for their SUI symptoms. It is therefore pleasing that Bulkamid represents an attractive first line treatment for patients given it is minimally invasive and requires no cuts, so we are delighted at the number of women who have already been able to access treatment with Bulkamid. As we continue our expansion into the US, our goal is to encourage women to not put up with the symptoms of SUI and to seek safe, effective treatment without fear of invasive surgery***."

In light of the Covid-19 pandemic, there has been a significant reduction in elective surgeries, with patients minimising risk and avoiding visits to the hospital. Casey Kanel, Vice President of US Sales at Contura comments: "***Despite the setbacks that came with the pandemic in 2020, we had a great launch year for Bulkamid with a long list of satisfied patients. In wanting to keep away from the acute environment, we have seen a willingness for patients to be treated in the doctor's office. This has allowed patients to safely access what is one of the most innovative treatment options for SUI on the market and we are glad to see that patients are choosing it for its impressive safety and efficacy profile."***

Contura plans to continue this growth with the expansion of the sales and marketing team in 2021. The recent publication demonstrating Bulkamid's durability to at least 7 years[2] will be followed by further new evidence that will support Bulkamid's role as a prominent 1st line treatment for women with SUI.

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About Bulkamid

Bulkamid is a soft hydrogel that consists of 2.5% polyacrylamide and 97.5% water. Once injected, Bulkamid provides additional volume to the urethra and acts as a scaffold for cells to grow through, helping to provide long lasting relief of SUI symptoms.

About Female Stress Urinary Incontinence

SUI is very common among women of all ages and increases with age. Other contributing factors include childbirth, obesity or some form of a pelvic floor disorder. SUI is caused by a weakness in the pelvic floor, preventing the urethra (the tube that urine comes out of) from closing fully when sudden pressure is put on the bladder. This can allow urine to leak out during normal daily activities for example when coughing, laughing, walking or exercising.

About Contura

Contura is headquartered in London and has its manufacturing facility in Copenhagen, Denmark. It specialises in the distribution and sale of healthcare products, both pharmaceuticals and medical devices, focused primarily on women's health and pain. Its lead products are Bulkamid®, Arthrosamid®, Aquamid®, Regurin® XL and Cystistat®. Arthrosamid®, the Company's treatment for osteoarthritis of the knee, is the most recent addition to its suite of products and is due to be launched onto the European market in mid-2021. Contura has an established sales and marketing infrastructure in the leading European and worldwide markets. It has its own offices in the UK, United States, Denmark, Germany, France and Italy, currently employing around 55 staff worldwide.

References

1. Sokol et al. Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: a randomized, prospective, multicenter North American study. J Urol. 2014 Sep;192(3):843-9.
2. Brosche et al. Seven-year efficacy and safety outcomes of Bulkamid for the treatment of stress urinary incontinence, Journal of Neurology and Urodynamics; 2021 Jan; 40;502-5

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