FDA approves Bulkamid® in the United States and is now set for launch in Quarter 1 2020

January 31 2020: Contura is pleased to announce that on January 28 2020 it received official notification from the Federal Drug Administration ("FDA") that the premarket approval application ("PMA") for Bulkamid has been approved. Bulkamid is Contura's proprietary medical device and its approved indication in the US is for the treatment of stress urinary incontinence ("SUI") due to intrinsic sphincter deficiency in adult women who have SUI or stress predominant mixed incontinence.

Bulkamid is currently marketed in more than 25 countries throughout the world. The pivotal North American study[1] reporting on the efficacy and safety of Bulkamid for the treatment of female stress incontinence formed the basis of Contura's PMA.

Commenting on its approval, Rakesh Tailor, Director of Contura said: ***"We are extremely proud to have gained Bulkamid's approval in the US. We are particularly excited that Bulkamid will, in the coming weeks, be available to women in the US suffering from symptoms that significantly affect their day to day lives. There is a degree of patient apprehension with the currently available treatments for SUI and Bulkamid, with its excellent safety and effectiveness profile, supported by recent clinical data[2], is now a true 1st line alternative for those women."***

The US approval comes on the back of recent evidence showing that when women with SUI are given a choice of treatments, their preferred option is urethral bulking.[3,4] The minimally invasive Bulkamid treatment is increasingly being used in Europe and now represents the number one SUI treatment in the UK after conservative measures such as physiotherapy. In the US, many hundreds of thousands of women are diagnosed with SUI annually, but only a small proportion are treated.

Professor Roger Dmochowksi, a pelvic floor specialist in Nashville, Tennessee explains: ***"Given the currently available options for SUI, many women simply choose not to have treatment given the safety concerns that prevail. Bulkamid offers these women a new safe and effective option which probably represents the most innovative treatment for SUI to arrive in the US in the last 10+ years."***

Contura will expand its operations into the US and will establish its own US office in Los Angeles. It has a commercial team in place finalising the US launch plans of Bulkamid which will take place at the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction Winter Meeting from 25th to 29th February 2020 in Scottsdale, Arizona.

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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 in women's health. Its lead products are Bulkamid®, Aquamid®, Regurin® XL and Cystistat®. It also has a number of ongoing development programmes focused upon additional uses of its proprietary hydrogel technology, such as Arthrosamid® for the treatment of osteoarthritis in the knee. Contura has an established sales and marketing infrastructure in the leading European and worldwide markets, either through its own sales force or through distribution partners. It has its own offices in the UK, Denmark, Germany, France and Italy, currently employing around 50 staff worldwide.

References

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3. Dwyer et al. "Voice your choice": a study of women's choice of surgery for primary stress urinary incontinence. Int Urogynecol J. 2019 Dec 18.
4. Ong et al. Development, validation and initial evaluation of patient-decision aid (SUI-PDA©) for women considering stress urinary incontinence surgery. Int Urogynecol J. 2019 30:2013-2022

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