For Immediate Release

Significant Achievement for OstomyCure AS and TIES®Solution

Approval for multicenter study "TIES-C03" in major university hospitals in Leeds, UK & Umeå, Sweden.

OstomyCure AS has achieved an important milestone on the way to making the revolutionary TIES® Solution available to ileostomy patients, a patient population that has not experienced any meaningful improvements in "standard of care" in the last 30-40 years. The study aims to gather more and longer term clinical data regarding safety, performance and Quality of Life.

The study has started at Norrland University Hospital, Umeå, Sweden with Associate Professor Karin Strigård and Prof. Ulf Gunnarsson and at St. James Hospital, Leeds with Professor David Jayne as the main investigators. OstomyCure plans to commit additional clinical centers (primarily in the UK) to participate in the "TIES-C03" study.

The TIES® Solution is a "no skin touch" solution which uses a titanium ring implanted at the stoma site, creating an external attachment point for lids or drainage bags. The indwelling part of the device is a porous mesh that allows the intestinal and surrounding skin tissues to grow through, creating a tight seal and a safe and stable junction between intestinal and dermal tissues and implant. The device extends a few millimetres above the skin, allowing it to be sealed with a fitted plastic lid with a hatch and a bag attachment system that allows patients to drain the intestine easily and at their convenience, with no direct contact with the skin. The TIES® aims to provide a tested alternative to the current standard of external stoma pouches glued to the skin that overcomes the problems of skin infection/irritation and fungi that afflict almost all ostomates today. With a tightly sealed stoma and no constant need for external bags, patients can now control waste discharge directly, and are free to bathe, swim, and engage in other activities that are restricted or impossible with the traditional solutions, none of which offer a continent seal.

OstomyCure's system is expected to largely eliminate the painful skin issues associated with stoma care today, and greatly reduce the inconvenience and cumbersomeness of current systems. The TIES® device – leak-free, sanitary and odourless – gives patients greater independence and control and significantly improves their quality of life. The product is already CE-marked in Europe, but OstomyCure, in consultation with its regulators, is undertaking the current trial to increase the base of safety and efficacy data available before a full commercial launch.

Dr. Ben Broennimann, M.D., CEO of OstomyCure, saluted his team. "Our team at OstomyCure has worked incredibly hard and tenaciously at establishing this study on schedule. The outstanding collaboration between all internal and external stakeholders has been a great contributor to the success in achieving the initiation of the study according to plan. This is a significant milestone for our company, and brings the TIES® Solution closer for the many thousands of ostomy patients who have waited so long for innovative products to improve their lives."

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“We are pleased to see the high interest and commitment of a number of highly renowned clinical centers and opinion leaders, as well as of the patient community for the TIES® Solution clinical study”, added Dr. Ben Broennimann.

OstomyCure AS is a privately-owned Norwegian medical technology company developing a revolutionary technology called the Transcutaneous Implant Evacuation System (TIES®), addressing a market estimated to be worth $2bn annually. For more information, please visit www.ostomycure.no. The stoma market today is dominated by Coloplast, Convatec & Dansac/Hollister but other players such as B. Braun, Medtronic, Johnson & Johnson/Ethicon, Baxter, Salts Healthcare, Welland and Fresenius Kabi also participate.

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