

ConvaTec Receives U.S. FDA 510(k) Clearance for Avelle™ Negative Pressure Wound Therapy System

- *First and only system to combine Negative Pressure with the benefits of Hydrofiber® Technology*
- *Lightweight, disposable system offers extended usage up to 30 days, suitable across different care settings*

READING, UNITED KINGDOM (26 October 2018) — ConvaTec Group Plc (“ConvaTec”), a leading global medical technology company, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Avelle™ Negative Pressure Wound Therapy (“NPWT”) system. The novel system is ConvaTec’s entry into the fast-growing disposable space of the \$1.1B U.S. NPWT market¹.

The unique, disposable device combines negative pressure wound therapy with the benefits of Hydrofiber® Technology, and the pump can be used for up to 30 days*. ConvaTec’s proprietary Hydrofiber Technology, which is also featured in the company’s AQUACEL® line of advanced dressings, is designed to help create a beneficial moist wound environment for healing². The Avelle system is the only product on the market to offer this combination of advanced wound care technologies.

For patients, the Avelle NPWT system is designed to be lightweight, portable and easy-to-use, helping to give them more mobility and resume their daily activities, both in and out of the home, whilst their wounds progress towards healing³. In addition, Hydrofiber Technology helps prevent periwound maceration^{4**}, a potential complication associated with NPWT that can lead to delayed healing⁵.

“We are very pleased to bring the benefits of the Avelle NPWT system to healthcare professionals and patients in the U.S., where demand for disposable single-use negative pressure devices is growing at double digit rates¹,” said Fiona Adam, Interim President, Advanced Wound Care, ConvaTec. “Customer response in European markets has been very positive, with clinicians and patients noting the disposable system’s ease of use as well as its suitability from hospital to home.

At ConvaTec, we are committed to providing our customers with further differentiated technologies and complete solutions for managing chronic and acute wounds, and helping them improve outcomes with the right product, for the right patient, at the right time.”

The Avelle NPWT system delivers negative pressure wound therapy in a simple, canister-less system, offering flexibility across different care settings. The small, ergonomically-shaped pump fits within a pocket and runs quietly for added discretion. The disposable pump has a 30-day lifetime* giving the option of extended therapy with a single device, and an economic advantage over pumps with shorter lifetimes.

The Avelle NPWT system can be used on a broad range of low- to moderately-exuding wound types, including chronic, acute, traumatic, sub-acute and dehisced wounds, skin grafts, and

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surgically closed incisions. The Avelle NPWT system is currently available in 24 markets, including the UK, Germany, France, Canada, Australia and South Africa.

For more information, call ConvaTec customer service at 1 (800) 422-8811.

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About ConvaTec

ConvaTec is a global medical products and technologies company focused on therapies for the management of chronic conditions, with leading market positions in advanced wound care, ostomy care, continence and critical care, and infusion devices. ConvaTec's products provide a range of clinical and economic benefits including infection prevention, protection of at-risk skin, improved patient outcomes and reduced total cost of care. To learn more about ConvaTec, please visit www.convatecgroup.com where a copy of this announcement can also be found.

*Battery change may be required during pump lifetime.

**As demonstrated in vitro

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¹ Smartrak.

² Bishop SM, Walker M, Rogers AA, Chen WYJ. Moisture balance: optimizing the wound-dressing interface. *J Wound Care*. 2003;12:125-128.

³Data on file.

⁴ Waring MJ, Parsons D. Physico-chemical characterisation of carboxymethylated spun cellulose fibres. *Biomaterials*. 2001;22(9):903-912.

⁵ Hanft JR, Henao M. How To Prevent Periwound Maceration With VAC Therapy. *Podiatry Today*. 2010; 23(6)