Edixomed’s Nitric Oxide Generating Dressing achieves significant improvement in healing Diabetic Foot Ulcers

Edixomed, the clinical-stage biopharmaceutical company developing and commercialising innovative nitric oxide generating wound care technology, presented their interim data from the ProNOx 1 study at the 7th International Symposium on the Diabetic Foot, The Hague, May 2015.

The interim results demonstrated compelling evidence for healing chronic diabetic foot ulcers. The study established:

- Completely healed wounds treated with the Company’s nitric oxide generating dressing (NOx) is double that of standard of care (SOC) \( p<0.01 \)
- Almost 2/3 patient’s ulcers decreased in area by more than 90% using the NOx dressing compared to 1/3 treated in SOC
- Only 3% of NOx treated patients wounds materially worsened compared to 34% of SOC \( p<0.01 \).

Professor Mike Edmonds, Consultant Diabetologist, Kings College Hospital, London said, “I believe 2 key challenges to overcome for successful healing in diabetic foot ulcers are ischaemia and infection. This dressing may address both of these issues and the improved healing seen in the interim data suggests the dressing may have real potential”.

Dr Brian Kennon, Consultant Diabetologist, Southern General, Glasgow, adds, “If in addition to improving ulcer healing time this dressing is shown to reduce the number of amputations and serious life-threatening complications of foot disease, then clearly this will be a major advance”.

Professor David G. Armstrong Professor of Surgery, University of Arizona said “This technology potentially represents a significant breakthrough in the treatment of diabetic foot ulcers, offering a simple, easy to apply dressing that, preliminarily, appears to show promise. If this progress continues, then we think the ultimate beneficiary will be our patients”.

Of equal importance is the avoidance of serious adverse health outcomes:

- In the SOC treated patients there have been 9 index ulcer-related serious adverse events; 3 below the knee amputations and 6 hospitalisations for serious infection, osteomyelitis or cellulitis
- In NOx patients there have been no index ulcer-related serious adverse events.

Diabetic foot ulcers are one of the most significant, prevalent and recurring co-morbidities of diabetes, and unhealed diabetic foot ulcers can lead to amputation and severe disability. The diabetic wound care market is estimated to be over $5 billion worldwide, and according to www.DiabeticFootOnline.com every 20 seconds someone in the world loses a limb due to complications of diabetes. Currently the NHS in England spends an estimated £639 million, 0.7% of its budget, on diabetic foot ulceration and amputation.

“This ProNOx1 data is beneficial to the patient and also has important advantages for the funding costs of health services. The ability to reduce the burden on the patient and the health service provides strong health economic reasons for adoption of this innovative technology, which could revolutionise the management of diabetic foot wounds and create positive change for these patients,” says Syd Hanna, Edixomed’s CEO.
The ProNOx1 study is a randomised controlled clinical study in chronic DFUs, recruiting 120 patients in ten leading sites across the UK. An interim analysis has been performed on the first 51 patients recruited, who have healed or completed 12 weeks of treatment with the NOx dressing or standard of care (NOx n=30; SOC n=21). The 2 groups were very similar with regard to age, original ulcer size and length of time that the ulcer had been present. The analysis compared the area of the wound at baseline to that of the wound after 12 weeks of treatment or until completely healed, whichever was earlier.

Prof Chris Wood, Chairman of Edixomed said: "This study highlights our commitment to providing robust clinical evidence to support the science behind our innovative nitric oxide technology. Our research is advancing the treatment of hard-to-heal wounds. We want to thank all of the investigators and patients that participated in our study".

The study anticipates being fully recruited shortly with final evaluation by year end.

About EdixoMed
Edixomed Limited is a clinical-stage biopharmaceutical company developing an innovative and active nitric oxide generating technology that has broad medical application in Advanced Wound Care, Critical and Respiratory Care and in Transdermal Drug Delivery. The Company’s range of technologies has been used to treat over 200 patients in a variety of studies and further clinical adoption studies are planned for later this year. Edixomed has developed a safe, efficacious, cost-effective and clinically proven breakthrough for the treatment of chronic wounds and ulceration and expect to begin commercialisation in 2016.

About NOx
NOx is the Company’s proprietary Advanced Wound Care technology. NOx is a wound dressing that provides the important moist environment and absorbs wound exudate that generates nitric oxide. The nitric oxide is released in a controlled and sustained fashion and mimics the natural physiological process in normal, healthy skin. As a potent vasodilator and broad-spectrum anti-microbial agent, the nitric oxide targets both ischaemia and infection. NOx has the potential to be the first line treatment in DFU, VLU, pressure ulcers and surgical wounds and dramatically lower the incidence of critical complications of several diseases.
About Nitric Oxide
Nitric Oxide is an important cellular signalling molecule involved in many physiological and pathological processes. This simple molecule is an important biological regulator and is therefore a fundamental component in the fields of neuroscience, physiology, and immunology. It is the body's natural regulator of blood flow and functions in the wound tissues to stimulate local vasodilatation and angiogenesis and also as a potent antimicrobial agent. Diabetic patients have a reduced ability to generate nitric oxide, making the dressing particularly suitable for this type of wound. Nitric Oxide was proclaimed “Molecule of the Year” in 1992 and research into its function led to the 1998 Nobel Prize for discovering the role of nitric oxide as a cardiovascular signalling molecule.

For further information please contact:

Martine Morris: Media Relations +44(0) 7939 801100 martinemorris@edixomed.com
Carl Daintree: Director of Operations carldaintree@edixomed.com

You can also visit our website at: www.edixomed.com