Press Release

DEB^x Medical Receives CE Mark Clearance and ISO 13485 Certification for Debrichem®, a Novel Desiccant Gel for Chemical Debridement to Initiate Healing in Infected, Chronic Wounds

- Debrichem® offers a very effective, alternative approach to chronic wound care, initiating healing in more than 90 % of cases after one application[1]
- CE mark and ISO 13485:2016 certification are important prerequisites for upcoming launches in markets worldwide
- Chronic wounds affect 1 – 2 % of developed countries' populations,[2] unsuccessful treatment may lead to enlargement of the wound, bone involvement or in the worst case, amputation[3]
- Debrichem soon to be launched in Europe, Hong Kong, South Africa, New Zealand and Australia

Rotterdam, The Netherlands, February 25, 2021 – DEB^x Medical, the Dutch medical technology company revolutionizing the management of chronic wounds, is excited to highlight today the successful completion of the CE conformity assessment procedure for Debrichem®. The innovative topical agent offers a superior alternative to surgical debridement, the current standard of care. Debrichem can now carry the CE mark for a medical device class IIb and has also been awarded ISO 13485:2016 certification. These certifications endorse the quality and safety of Debrichem to treat a high unmet medical need and the strength of the DEB^x Medical team to achieve this quickly even in such difficult times. DEB^x Medical plans first to launch Debrichem in Europe, South Africa as well as Hong Kong, New Zealand and Australia through a network of distribution partners; other markets will follow. DEB^x Medical has started consultations with the FDA about the pathway to approval earlier this year.

Debrichem is a topical desiccant gel for chemical wound debridement used for the treatment of chronic infected and/or necrotic wounds. This novel product desiccates (dehydrates) the biofilm and the pathogens in the wound bed, debriding the biofilm chemically instead of surgically. Surrounding healthy skin is not affected.[4] The data underlying the CE mark approval show that, after a one-time 60-second application, more than 90 % of wounds result in full granulation,[1] an important step in the healing process.[5] Due to its fast action and applicability outside the surgery room, Debrichem can easily be integrated within standard wound care procedures.[4]

"Being granted the CE mark and ISO 13485 certification for Debrichem in less than two years after founding DEB^x Medical is an exciting and important milestone. I am proud of our achievements and would like to thank the whole team involved in this huge effort," said Dr. Bertus Quint, founding CEO of DEB^x Medical. "Chronic wounds are painful and debilitating and patients have very limited options for healing. With Debrichem, we set out to significantly improve this situation which is frustrating for healthcare professionals and patients alike. We believe that Debrichem has the potential to meaningfully improve health outcomes and quality of life for millions of patients worldwide."

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"In my day-to-day work, I experience the patients' despair associated with chronic wounds and the doctors' frustration with their inability to provide patients long-term healing. With the current COVID-19 pandemic, the situation has been exacerbated: many of our patients are in high-risk groups – elderly, diabetic or chronic cardiovascular patients – who now cannot go to the hospital for their urgently needed treatment," said David L. Helfet, MD, Professor of Orthopaedic Surgery, Weill Cornell Medical College and Hospital for Special Surgery, New York Presbyterian Hospital. "The major advantage of Debrichem is that with a relatively simple, quick, one time application it destroys the biofilm. Removing the biofilm is absolute key to get chronic wounds to heal. Debrichem is an important step forward in the management of chronic wounds and will find its place in the standard of care in a very short time. It may even have the potential to become the new gold standard for debridement in chronic wound care."

Chronic wounds are defined as wounds that have not healed, at least in part, after 4 to 12 weeks.[6] Physiologically, healing of chronic wounds is corrupted, among other factors, by excess inflammation and a recurrent or persistent, if not drug-resistant, microbial infection, often in the biofilm on a wound bed.[4] The current gold standard treatment, maintenance surgical debridement, is a painful procedure performed in a sterile environment. Surgical debridement does not reliably initiate healing of the wound but can be part of an extensive wound management program requiring patients to repeatedly come into the hospital. Not surprisingly, general quality of life is impaired in patients with chronic wounds.[6] Chronic wounds are estimated to have a prevalence of up to 2 % in the general population.[7] The wound etiology has an impact on outcome, arterial ulcers and venous leg ulcers are notoriously difficult to heal. Chronic wounds are also a common comorbidity of diabetes,[8] 13 % of patients with diabetes in North America to 17 % in Belgium are suffering from chronic wounds.[9] The burden of chronic wounds to healthcare systems and society around the world is substantial, exacerbated by the high rate of amputation in especially diabetic patients which is close to 34 % for diabetic foot ulcers.[8] In the UK alone, chronic wounds generated costs of GBP 5.6 bn in 2018. The total wound care costs in the UK increased annually by 8 – 9 % with chronic wounds accounting for the largest share.[10]

About Debrichem®

Debrichem® is a disruptive new treatment option to address the infection in chronic wounds. The topical agent offers a superior alternative to surgical debridement, the current standard of care. Debrichem has been demonstrated to remove the biofilm and the pathogens from the wound bed that disrupt the onset of the natural healing process. Out of the more than 1.000 patients treated so far, more than 90 % of chronic wounds started to heal after only one treatment with Debrichem.[4] The product is applied in a fast and simple, non-invasive procedure. Healthcare professionals should always consider using local anesthetics when applying the treatment. Debrichem can be used outside a surgical environment which can be particularly useful in situations, such as during the COVID-19 pandemic, where patients cannot get to hospitals to undergo surgery, avoiding long-term complications like amputation. Debrichem will be sold through a worldwide network of distributors, with the first market launches expected in Q1 2021.

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About DEB^{x} Medical

DEB^{x} Medical B.V. is a Dutch medical technology company dedicated to revolutionizing the management of chronic wounds by enabling their healing, thereby improving the outcomes for millions of patients. DEB^{x} Medical supports doctors and their patients from diagnosis through treatment, follow-up care, and maintenance of a healthy wound bed. The Company focuses its pipeline on targeting pathogens that corrupt wound healing, aiming to deliver affordable and effective treatment approaches that can easily be applied and implemented in daily clinical practice. Debrichem®, DEB^{x} Medical's first product, received a CE mark in early 2021 and will be launched in markets around the world. Debrichem offers a disruptive approach to debridement that has been demonstrated to enable healing of chronic wounds in more than 90 % of cases.

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