A breakthrough laser-based medical device to eradicate bacterial biofilm in chronic wounds and accelerate wound healing.

Sprawozdania

Informacje na temat projektu

LASER-HEAL

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Strona internetowa projektu

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VULCUR MEDTECH
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Periodic Reporting for period 1 - LASER-HEAL (A breakthrough laser-based medical device to eradicate bacterial biofilm in chronic wounds and accelerate wound healing.)

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Podsumowanie kontekstu i ogólnych celów projektu

Chronic wounds affect 10M in Europe and 6.4 million people in the US, with annual costs of >€72Bn in Europe and >€22 Bn
in the US. It is a silent epidemic. Key to this problem is the lack of truly effective solutions that fully eradicate bacteriaprotecting
biofilms deep within chronic wounds.

Vulcur Medtech has a game-changing new solution to tackle this problem: LASER-HEAL. LASER-HEAL is a medical device that
consists of 1) a laser-generating unit that can reach deep within wounds; 2) optomechatronics to move the laser in a
controlled manner and 3) software to recognize the contours and depth of wounds. LASER-HEAL enables, for the first time,
non-invasive, safe, low-cost (€1.500 p/treatment), rapid (30 mins/session, total ~10) treatment, compatible with standard of
care. We have preliminary data showing killing of all relevant species of bacteria, while human skin cells are left intact.

As an overall conclusion of the action, the SME Phase 1 grant enabled Vulcur Medtech to conduct a fruitful feasibility analysis into the road to market, including;
(1) a full understanding of the competitor landscape,
(2) analysis of the regulatory landscape to identify the regulatory pathway to commercialization,
(3) creating a de-risked development strategy and
(4) create a pricing strategy.

Prace wykonane od początku projektu do końca okresu sprawozdawczego oraz najważniejsze dotychczasowe rezultaty

Results that have been achieved so far:
-Findings from our competitor study are very promising as it showed that our technology is not yet on the market for treating chronic wounds. There is however a somewhat similar technology in development that might claim market share if it reaches the market. Minimizing our time-to-market is essential.
-Our device is suitable to apply for 510(k) in the US, which is the preferred regulatory road.
-To de-risk our (pre-)clinical development we will test the minimal viable product (MVP) on chronic wounds from amputated limbs to acquire the preferred data before initiating first-in-human studies. Tissue is supplied by Bispebjerg Hospital and the experiment has been approved by the Danish ethical committee. After obtaining a 510(k) FDA approval (2020), we will test the technology in three wound care clinics in California. Conversation is ongoing with Wound Care Advantage facility in Los Angeles.
-Based on customer interviews and reimbursement codes we expect an average of ten treatments

over ten weeks. Resulting in reimbursement of over 1500 USD (depending on state and in/outpatient status). To reach most patients and thereby the highest earnings we believe our best price point to be 150 USD per treatment.

Innowacyjność oraz oczekiwany potencjalny wpływ (w tym dotychczasowe znaczenie społeczno-gospodarcze i szersze implikacje społeczne projektu)

Due to the limitations with existing individual methods, clinicians must utilize multiple and concurrent strategies to support wound healing and tackling biofilm colonies.

A light-based solution previously used for chronic wounds is known as ‘Low Level Laser Therapy (LLLT)’. It does not tackle biofilm directly, but it stimulates tissue repair mechanisms in a wound. Clinical trials using human models do not provide sufficient evidence to establish the usefulness of LLLT as an effective tool in wound care regimes.VulCur is advancing the state-of-the-art by developing the first non-invasive, laser-based medical device with no side effects. LASER-HEAL can potentially kill all bacteria (even drug resistant ones) within biofilms, at the surface and deep within a chronic wound. Our solution is not based on pharmacological targeting of bacteria like antibiotics and antibiofilm agents do (as this can drive drug resistance). LASER-HEAL is since bacteria have a ceiling temperature for survival. LASER-HEAL exploits this weakness of bacteria and can selectively kill them and ultimately destroy biofilm. Such a solution does not exist on the market. LASER-HEAL will be used in adjunct to the current standard-of-chronic wound care.

The state of the art solutions within this sector have not changed since the application of the SME instruments report.

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