



REGULATING INFLAMMATORY RESPONSE, INCLUDING HARD-TO-HEAL WOUNDS, INFECTIONS AND PERIODONTITIS

Market need and potential

Chronic wounds

Non-healing chronic wounds are a major global health problem. Most problematic are diabetic ulcers, venous ulcers, and pressure ulcers. Diabetes patients in general have insufficient wound healing, and diabetic wounds are among the most severe types of chronic wounds. There are close to 400 million diabetic patients in the world, and the number is constantly increasing. Between 15-20% of these patients develop non-healing wounds at some point in their lives. As a result, millions of lower limb amputations are performed annually. Pre-clinical results show that plasminogen restarts the healing of chronic wounds and leads to healed wounds.

Tympanic membrane perforation (TMP)

Chronic wounds on the ear drum, as a result from trauma or ear infections, are often treated with surgery. Pre-clinical experiments have shown excellent results for using plasminogen as a treatment for TMP.

The Canadian company Liminal Biosciences (TSX:LMNL) has licensed the indications of chronic wounds (market size ~\$10B) and tympanic membrane perforation (market size ~\$5B). Clinical trials Phase I has been started for tympanic membrane perforations.

Periodontitis and peri-implantitis

Severe periodontitis affects 700 million patients and often leads to tooth loss due to the erosion of the alveolar bone, where the tooth is fastened in the jaw. A similar condition, peri-implantitis, affects 20% of the patients receiving implants, leading to loss of implants. Pre-clinical experiments show the ability of plasminogen to not only slow down the periodontitis, but also the stimulation of re-growth of alveolar bone.

The market for periodontitis treatment is estimated to about \$2B.

Infections

Plasminogen is a pro-inflammatory activator and has in pre-clinical experiments shown the ability to enhance the host defence against bacterial infections, including infections by antibiotic resistant bacteria (MRSA). The overall infection area is valued at \$50B, but what niches to be targeted is not yet determined.

Our solution

Omnia has discovered that locally increasing the level of the innate protein plasminogen improves wound healing substantially and can even restart the healing process in chronic wounds; with similar results for the other indications.

The candidate drug is thus an injectable of plasma-derived plasminogen. We will develop additional formulations like topical application for wound healing and gum pocket granules for periodontitis.

Competitive advantages

- Omnia has already a license agreement for some indications
- Liminal BioSciences has a proprietary process for fractionating plasma and will make the plasma protein plasminogen available to Omnia.
- Toxicology is a non-issue as plasminogen has been administered intravenously at high concentrations in clinical trials for other indications.
- Clinical trials for tympanic membrane perforation have started, with no reported SAEs
- Omnia has been operational since 2001 with very competent staff.

Competition

Wound care has improved substantially with specialized dressings and vacuum treatment, but none of these methods initiate or reactivate healing process.

Treatment of bacterial infections is traditionally made with antibiotics. As plasminogen treatment will stimulate the host's defense system instead of killing bacteria, there is no further resistance to antibiotics developed.

Periodontitis is currently treated by mechanical cleaning with metal scrapers, and in some cases with antibiotics. This treatment is often unsuccessful.

Current status

In addition to pre-clinical studies, the focus is on identifying potential licensees for the indications of periodontitis and infection.

During first half of 2020 the focus is on developing the interactions with implant and oral care companies.

2015-19 >€3 M in combined revenue.

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Specific area

Wound Healing/anti-infection/periodontitis.

IPR

Omnia has 4 different patent families covering wound healing, healing of tympanic membrane perforation, enhancing host defence against infection, and treatment of periodontitis respectively. The first, outlicensed, patents expire 2022 and the last ones 2028. In September of 2015, the company submitted an additional patent application for regulation of inflammatory response, leading to increasing efficiency in radiotherapy for cancer patients. The company also expects to file for protection of formulations for the different indications before respective clinical trial's commencement.

Partnership/collaboration sought

Omnia is seeking investments of €800 k to cover pre-clinical development through 2020.

We offer partnering possibilities for treatment of both infections and periodontitis

Additionally, the company is looking for drug development and regulatory competence for board and management positions.

Team

Patric Stafshede, CEO, MSC, MBA

Tor Ny, Founder and VP R&D, Prof. Authority on plasminogen's role in wound healing

Malgorzata Wilczynska, CSO, specialist on plasminogen and wound healing, PhD

Research background

Omnia was founded by Professor Tor Ny at Umeå University in 2001. The company uses the knowledge of plasminogen's role in wound healing as the basis for in-vivo and in-vitro drug development, supported by genomic expression analysis.