

MUCOCORT[®]

PROVIDES AN IMMEDIATE PAIN RELIEF FOR PATIENTS WITH RECURRENT MOUTH ULCERS



PROJECT PROFILE

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IPR

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Partnership

We are looking for collaborations/partnership and possible market actors interested to acquire the product/company

Team / Scientific advisors

Thomas Hedner
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Mats Jontell
Professor, Oral Medicine and Pathology, University of Gothenburg

Olle Isaksson
Professor of Endocrinology, Sahlgrenska University Hospital /Gothenburg

Jean Lycke
Advisor, Management and marketing, Emerentia Gruppen AB

Helén Fält
Business Coach, Umeå Biotech Incubator AB

Market need and potential

Recurrent aphthous stomatitis (RAS) is the most common ulcerative condition of the oral mucosa, affecting millions of people worldwide. RAS escalates the negative oral health impact on patients and consequently lowers their quality of life with increasing anxiety and depression as a result, due to the high degree of pain experienced by the lesions.

Prevalence has been estimated to 1.5%, the annual prevalence to 20% and the lifetime prevalence to 40%. Despite extensive scientific efforts, the aetiology behind RAS is unknown. Current treatment strategies of RAS remain unsatisfactory, since most therapies merely reduce the severity of the ulcerations and do not prevent recurrences.

We have now a new product in development (MO45A) that will improve the treatment of RAS! The global market for oral treatments was valued at approximately 11 billion SEK in 2016 and amounts to approximately \$ 14 billion (US 1.6 billion) by 2020 with an annual growth rate (CAGR) of 3.8%. Converted to Swedish conditions, this means a potential market (2016) of about 20 million a year in Sweden. Even in Sweden, a strong market growth can be expected in line with global forecasts.

Business idea

(MO45A) consists of a unique galenic preparation - an oral film/patch or gel with very powerful mucoadhesive and hygroscopic properties that can be applied over the wound in the mucosa. The patch consists of a 3-component synthetic biofilm of polymeric material with a self-adhesive surface that attaches very strongly to the oral mucosa absorbs fluid and bioactive substances in the wound area.

Depending on what substance is incorporated in the patch, products with different regulatory status can be developed, all from a CE class 2a to a drug-classified products. This principle makes it possible to manufacture products which effectively cover the wounds. Patches can also be produced with very low doses of antiseptic and anti-inflammatory substances, which releases a locally high concentration of therapeutically active substances in the wound and wound marginal area, but without systemic effect.

Our Business model is a holistic description of all dimensions relevant to designing, developing and managing an innovation so that it creates maximum value for its customers and other stakeholders. We only develop CTM (close to market) products.

Competition

There are several competitor products based on locally applied treatments such as patches, film/strips or adhesive tablets/discs that dissolve over time, which may be categorized as key competitors. Our analysis has also shown that only a few pharmacological candidates (secondary competitors) in development for aphthous stomatitis. The survey regarding need and "willingness to pay" with the professionals (Swedish dentists), showed clearly that there is a big market including both the professional- and the OTC market for a product like (MO45A).

Advantages

The expected benefits of our product-concept are;

- An OTC oral patch for pain reduction in patients with Recurrent aphthous stomatitis (RAS) or Aphthous Ulcers (AU)
- Easy to administer with high compliance
- A patch that can be adapted to different size and severity of RAS
- Allows future development of patches with various contents and regulatory status
- The primary product concept enables continued development of alternative products (different anti-inflammatory substances)

Current status

We are currently performing both technical and clinical validations for further proof of concept in-house and are preparing plans for both regulatory and product development. Our intellectual property evaluation is on-going, and we plan to develop an extensive patent portfolio. A first patent is pending. A clinical study is planned to take place in Q3-Q4 2019.

Photos by courtesy of Mucocort