Bio-Gels Pharmaceuticals

Mucosal Drug Delivery Systems

Concept

Mucosal Drug Delivery Systems:

- Treatment of aphthous ulceration
 - Promote healing, current products only treat the symptoms, not the disease
- Treatment for cold sore
 - Treat all stages of the disease, anti viral and promote healing
- Treatment of chronic oral candidosis
 - Potential long-term therapy for chronic denture stomatitis
- Take products from Pre-Clinical through phase I-II
 - Pre-Clinical and Clinical trial capabilities
 - Successfully completed several Clinical Phase I trials
 - Seek commercial partners to take products from Phase I-II to market through licensing
 - BigPharma is looking to reinvent their drugs
 - Several preparations for oral mucosal diseases withdrawn from market
 - Shorter time to market with known drugs in new delivery system

Treatment of Aphthous Ulcers

- Doxy-Gel to treat oral ulceration such as aphthæ
 - Wound healing through enzyme inhibition
 - A clinical need in the market for an effective treatment
 - Most current products only treat the symptoms - not the disease
 - In Clinical Trials Doxy-Gel speeded the healing from 7-14 days to 3-5 days!



Doxy-Gel Canker sores

Clinical Results



Aphthous ulcers healed within 3 days in 70% of the patients receiving the **Doxy-Gel** formulation, compared to only 25% of those receiving placebo (p< 0.004)/(50 patients)</p>

Treatment for Cold Sores

Doxy^M-Gel to treat Cold Sores

- Anti-viral and wound healing
- No treatment for all stages is currently on the market
- Patients have to start treatment early with current treatments
- DoxyM-Gel to treat all stages of the cold sore
- Finalized Doxy^M-Gel proof of concept in a clinical trial in 2005
- Received IADR/GlaxoSmithKline Innovation in Oral Care Awards March 2005



Doxy^M-Gel Cold sore

Treatment for Candidosis

Clinical appearance of candidosis under a denture

Inhibitory effect of monocaprin *in vitro*



Clinical appearance of denture stomatitis



Potential being studied for further development with the aim to reduce symptoms of dry mouth and inhibit Candida infection

Bio-Gels - Patent Status

- PCT application WO 98/20872 Topical formulations containing as a therapeutic active agent fatty acids or fatty alcohols or monoglyceride derivatives thereof for treating of mucosa infections.
 - Australian Patent nr. 729546 published 17.5.2001
 - United States Patent nr. US6,596,763 B1 published 22.7.2003
 - ARIPO Patent nr. AP 1209 published 30.9.2003
 - The application is under examination in Europe
- PCT application WO 01/28515 Pharmaceutical composition for treatment of mucosal epithelial ulceration and/or erosion.
 - Australian patent 778498, published
 - The application is under examination in US and Europe