

MED3000: Excitement builds over “unique” topical ED treatment

Futura Medical’s MED3000 topical ED treatment has been shown in a clinical trial to provide similar efficacy to certain established systemic treatments but with quicker onset, fewer contraindications and no significant side-effects. Following positive discussions with regulators in the USA and EU, the company is confident it will soon be in a position to file for medical device authorisation to provide a unique treatment option for men.

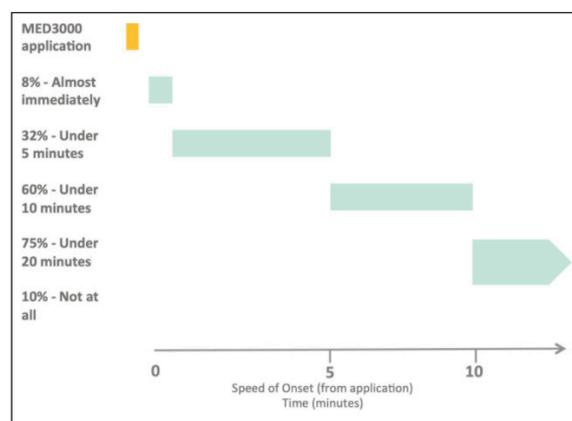
Focus on topical delivery

Futura’s strategy is to develop a portfolio of products to late-stage before partnering with pharmaceutical players for launch. The leadership team includes individuals with R&D backgrounds and expertise in OTC, with several formerly at GSK. Transdermal delivery is Futura’s speciality, using proprietary gel-based technology DermaSys, which is based on volatile solvent and / or penetration enhancer components tailored to suit the specific therapeutic indication, speed of onset and duration of action for each product. Its portfolio includes pain relievers TPR100 and TIB200, formulated with diclofenac and ibuprofen respectively and shown to provide fast, effective and long-lasting relief when delivered using DermaSys, while a j-v collaboration agreed in September 2019 with CBDerma Technology is exploring using DermaSys alongside cannabidiol.

Strong trial results

Futura’s main focus is MED3000, which it describes as a “breakthrough clinically-proven treatment for ED”. The cooling effect from the evaporative mode of action of DermaSys gel, and subsequent warming, acts to stimulate the penis glans to cause an erection.

The excitement over MED3000 stems from the results of the company’s comprehensive FM57 clinical trial (published December 2019), which involved 1,000 participants in 60 centres across nine countries and provided even better outcomes than anticipated, with



MED3000 speed-of-onset results from the FM57 clinical trial

statistically significant improvements for men with mild, moderate and severe ED symptoms. Efficacy was comparable to lower-dose PDE5 inhibitors (tadalafil 5mg), working immediately in some males and within 5-10 minutes in 60% of others, with only a low level of mild side-effects reported by men or their partners.

CHC brand opportunity

MED3000’s non-medicated formula and low side-effects make it ideal for the CHC market, as it is not subject to the contraindications associated with currently-available systemic ED treatments, while it also offers an easier regulatory pathway as a medical device. Its topical action (15-second application, which can be done by a partner as part of foreplay) and relatively fast onset are more conducive to a normal sexual experience than medicated systemics (30-60 minute onset), offering a key point of difference. This may also make the product

attractive to younger men, whom some studies suggest are experiencing rising incidence of ED owing to factors such as feelings of inadequacy or stress & anxiety. There is also scope for MED3000 to be used alongside established systemic medicated treatments for enhanced efficacy.

Outlook

Futura has held positive discussions with the relevant EU notified body and the US FDA regarding medical device approval, anticipating being in a position to file applications with both in H2 2020. It is therefore seeking a distribution partner or partners to rollout the product in these regions as a priority, while also hoping to expand into A-P and LatAm.

The growing retail CHC market for ED products – driven mainly by sildenafil launches in Europe over the past few years – provides an excellent opportunity for MED3000,

MED3000: Key claims & attributes

- A first in the world, easy to apply gel
- Highly effective in mild, moderate and severe ED
- Works in 5-10 minutes for spontaneous sex
- Use as part of foreplay
- Very low side-effects
- No drug interactions
- Patent protected
- Rx and OTC potential
- Faster medical device regulatory pathway
- Major near term opportunity

Source: Futura Medical

with its topical format and non-medicated action offering an alternative to existing treatments for men looking to maintain or improve their sexual wellbeing. 