MED3000, a clinically proven, fast-acting topical product for Erectile Dysfunction with the prospect of being the first globally available OTC treatment for ED

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Introduction

MED3000 is a topical gel with a unique evaporative mode of action which is applied to the glans penis by the male or his partner for treatment of erectile dysfunction (ED).

Objective

To assess the effectiveness, onset of action and safety of MED3000 gel over a 24-week treatment period in male patients clinically diagnosed with ED

Methods

100 male patients clinically diagnosed with ED were randomised into two treatment groups, 50 to MED3000 and 50 to Tadalafil (5mg) in 11 Investigational sites in USA, Poland Georgia and Bulgaria

Results

Both Co-Primary end points were achieved (P<0.001)

(1) Mean IIEF-EF change from baseline at 24 weeks

(2) Minimal clinically important difference (MCID) exceeded at 24 weeks).

61% of MED3000 users exceeded the MCID at 24 weeks compared with 87% tadalafil users

Secondary Endpoint 10 minute onset of action

FDA agreed standard for achieving a 10 minute onset of action was achieved. A key differentiator from PDE5i's

Effective in Mild, Moderate and Severe ED

MED3000 also delivered a clinically meaningful outcome over 24 weeks in accordance with the Rosen 2, 5 and 7 criteria (Rosen et al 2011)[1] in mild, moderate and severe ED subjects

Adverse Events (<2 incidences) are detailed in figure 1).

Figure 1 – Comparison of Adverse events MED3000 vs Tadalafil (5mg) (>2 incidences)

Adverse Events - Males	MED3000 Patients	MED3000 Total AE's	Tadalafil Patients	Tadalafil Total AE's
Headache	2 (4.3%)	2	9 (19.1%)	18
Back pain	0 (0%)	0	2 (4.3%)	2
Non cardiac chest pain	0 (0%)	0	2 (4.3%)	4 *
Nausea	2 (4.3%)	2	0 (0%)	0

Adverse Events - Females	MED3000 Patients	MED3000 Total AE's	Tadalafil Patients	Tadalafil Total AE's
Headache	3 (6.4%)	3	0 (0 %)	0

* All occurred on Tadalafil in US African American patients

Reference
1 – Rosen RC et al "Minimal clinically important differences in the erectile function domain in the International Index of Erectile Function Scale
Eur Urol 2011;60(5):1010-6

Conclusion and next steps

MED3000 has been shown to deliver a clinically meaningful response and is fast-acting. It was also shown to be clinically effective in mild, moderate and severe ED. Results were generally consistent with a previously conducted clinical study used for European approval

MED3000 was shown to have minimal adverse events. Its "drug-free" formula provides a further margin of safety with no propensity for adverse drug interactions. This profile makes it suitable for OTC use.

FDA filing for marketing authorisation as a De Novo medical device occured in October 2022

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