Futura Medical

FM71 achieves all primary and secondary endpoints

31 August 2022

- Futura Medical has announced that FM71, the clinical study specifically conducted over 24 weeks to support the US FDA application for MED3000 as an OTC treatment for erectile dysfunction (ED), has met its primary and secondary endpoints. The results of FM71 were consistent with those seen in the previous 12 week FM57 Phase III study. Importantly, the improvements in erectile function were sustained throughout the longer period. The 24 week data had been explicitly requested by the FDA.
- There were two co-primary endpoints. The first showed a highly statistically significant improvement in erectile function ($p<0.001$) against baseline at 24 weeks (measured by the gold standard, internationally recognised IIEF-EF score) across 'pooled' severities of ED (mild, moderate and severe). The second showed a 5.73 unit change in IIEF-EF score versus baseline at 24 weeks. This comfortably exceeded the 4 unit difference agreed with the FDA and defined as the Minimal Clinical Important Difference (MCID).
- Whilst the primary endpoints focused on efficacy, the secondary endpoints examined the onset of action. The data, using FDA agreed criteria where patients experienced an erection, showed a highly statistically significant improvement ($p<0.001$) at 10 minutes. This endpoint was included to demonstrate a rapid onset, which the oral tadalafil 5mg tablet comparator failed to show. Typically, oral PDE5 treatments take 30-60 minutes to work.
- Additional results from FM71 include: MED3000 exceeded the 4.0 MCID IIEF-EF score at all timepoints throughout the study; over the 24 weeks the MCID was also exceeded for each of the mild, moderate and severe ED sub-groups; and, using the SEAR (Self Esteem and Relationship) questionnaire, at week 24 85.4% of MED3000 users felt sex could be spontaneous. No serious adverse events were recorded in any patients on MED3000; 19.1% of subjects on tadalafil experienced headache versus 4.3% on MED3000; there were no instances of back pain or 'non-cardiac' chest pain on MED3000 versus 4.3% for each on tadalafil, whereas 4.3% on MED3000 noted nausea.

Price	37.0p
Market Cap	£106.3m
Primary exchange	AIM
Sector	Healthcare
Company Code	FUM
Corporate client	Yes

Company description:

Futura Medical is an R&D driven small pharma company, with a novel DermaSys transdermal delivery platform. The lead programme, a topically applied gel (MED3000), has been approved as an OTC product for ED (erectile dysfunction) in Europe, with final trials now complete in the US.

Trinity Delta view: The successful outcomes from the critical FM71 study pave the way for MED3000 to be submitted for FDA review, as a *De Novo* medical device, for the OTC treatment of erectile dysfunction. The dossier, including data from FM57, is expected to be submitted by end-September, with US marketing authorisation likely by end-Q123. The excellent safety and tolerability profile, coupled with the rapid onset of action and now demonstrated longer-term efficacy, means MED3000 is well positioned to become a clearly differentiated ED product. These clinical results now shift the focus from regulatory aspects to execution, much as the European CE Mark did in April 21. We expect discussions to address the commercially important US market will now begin in earnest. We currently value Futura Medical at £264m, equivalent to 92p per share but expect to review this as visibility on expected launch timings and likely commercial potential in the various markets increases.

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