Futura Medical

MED3000: more detail on FM57 results

2 April 2020

- Futura Medical has presented detailed data from the pivotal FM57 Phase III Erectile Dysfunction (ED) study in a webcast. The headline results were released in December 2019 (see Update note). These showed no statistical difference between the three GTN dose arms and the DermaSys (placebo) arm, yet a strongly statistical difference vs baseline. These results suggested that this specific DermaSys formulation, now known as MED3000, was effective in its own right.
- FM57 was a large double-blind, multi-centre trial involving 1,000 patients across c 60 centres in nine countries and undertaken by two CROs (specialist clinical research organisations). The primary efficacy endpoint was based on the erectile function domains of the IIEF questionnaire, with SEP2 and SEP3 questions from the Sexual Encounter Profile (SEP) questionnaire added. A number of secondary endpoints were also assessed.
- The analysis shows that MED3000 achieved clear and statistically meaningful improvements over baseline across all primary and secondary endpoints, with p values of <0.001 across the Mild, Moderate, and Severe forms of ED. The results were consistent when viewed across patient groups, study centres, geographies, and CROs performing the study.
- As we said at the time, whenever a well-structured and planned clinical trial throws up such remarkable results the first question should be whether something has gone awry in the study execution. Examples would include formulation errors, administration issues, and problems with data collection and processing. However, the analyses presented support the view that MED3000 is a potent and effective treatment for all forms of ED.
- The quality of the data is also supported by the positive interactions with the FDA and European regulators. The documentation to support a medical device filing in Europe (Class II) and US (*de novo*) is being prepared and, assuming no further clinical work is required, on track for submission by end-July (Europe) and end-Q320 (US).

Trinity Delta view: The analysis of the FM57 data shows a remarkably consistent outcomes across all treatment groups and supports the view that MED3000 is an effective and safe therapy for ED. Regulatory submissions for approval of MED3000 as a medical device opens a potentially faster route to market, with probably no further clinical work required for Europe and (possibly) a small study for the US. Although difficult to compare without direct trials, the efficacy seen would suggest an activity approaching that of oral PDE5s such as tadalafil (Cialis), but with a faster onset of action and fewer side-effects. As we highlighted previously, significant unknowns remain, but the outlook is increasingly positive. We suspended our forecasts and valuation at the time of the top line FM57 results and aim to reinstate them as soon as practicable.

Price	9.5p
Market Cap	£23.34m
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, MED3000, is a topically applied gel being developed for erectile dysfunction (ED). A pain relief gel, TPR100, is awaiting UK approval.

Analysts

Lala Gregorek
lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori
fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Lala Gregorek lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori fgregori@trinitydelta.org
+44 (0) 20 3637 5041

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