Futura Medical

MED3000 European regulatory pathway is clearer

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- Futura Medical has announced that it has had positive discussions with the European regulators regarding the approval of MED3000 as a medical device for the treatment of erectile dysfunction (ED). MED3000 is the project name for the base MED2005 DermaSys formulation used as the placebo in the pivotal FM57 Phase III study.
- The discussions clarified the regulatory requirements and it appears that the full FM57 data, together with the usual technical dossiers, will be sufficient for European approval. Management expects the technical files will be ready for submission by mid-2020.
- The FM57 Phase III trial for MED2005, an erectogenic gel containing glyceryl trinitrate (GTN), showed MED2005 met the primary endpoints against baseline and, rather surprisingly, also demonstrated a significant clinical benefit for the DermaSys gel formulation alone (now MED3000).
- MED3000 appears to work through a specific and targeted evaporative effect which stimulates the nerve endings in the glans penis, causing an erection.
- The recent equity raise, along with existing cash resources, means that we believe sufficient funding is in place for the closing out costs for the FM57 study and to pursue a medical devices pathway for the regulatory approvals of MED3000. This assumes that MED3000 approval in the US would not require material additional clinical studies to be performed.
- The regulatory pathway in the US is expected to be similar, but cannot be confirmed until the face-to-face meeting with the FDA in Q120 has happened.
- The full data from FM57 is still being evaluated and will be presented once the analysis is complete. Completion of the clinical study report is expected by the end of April 2020.

Trinity Delta view: The remarkable FM57 pivotal study results have created understandable uncertainty. However, there are material commercial opportunities for MED3000 to be approved as a treatment for ED, including the extended patent life and wider market opportunities, eg use with existing ED medications such as PDE5 inhibitors. Clearly there are significant potential unknowns that remain. The positive interactions with the European regulators bring a welcome improved clarity to the likely approval pathway. The planned meeting with the FDA this quarter will shed further light on the next steps for the important US market. We suspended our forecasts and valuation at the time of the FM57 results and intend to reinstate them as soon as practicable.

Price	12.2p
Market Cap	£29.9m
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

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