Futura Medical

MED3000: FDA details the scope of confirmatory study

22 October 2020

- Futura Medical has reported details of its third meeting with the FDA that firmed up the format of the six-month confirmatory study. The new trial, known as FM71, will involve c 100 patients with erectile dysfunction (ED). Around c 20 will be in the US and the balance will be similar to those who took part in the FM57 Phase III trial. The primary endpoint is efficacy against baseline assessment. The important secondary endpoints relate to speed of onset of effect and adverse events. There is no placebo and a comparison arm, using 5mg tadalafil (Cialis), will employ the same endpoints and provide an appropriate reference frame for an overall MED3000 risk/benefit analysis.
- In the US, MED3000 is being filed as a medical device with a De Novo Classification, as there is no similar predicate device to allow a 510(k) submission. The pre-submission meetings with the FDA have confirmed the OTC (over the counter) route to market. The clinical study report (CSR), and additional clinical, safety, stability, and manufacturing information are similar to the European requirements and this technical dossier has already been collated. Development of the OTC label and associated patient information leaflet will be performed in parallel with FM71.
- In Europe, MED3000 has been submitted for approval as a Class 2B medical device. The designated EU Notified Body has audited the QMS (Quality Management System) documentation and finished the completeness checks of the Technical Dossier. These are currently under formal review, which, in our view and COVID-19 permitting, support a regulatory approval in 2021.
- No details of the likely cost of FM71 have been provided but this should be relatively modest (a fraction of that expected for FM57). Cash of £2.62m (at end-June 2020) provide a runway to Q221, but this does not include the costs of FM71. Management has previously stated that it could be funded by a licensing deal, debt, other non-dilutive funding, or an equity raise. Talks for the licensing rights in non-US and non-Europe regions are underway and management has a "reasonable expectation" of their completion. The upfront element of a successful deal could, in our view, fund the FM71 study.

Trinity Delta view: Futura Medical has now had three constructive meetings with the FDA that clarified MED3000's regulatory pathway. MED3000 is expected be the first clinically proven ED product that is approved for OTC use in Europe and the US. Its rapid onset of effect, undoubted safety, and ease of use suggest MED3000 would offer an attractive, clearly differentiated, and competitive clinical profile. Whilst risks clearly remain, the discussions with the regulatory bodies have been encouraging and supportive, which suggests the inevitable pre-approval questions should be relatively straightforward and timely to address. We value Futura Medical at £153.8m, equivalent to 60.9p a share.

Price	13.5p
Market Cap	£33.2m
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.

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