Futura Medical

EU Notified Body recommends MED3000 approval

19 March 2021

- Futura Medical has reported that the designated EU Notified Body has completed its review of MED3000's Technical Dossier and recommends its certification as a Class 2b approved medical device. The certificate is expected to be issued before the end of May, which is ahead of the timings we had expected (we had estimated mid-2021 in our modelling). This makes MED3000, a proprietary topical gel for erectile dysfunction (ED), the first clinically proven OTC treatment that is approved across Europe.
- We continue to view MED3000's European approval as a key near-term determinant for the negotiation of various commercial partnerships. The CE Mark is seen as a gateway for rapid product introductions in several markets globally, including many countries in Latin America, Middle East and South East Asia. Management has confirmed that it has received commercialisation proposals from a number of parties, and we suspect that these will now be progressed to completion relatively swiftly.
- We believe the Latin America and Middle East regions will likely be covered through traditional deals that involve royalty payments, fees and milestones. The diverse nature of OTC marketing in Europe, coupled with differing cultural attitudes, suggest we will see several partnerships and no one single pan-European approach will be pursued. Interestingly, EU approval will allow Co-High, the SE Asian partner announced recently, to address a number of its markets quickly. Additionally, when formal approval is granted, should Futura Medical's share price exceed 30p for a month, the £1.5m in convertible loan notes will mandatorily convert into equity.
- The fourth meeting with the FDA to clarify MED3000's regulatory pathway in the US took place in late-February and management is awaiting the official minutes. We expect the new US trial, to be known as FM71, will involve c 100 patients with ED. Around 20 will be in the US and the balance similar to those who took part in the FM57 Phase III trial. The primary endpoint is efficacy against baseline assessment. The secondary endpoints will likely relate to speed of onset of effect and adverse events. There is no placebo and a comparison arm, using 5mg tadalafil (Cialis), will be employed.

Trinity Delta view: MED3000's regulatory approval in Europe de-risks the Futura Medical investment case, removing a major uncertainty and paving the way for commercialisation discussions for a number of geographies to proceed at pace. The major sensitivities in these markets now shift from regulatory risk to execution risk. In the US, the outcome of the fourth meeting with the FDA is awaited, but it is unlikely any major unknowns will be revealed. We are maintaining our Futura Medical valuation, based on conservative assumptions, at £181.5m or 73.1p per share (71.3p fully diluted) until we have further clarity on the likely structure and economics of commercialisation deals across EU (and other) markets.

Price	18.0p
Market Cap	£44.2m
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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