Destiny Pharma

XF-73 green light for the fast track

19 March 2018

Destiny Pharma (DEST) has confirmed that its lead candidate, topical antimicrobial XF-73, has been granted FDA Fast Track Designation in the new FDA-backed indication - prevention of post-surgical staphylococcal infection. Following the recent Investigational New Drug (IND) opening, XF-73 is due to enter Phase IIb studies this year, positioning it as a potential first-to-market product in the indication.

Fast track designation is one of a range of incentives granted under Qualified Infectious Disease Product (QIDP) status granted to XF-73. QIDP supports the development of drugs against priority pathogens, such as *S aureus,* including methicillin-resistant *Staphylococcus aureus* - MRSA.

- XF-73 is the lead product from DEST's XF series and is a topical gel for nasal administration and the first candidate from the XF group, which collectively have demonstrated activity against a wide spectrum of bacteria tested. These include eight of the twelve pathogens that appear on the priority list classified by the Centers for Disease Control and Prevention (CDC) and the World Health Organisation (WHO).
- Over the course of five clinical studies in 216 total subjects, of whom 166 received XF-73, it was shown to rapidly kill *S aureus*. XF-73 is active against a wide spectrum of bacteria – including MRSA, the life-threatening, drug-resistant form of *S aureus* – as well as its susceptible form, MSSA. **Significantly, in preclinical studies five of the world's major MRSA strains tested, failed to generate resistance to XF-73 even after more than 55 exposures to the product**. If approved, this could help overcome the urgent issue of antimicrobial resistance (AMR), providing a key commercial advantage for XF-73.
- We calculate that the value of the primary market for XF-73 alone is c $1.2bn - counting the six million patients classed as high risk who are also carriers of *S aureus* (based on data from US National Center for Health Statistics). In our view the low potential for resistance means that XF-73 should also be widely adopted for the c12 million high-risk non-carriers of *S aureus*. There appears to be limited competition in later stage pipelines in the preventative space and, with no approved drugs in the US, XF-73 could set a new standard and gain a strong foothold in the market.

We reiterate our DCF valuation of Destiny Pharma at £115m, or 263p / share, including our estimated end December 2017 net cash of £16.8m. On our forecasts DEST is well funded to cover the Phase IIb program with XF-73, as well as to cover its initial work on the follow-on pipeline, taking our estimated cash reach to the end of 2020.

Our valuation includes only XF-73 in the lead indication, so that the entry of preclinical candidates into human studies provides pure upside. Other news flow and developments to watch for include the start of clinical trials or announcements on policy-led incentives supporting antimicrobial development.

Company Data

EPIC	DEST
Price (last close)	123p
52 week Hi/Lo	235p / 114p
Market cap	£54m

Share Price, p

Source: ADVFN

Description

Destiny Pharma is a UK-based clinical stage developer of medicines for the prevention and treatment of infections caused by drug-resistant bacteria.

There are four candidates from the XF Drug series in development, the most advanced is on track to enter Phase IIb studies in 2018 in the Prevention of postsurgical Staphylococcal infection.

News flow

Phase IIb trial start with XF-73 in Prevention of post-surgical staphylococcal infection, 2018.

Entry of preclinical candidates into human studies or news on pipeline prioritisation.

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