Destiny Pharma plc

Clinical progress with XF drug platform

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Destiny Pharma (DEST) is developing a pipeline of novel antimicrobials from its XF drug platform, to help combat highly prevalent and virulent bacteria. These include eight so far tested of those classed as urgent threats by the World Health Organisation and Centers for Disease Control (CDC), including MRSA (methicillin-resistant *Staphylococcus aureus*). **The unique mechanism of DEST's new class of drug candidates could also help to overcome Anti-Microbial Resistance (AMR)** that is a major limiting factor with standard antibiotic treatments.

Recently, positive results from a blinded, placebo-controlled Phase I dermal irritancy study of lead product XF-73 in aqueous solution, showed that high concentrations of XF-73 applied topically to intact and abraded skin had a 'similar irritancy potential to water'. Pharmacokinetic sampling confirmed that XF-73 was not absorbed into the bloodstream of volunteers, supporting the drug's safety profile and that of other XF drugs, in treating and preventing dermal infections.

The data helps to pave the way for a Phase IIb study start in a gel formulation of XF-73 in the new FDA indication for prevention of post-surgical *Staphylococcus aureus* infection, due to be launched on completion of a second standard dermal safety study of the gel formulation of XF-73 in H2'18. Existing safety data in 166 subjects suggest that this is a relatively low risk hurdle to accomplish. The timeline for the Phase IIb study completion remains on track and is anticipated in H2'19.

The safety study results also complement the existing strong body of data on XF-73, including its ability to rapidly kill bacteria, and so reducing the potential for AMR to develop, compared to other antimicrobials tested. The data will further assist DEST in prioritising its pipeline that contains three other preclinical candidates. Notably the safety profile is also supportive of XF-73 for treatment of skin infections caused by MRSA and of other drugs in the XF series.

Product/Indication/Mode of delivery	Development status
XF-73/Prevention of post-surgical Staphylococcal infection/Intra-nasal	Phase IIa data/next step Phase I/IIb
XF-73/Prevention of hospital/ventilator associated Staphylococcal pneumonia/Throat	Pre-clinical
XF-70/Treatment of skin burn wound infections of antibiotic resistant bacteria/Dermal	Pre-clinical
XF-70/Treatment of bacterial biofilm infections/Lung	Early pre-clinical

Source: Destiny Pharma

XF-73 has potential to be first to a $1.2bn US core market. Post-surgical *S aureus* infection, including both its drug resistant and susceptible forms, can be prevented by means of decolonisation of *S aureus* that is carried in the nasal passages of up to 33% of people. DEST is targeting a primary market of up to 6 million high risk surgeries in screened *S aureus* carriers, with secondary market potential for so called Universal Decolonisation, for c 12 million non-carriers. Since there are no products currently approved in post-surgical S *aureus* infection in the US, XF-73 has potential to be first to the US market, setting a new standard of treatment.

Company Data

EPIC	DEST
Price	99p
52-week Hi/Lo	222p / 98p
Market cap	£43.1m

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 in development from the XF Drug series and the most advanced is about to enter Phase IIb studies in Prevention of post - surgical Staphylococcal infection.

News flow

Interim results due on 26 September

Phase I safety data XF-73 gel

Phase IIb trial start with XF-73 in Prevention of post-surgical Staphylococcal infection, H2'18

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

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Meanwhile, DEST's newly signed three-year research agreement with Aston University was formed to help accelerate the XF preclinical pipeline. This will include leveraging the institution's expertise in the study of resistant bacteria in biofilms, communities of bacteria embedded in an impenetrable mucous layer, which pose an elevated risk of infection as a result of their very high resistance to drug treatment.

The collaboration follows on from promising signs of *in vitro* activity demonstrated by XF drugs against MRSA in biofilms. The collaboration will also enable shared expertise to be applied in evaluating the potential of other XF candidates in treating drug resistant bacteria.

We reiterate our sum-of-parts DCF valuation of DEST, using a 12.5% discount rate, of **£117m (269p/share)**. We include only XF-73 in prevention of S *aureus* infection in our value, so providing upside on entry of other candidates into human studies.

In contrast, the current market valuation suggests a low probability of success of XF-73, despite the existing efficacy data in 166 subjects, and the up to twofold higher than average success rate for anti-infective drugs, providing an attractive entry point ahead of the Phase IIb trial start.

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