Destiny Pharma plc

Extending the clinical pipeline

5 October, 2018

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 potential versatility and the unique mechanism of DEST's new class of drug candidates could help to overcome Anti-Microbial Resistance (AMR) which is a major limiting factor with standard antibiotic treatments.

DEST is progressing its lead program for Prevention of post-surgical Staph infection with intra nasal candidate XF-73 and is on track to commence Phase IIb studies later this year. The company has also extended its clinical pipeline by adding a new program for high unmet need in treatment and / or prevention of skin infections in diabetic foot ulcers (DFU's) and in burns wounds. High unmet need in DFU and burns gives a global peak annual sales potential of up to $500m, and with XF-73 already shown to be active against the predominant pathogens associated with infection in these indications.

Highlights of the six-month period to June 2018 include positive results from a blinded, placebo-controlled Phase I dermal irritancy study of lead product XF-73 in aqueous solution, which showed that high concentrations of XF-73 applied topically to intact and abraded skin had a 'similar irritancy potential to water'.

A Phase IIb study for a gel formulation of XF-73 in the new FDA indication for prevention of post-surgical *Staphylococcus aureus* infection, is due to be launched on completion of a second standard 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 achieve. The timeline for the Phase IIb study completion remains on track and is anticipated in H2'19.

DEST has also started Phase I studies of XF-73 in **two additional indications**, for Diabetic Foot Ulcer DFUs and burns wounds. This follows on from Phase I study results showing that XF-73 is a suitable treatment for longer term treatment. This will be confirmed during additional Phase I studies planned in 2019, targeting the completion of a Phase II ready package in during 2020. This demonstrates the potential versatility of the drug being tested, for both preventative and treatment approaches. DEST reported a healthy cash balance of £15.1m at June 2018 – sufficient to run the ongoing planned studies of XF-73 – taking the cash runway into H2'20 on our forecasts including funding to complete a Phase II ready package for XF-73 dermal program. Reported expenses for the period were £2.1m – including £1.3m of R&D - in line with our forecasts.

Additional news flow includes the recent appointment of Dr. Jesus Gonzalez MD as full time CMO in line with the advancement of the development pipeline, reinforcing the company's capability ahead of increased clinical development activities.

Adding in these new indications, using conservative assumptions, **our valuation increases from £117m to £129m, equivalent to 296p per share**. By contrast, the current market capitalisation appears to provide an attractive entry point ahead of Phase II study start in the lead indication and given the expansion of the clinical pipeline.

Company Data

EPIC	DEST
Price	87p
52 week Hi/Lo	166p / 87p
Market cap	£38m
ED fair value / share	296p

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 two clinical stage 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

H2'18

XF-73 nasal Phase I study/ and Phase IIb study start

2019

XF-73 dermal Phase I study start

XF-73 nasal results readout

Potential update on grant funding

R&D collaboration

Emma Ulker (Analyst)
0207 065 2690
emma@equitydevelopment.co.uk

Hannah Crowe
0207 065 2692
hannah@equitydevelopment.co.uk

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/Treatment of skin infections of antibiotic resistant bacteria diabetic foot ulcers/burns wounds	Phase I
XF-73/Prevention of hospital/ventilator associated Staphylococcal pneumonia/Throat	Pre-clinical
XF-70/Treatment of bacterial biofilm infections/Lung	Pre-clinical

Source: Destiny Pharma

Commercial opportunity in DFU and Burns Wounds

There is a strong clinical and commercial rationale for developing XF-73 in DFU and burns since an estimated 24 million people in the US suffer with diabetes and around 1.5 million new cases develop each year.[1]

DFU is a widespread serious chronic condition which can lead to infection and even amputation. As many as 60% of sufferers are reported to develop an infection. Standard treatments include negative pressure wound therapy, offloading and debridement however, the rate of recurrence up to 70% remains high and is the reported to be the cause of over 70%[2] of limb amputations.

The chronic nature of DFU can increase the likelihood of infections and *S aureus* including MRSA were seen to be key pathogens in DFU infection. MRSA is reported to be responsible for increase in healing time of over three times compared to methicillin sensitive strains.[3]

Gram negative strains are associated with longer duration of infection. Therefore, there is a clear rationale for XF-73 owing to its demonstrated activity against both Gram negative and Gram-positive pathogens and which can be enhanced using photodynamic therapy (PDT).

It is early days and DEST will continue to work on formulating and testing XF-73 ahead of a targeted Phase II study start in 2020. However, if data are positive it suggests that the drug might be widely used – particularly if it can be used to provide both a treatment and potential preventative approach given the limitations of current treatment options.

The incidence rate of adult diabetes is around 1% in the US, around 1.5 million new cases per annum, approximately 25% develop DFU, giving a potential patient pool of 0.4m. Up to 25% of sufferers will develop DFU in both feet taking our peak global sales estimate to $500m at an average cost per course of treatment of $1,000, according to the company.

[1] https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf
Accessed September 2018
[2] Yazdanpanah, L, 'Literature review on the management of diabetic foot ulcer**' 2015, World Journal of Diabetes**

[3] Cervantes-Garcia E et al, 'Infections of diabetic foot ulcers with methicillin-resistant *Staphylococcus aureus.* , 2015 *Int J Low Extrem Wounds*

We estimate that DEST could achieve **up to 40% market penetration** if ongoing studies yield positive data and given the scale of the unmet need. Given the diabetes epidemic, global diabetes prevalence is estimated to reach over 500 million by 2030[4] providing scope for growth in this market.

In our opinion, the clinical rationale for introducing a new drug to help combat drug resistant pathogens in moderate to severe burns wounds is also well supported. The number of hospital admissions for burns wounds is approaching 90,000 per annum in the US according to the Centers for Disease Control, with at least 60% of these people at risk of infection due to hospitalisation equivalent to at least 70,000 patients in the US.

Infection is the most common cause of morbidity and mortality in this population, with almost 61% of deaths being caused by infection and the predominant burn wound pathogens are *Pseudomonas aeruginosa* and *Staphylococcus aureus.*[5]

Market research supportive of XF-73 nasal in a $1.2bn market

We are encouraged to hear that the results of recent 2018 US market research for XF-73 nasal have confirmed the potential suitability of the drug for use in its lead indication for prevention of *S aureus* infection which are supportive of its adoption given the lack of an FDA approved product and the increasing challenges caused by Antimicrobial Resistance.

The assessment included interviews with payers, hospital pharmacy directors and key opinion leaders which confirmed the positive clinical profile of the drug including its short treatment duration, low tendency to generate resistance as well as the acceptability of the projected pricing range of XF-73 nasal in prevention of post-surgical *Staphylococcus aureus* infection.

XF-73 has potential to be first to a $1.2bn US core market in post-surgical *S aureus* infection, which can be prevented by means of decolonisation of *S aureus* which 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 and to gain a strong foothold.

[4] Whiting, D, 'IDF Diabetes Atlas: Global estimates of the prevalence of diabetes for 2011 and 2030, Diabetes Atlas

[5] Church D et al, 'Burn Wound Infections, 2006 Clinical Microbiology Review

Financials

We have updated our forecasts to include the dermal indications for XF-73, using conservative assumptions for now and providing scope to increase over time provided study outcomes are supportive. Our updated sum of the parts valuation is summarised below, which uses a 12.5% WACC, 15% risk adjustment for XF-73 dermal and assumes a launch date in 2022.

We have increased our valuation from £117 to £129m, with rolling forwards our forecasts, and using conservative early stage assumptions in the dermal program.

Valuation summary

	Value £m	Per share (p)
XF-73 prevention of post-surgical infection, S aureus carriers, US	74.9	171.9
XF-73 prevention of post-surgical infection, Universal Decolonisation, US	31.1	71.4
XF-73 Universal Decolonisation in emergency surgery cases, US	6.3	14.5
XF-73 DFU/Burns wounds	8.8	20.3
Corporate costs 12 months	-6.2	-14.3
Est net cash Sept 2019	14.0	32.1
Total	**129**	**296**

Source: Equity Development

Head of Corporate

Gilbert Ellacombe
Direct: 0207 065 2698
Tel: 0207 065 2690
gilbert@equitydevelopment.co.uk

Investor Access

Hannah Crowe
Direct: 0207 065 2692
Tel: 0207 065 2690
hannah@equitydevelopment.co.uk

Felix Grant-Rennick
Direct: 0207 065 2693
Tel: 0207 065 2690
felix@equitydevelopment.co.uk

More information is available on our website

www.equitydevelopment.co.uk