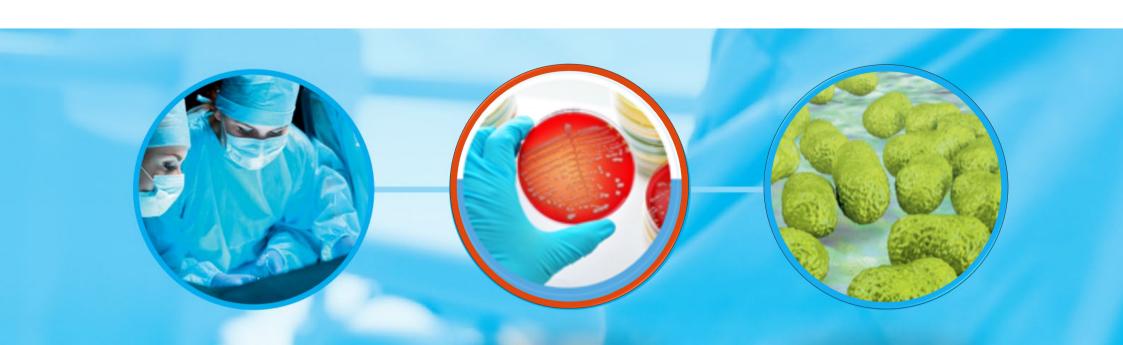


# **Developing Novel Medicines that Prevent Serious Infections**

February 2021

**Destiny Pharma - London AIM listed public company** 





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## Experienced management team and strong board

#### **Management Team**



**Neil Clark** FCA, CEO

Over 20 years in AIM listed biotech/ life sciences leadership positions



**Dr Bill Love** PhD, CSO

Founder of DP and coinventor of the XF Drug Platform and recognised thought leader in tackling AMR



Shaun Claydon FCA, CFO

Experienced life science CFO and investment banker/corporate financier



**Dr Jesus Gonzalez** MD, CMO

Expert in the design and execution of clinical trials for anti-infective drug candidates. FDA, biotech and pharma experience



**Dr Stephanie Bewick**PhD,CBO

Over 20 years experience in Business Development within public, private biotech and mid-sized pharma

#### **Non-Executive Board Members**



Nick Rodgers Chairman

Investment
banker/corporate financier
with extensive broad
experience in life science
in private and public
companies. Ex-Chair of
Oxford Biomedica



Peter Morgan
Director

Pharma industry
consultant including AIM
companies. Background in
product and general
management in Ciba Geigy
/ Novartis



**Dr Huaizheng Peng MD**Director

GM and international Director of China Medical Systems.
Background in City fund management and investment banking. Medical doctor by training



**Dr Debra Barker MD**Director

Ex-Roche, GSK and, most recently, at Polyphor. Held several senior roles at Novartis.
On the board of Hutman Diagnostics and BerGenBio



## Destiny Pharma's 5 Year Plan

Destiny Pharma's goal is to become a world leading infection prevention biotech with late-stage clinical assets targeting areas of high unmet need

- Build a world leading infection prevention company
- Focus on novel, preventative medicines for hospital/care home markets
- **Develop** existing microbiome and XF clinical and research programs
- Expand pipeline by in-licensing and M&A
- Maximise potential of portfolio through out licensing at key inflection points
- Collaborations/grants/out-licensing help fund a vibrant pipeline

"Prevention is better than cure"



## Recent healthcare crises support our focus on infectious disease

- COVID-19 has highlighted to the world the health and economic threat of untreatable infections
- A significant % of COVID-19 deaths are associated with serious bacterial infections
- These bacterial infections are often poorly treated by old antibiotics that have the potential to generate resistant bugs

"Antibiotic resistance is a slow-motion pandemic – whose speed will increase because of COVID-19. A concentrated global effort is now needed to ensure it is addressed with the same urgency that's likely to bring us a COVID-19 vaccine in the months ahead..."

http://bsac.org.uk/antibiotic-resistance-the-other-pandemic-lurking-behind-covid-19/

- UK government has established a pioneering initiative to support the purchasing by hospitals of selected novel anti-infective drugs in recognition of the clinical need. Similar PASTEUR Act drafted in US in 2020.
- Several large pharma companies have combined forces and announced an AMR Action fund of \$1 billion starting 2021. Investing in clinical phase, novel antiinfective programmes
- Ineos also recently donated £100m to Oxford University for AMR research

"This looming global AMR crisis has the potential to be as large, or even larger than COVID-19 in terms of deaths and economic costs."

https://www.amractionfund.com/

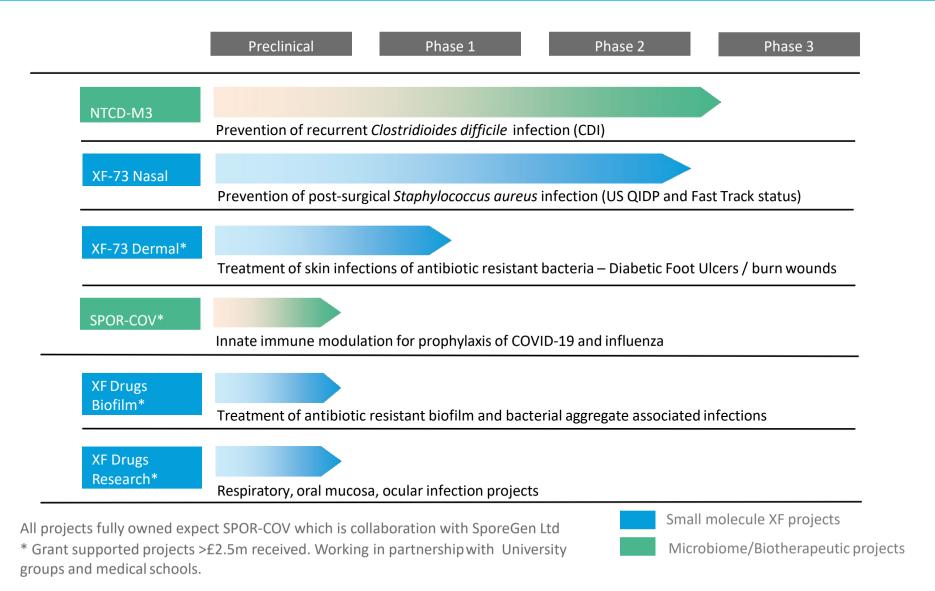


#### At a Glance

- Global interest in infectious disease driven by rise of drug resistant superbugs/AMR and COVID-19
- Two late-stage clinical assets under IND in US with Fast Track status
- Each asset targeting >\$1 billion global markets with clear differentiation to competition
  - XF-73 to prevent post-surgical infections announcing Phase 2b results Q1 2021
    - Recruitment completed December 2020
  - NTCD-M3 to **prevent** C. difficile gut infections 95% prevention of infection recurrence in Phase 2
- Earlier pipeline targeting COVID-19 and additional bacterial infections funded by grants
- Funded to Q4 2022 after £10.4 million raised in November 2020



## Pipeline of Novel Medicines to Prevent Infections





## XF-73 for the Prevention of Post-surgical infections caused by *S. aureus*

#### Patients with wound infections stay in hospital 15 days longer than patients without infections



Clean, healing wound post-surgery



Post-surgical leg infections – superficial and deep wound

"The hospital has the biggest financial incentive to reduce post-operative surgical infections and can absorb the [XF-73] cost in the DRG payment"

Quote from independent hospital (US market research 2018)



## Established Hospital Risk of Post-surgical Infection with Huge Opportunity

1 in 3

people carry
S. aureus

Carriers have **10**X

higher risk of postsurgical infection

**40 million** US surgical patients at risk of post-surgical infection

Annual cost of complications in US due to post surgical infections

<\$10 billion

XF-73 target market a \$1 billion US peak sales opportunity



## XF-73 has Blockbuster Potential for Preventing Serious Infections

XF-73 is uniquely differentiated – highly novel mechanism, clinical profile is compelling, with a strong IP position protecting product franchise into 2030s

QIDP status gives 5 years data exclusivity extension in the US

Hospital-only setting leverages its unique no/low resistance profile

Targeted, topical delivery for acute use and no systemic absorption minimises potential tolerability/side effective profile

Reducing nasal S. aureus carriage reduces post-surgical infection by c.60%

XF-73 has blockbuster potential – favourable pharmaco-economics support the pricing strategy and a strong cost benefit argument, particularly in US

Inclusion in total surgical cost for reimbursement

Positive interim safety review in mid 2020

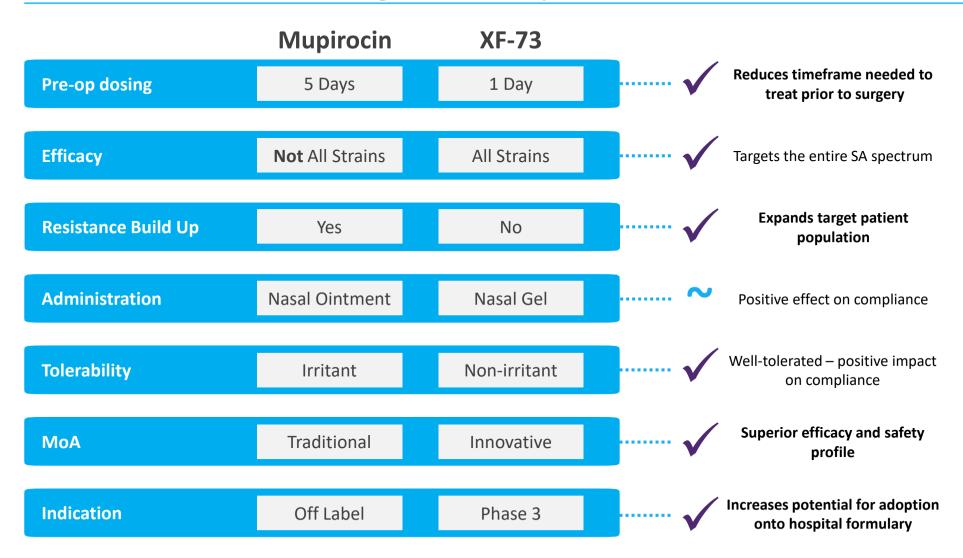
Recruitment completed 2020

Data Q1 2021

Upcoming significant value inflection point from Phase 2b trial



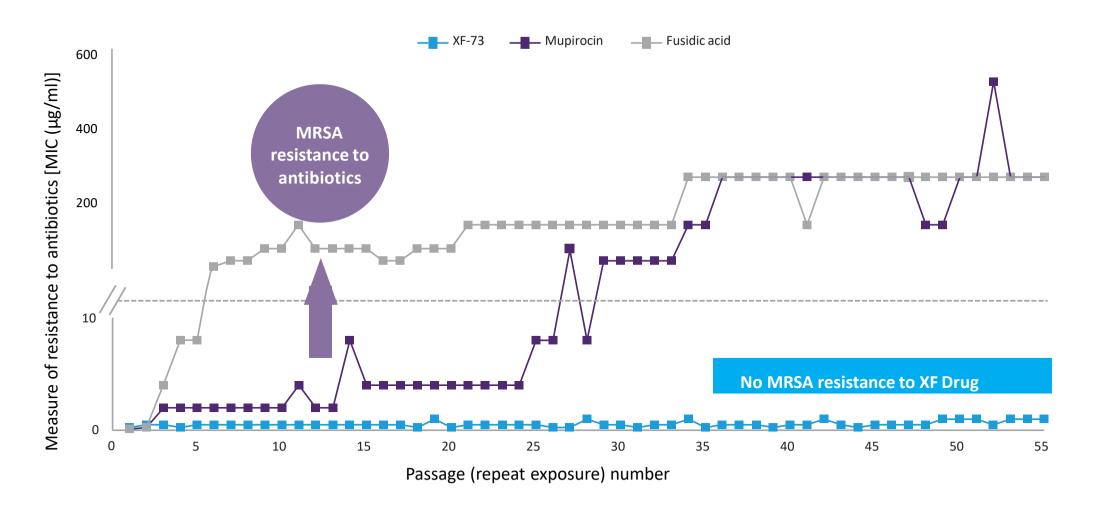
## XF-73 Offers Clear Advantages Over Mupirocin





### XF-73: Unique No / Low Resistance Profile

#### Supported by 2020 Oxford University review in tackling AMR



Farrell, et al.; Investigation of the potential for mutational resistance to XF-73, Retapamulin, Mupirocin, Fusidic acid, Daptomycin and Vancomycin in MRSA isolates during a 55-Passage study. Antimicrobial Agents & Chemotherapy (2011); 55; (3) 1177-1181



## Independent Research Supports XF-73 Market Positioning







Mupirocin Resistance in *Staphylococcus aureus*: A Systematic Review and Meta-Analysis

- Dadashi et al 2019
- Global mupirocin-resistant Staphylococcus aureus prevalence has now increased to 7.6% and that mupirocin- resistant MRSAs have significantly increased to 13.8%
- The authors conclude that monitoring of mupirocinresistance development remains critical.

Guidelines for Perioperative Care in Cardiac Surgery: Enhanced Recovery After Surgery Society Recommendations

- Engelman et al, 2019
- Article instructs US surgeons to, "Perform topical intranasal decolonization prior to surgery", with the highest IA recommendation
- Enhanced Recovery After Surgery recommended that topical therapy be applied universally to all cardiac surgical patients, not only Staphylococcus aureus carriers.

## New Asian guidelines recommend decolonisation

- Ling et al, 2019
- Guidelines warn of issue of antibiotic resistance highlighting the need for new approaches
- Recommend decolonisation of Staphylococcus aureus in surgical patients to prevent surgical site infections
- The APSIC guidelines also support Destiny Pharma's strategic approach in China where it has a regional collaboration with China Medical Systems



## XF-73 Nasal Ongoing Clinical Development Plan

Stage	Status
Phase 2b, 125 patient, microbiological efficacy trial in US/Europe	<ul> <li>Recruitment completed. Results due Q1 2021</li> <li>Interim safety review now completed: No issues</li> </ul>
Easy to use single dose applicator for Phase 3 study (photos below)	Ongoing development with Swiss contractor
Phase 3 study	<ul> <li>Discuss design with FDA in 2021</li> <li>Complete study in 2022/23</li> <li>US / EU / International sites included</li> </ul>
US registration	• Submission in 2024/5
EMA marketing authorisation application	Options to be discussed with regulators
China FDA registration	Strategy led by partner CMS

#### **Un-dispensed**



#### Dispensed



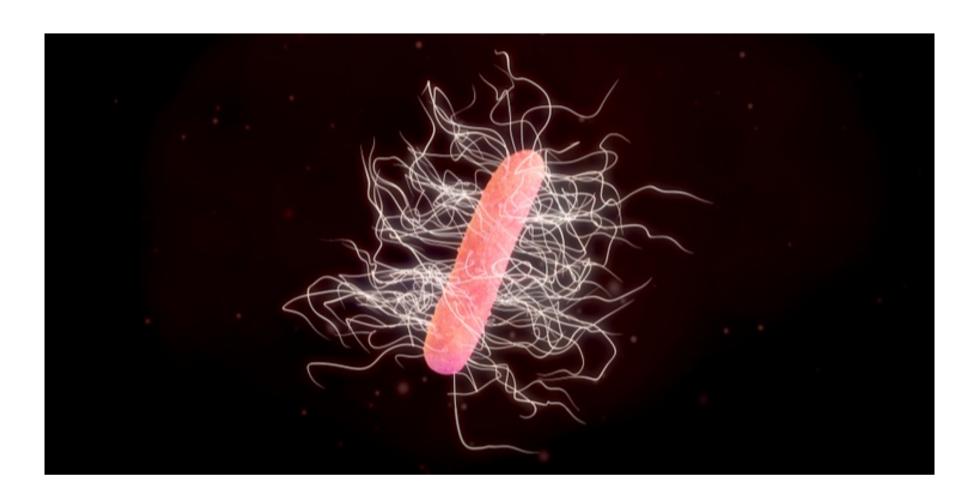
#### XF-73 nasal gel product applicator:

- Easy use for self or nurse administration
- Dispenses single clinical nasal dose
- Convenient & encourages compliance
- Efficient and accurate dosing
- Minimises product wastage



## NTCD-M3 – Phase 2 Completed. Phase 3 planned to start 2022

Biotherapeutic treatment for the prevention of recurrence of *Clostridioides difficile* gut infections





## C. difficile - a Leading Cause of Hospital Acquired Infection in the US

c.29,000

deaths in the US a year

\$6 billion in US

healthcare burden each year

c.500K cases of CDI\*

within the U.S. each year, 25% of these initial cases then recur

CDI target market estimated at \$1.7 billion NTCD-M3 peak sales opportunity \$500 million (\$200 million in US)

<sup>\*</sup> Clostridioides difficile infection (CDI)



## What Causes C. difficile Infection?

- C. difficile bacteria are found in the environment including the human gut and in faeces
- The use of antibiotics disrupts a patient's gut microbiome and enables toxic forms of C.
  difficile to flourish in the microbiome attacking the gut lining and resulting in severe
  diarrhoea, abdominal pain, fever and nausea
  - High hospital mortality rate of 25% in the elderly
- The use of antibiotics (e.g. generic vancomycin) as first line therapy to treat CDI kills the
  initial infection but disrupts the patients' microbiome further and enables toxic forms of C.
  difficile to grow and flourish, causing a recurrent infection typically within 30 days
  - 25% of patients have a first recurrence but this rate rises dramatically with 65% of patients with a third episode with have a subsequent recurrence
- Current standard of care does not control recurrence and this leads to significant morbidity and mortality and significant hospital costs



#### NTCD-M3 Mechanism of Action Harnesses the Human Microbiome

- NTCD-M3 is a naturally occurring bacterial spore
- Oral formulation of spores of a non-toxigenic strain of *C. difficile* (REA type M3)
   originally isolated from an asymptomatic patient by world leading expert, Professor
   Dale Gerding MD
- NTCD-M3 acts as a safe "ground cover" preventing toxic strains of C. difficile proliferating in the colon after antibiotic treatment
- NTCD-M3 lacks the genes that can express *C. difficile* toxins
- Patients colonized with NTCD-M3 were found to be protected from CDI.
- Temporarily colonizes the human gut without causing any symptoms

See Gerding DN et al JAMA 2015;313:1719, May 5,2015



## NTCD-M3 is a Phase 3 Ready Asset Targeting a Large Market

- Destiny Pharma owns global rights to this Phase 3 ready asset for prevention of *Clostridioides* difficile infection ("CDI") recurrence
- Positive Phase 1 and 2 clinical data for prevention of recurrence of C. difficile infection
- Targeting \$1.7bn\* market peak sales estimate \$500m (\$200m US), plus additional indications
- Phase 3 clinical and manufacturing plans discussed with US FDA in July 2020

<sup>\*</sup> Estimated CDI market size in 2026



## Compelling Phase 2 Data Preventing C. difficile Infection Recurrence

- Phase 2: Randomized, double-blind, placebo-controlled, among 173 patients aged >18 years, who were diagnosed as having CDI (first episode or first recurrence)
- Strong, statistically significant data reported. Rapid onset of colonization which provides
  protection during the early post-treatment period making it an ideal complement to a
  vaccine and other antibiotic treatments.
- Rate of recurrence (RR) of CDI after treatment with NTCD-M3 only 5% (placebo 30%) p<0.01
- Compelling efficacy compared with clinical trial data from other approaches including FMT treatments
  - Zinplava is the only approved drug for reducing recurrence of CDI. Expensive infusion of monoclonal antibody and RR of 17%



## NTCD-M3 Phase 3 Design – Discussed With FDA July 2020

- One randomized, double-blind, placebo-controlled Phase 3 trial
  - 800 patients in 2:1 randomization (550 active 250 placebo)
- Primary endpoint: Rate of recurrence of CDI at 6 weeks post-treatment
- Population: Adult patients treated with antibiotics for a first episode or first recurrence of CDI
- Regimen: NTCD-M3 dose of 10<sup>7</sup> spores (or placebo) oral capsule once daily for 7 days starting after last antibiotic course
- Sampling to:
  - Confirm NTCD-M3 colonization
  - Assess changes in faecal microbiome during treatment with NTCD-M3
  - Document recurrence of CDI
- Timeline: Complete manufacturing tech transfer and set up 2021. Start Phase 3 recruitment 2022 and finish 2024

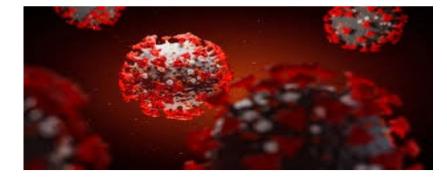


## NTCD-M3 is a Potential Breakthrough in Prevention of CDI Recurrence

- Clinical data appears superior to all current treatments and drugs in development
- Can be used as an adjunct to any standard of care CDI antimicrobial/antibiotic therapy
- Strong safety profile, simple to administer as a solid capsule once daily and rapidly effective
- First line therapy not limited for use by FDA to treat CDI "not responding to standard therapies" as is the case for Faecal Matter Transplants ("FMT") and their derivatives
- Avoids concern about the long-term safety of permanently altering the microbiota of patients who receive FMT since NTCD-M3 has a maximum detection period in the stool of 22 weeks, an indication that the patient's own microbiota has recovered
- Low cost of goods long shelf life lower treatment costs



## SPOR-COV™ Research Collaboration for COVID-19/Influenza Prevention



- SPOR-COV™ is a novel formulation of the bacteria Bacillus
- Easy to use nasal product with potential rapid protective action against COVID-19 and influenza
- SPOR-COV™ in vivo studies support its Innate Immunity Boosting property:
  - Nasal dosing of SPOR-COV™ 100% protection against flu viral infection in mice
  - SPOR-COV™ potentially stimulates various components of immune system pathway
  - To be tested under grant funded preclinical work in influenza and COVI
- In partnership with SporeGen Ltd leading Bacillus experts
- UK COVID-19 government grant of £800,000 awarded September 2020
- Aims to deliver clinical ready COVID-19 prevention product early 2022



## XF Earlier Stage Programmes Grant funding validates XF platform potential



- Grant funded biofilm research projects signed with Aston, Southampton and Sheffield Universities targeting dermal, ocular, oral and respiratory infections
  - Biofilms are a key component in serious infections associated with cystic fibrosis, medical devices, oral conditions, implants and catheters
- Awarded up to £1.6m under UK-China AMR fund
  - Research projects addressing infections (including ocular) and AMR in collaboration with Cardiff University, Tianjin University and Chinese partners
- Seeking to enter further collaborations/grants to extend XF drug platform projects













## Licensing Strategy: Major Partnering Deal for China in place

EU/US/RoW strategy to capitalise on commercial opportunities, including partnering and licensing

- XF-73 nasal and NTCD-M3
  - US priority clinical studies most advanced under IND
  - Additional EU and ROW opportunities

China regional deal with China Medical Systems singed in 2017



- CMS specialty pharma company based in China, focused on marketing, promotion and sales of prescription drugs and other medicinal products to hospitals nation-wide; 2019 sales of >\$800m
- CMS has regional rights to all XF platform drugs and potential for Destiny Pharma to receive manufacturing margin and sales related milestones
- CMS funds China-related research and development



## **Expected News Flow 2021 Onwards**

Year	News
2021	Q1 - Report results from XF-73
	Finalise plans for Phase 3 for XF-73 with FDA
	Progress CMC and Phase 3 planning for NTCD-M3
	Close partnering deals for XF-73/NTCD-M3
2022	Commence Phase 3 for XF-73
	Commence Phase 3 for NTCD-M3
	Start Phase 1 with SPOR-COV/COVID-19
	Start Phase 2 for XF dermal clinical study
2023/24	Complete Phase 3s for XF-73 and NTCD-M3
	Complete SPOR-COV and XF dermal studies
2024/25	File NDA for XF-73 and NTCD-M3

- ➤ Partnering for XF-73 and NTCD-M3 Phase 3 targeted in 2021
- Grant aid financing possible across all portfolio



## Summary: Investment Rationale

- Destiny Pharma's goal is to become a world leading **infection prevention** company
- Currently developing two late-stage clinical assets focused on US market with additional global opportunities
  - NTCD-M3 risk reduced due to quality of Phase 2 data and recent FDA review of Phase 3 plans
  - XF-73 Phase 2b on track to report Q1 2021
- Pipeline diversity with small molecule and biotherapeutic/microbiome programs
- Funded through to Q4 2022

"Prevention is better than cure"





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