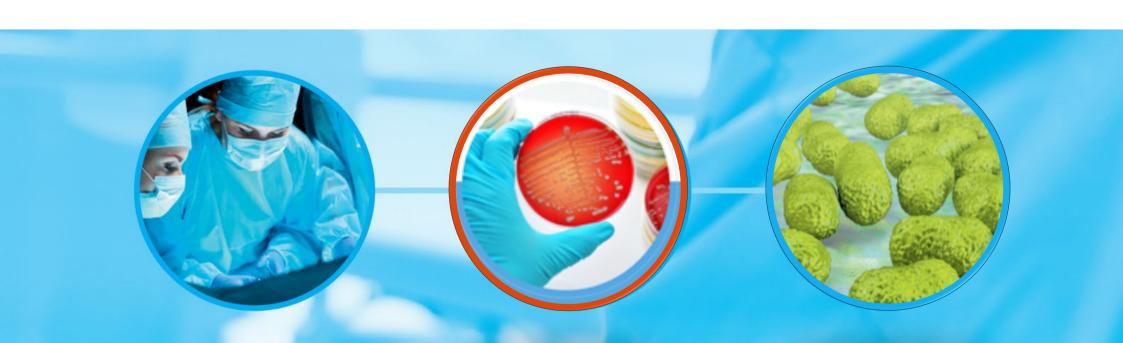


# Developing Novel Medicines that Prevent Serious Infections

March 2023

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#### Destiny Pharma - Focused on infection prevention



Dedicated to development and commercialization of anti-infectives to improve patient outcomes and reduce healthcare burden



Rich pipeline of preventative anti-infectives targeting areas of high unmet need including *C. diff*, staphylococcal infection, COVID-19 and influenza



NTCD-M3 entering Phase 3 clinical trials in 2024 + US partner Sebela Pharma for prevention of *C. diff* infections - estimated peak sales of \$500M.



Late-stage clinical candidate, XF-73 Nasal, targets prevention of post surgical *S. aureus* infections, expected to enter Phase 3 in 2024; projected peak sales estimated at ~\$1 billion



Seasoned leadership team with over 20 years experience in development of antiinfectives

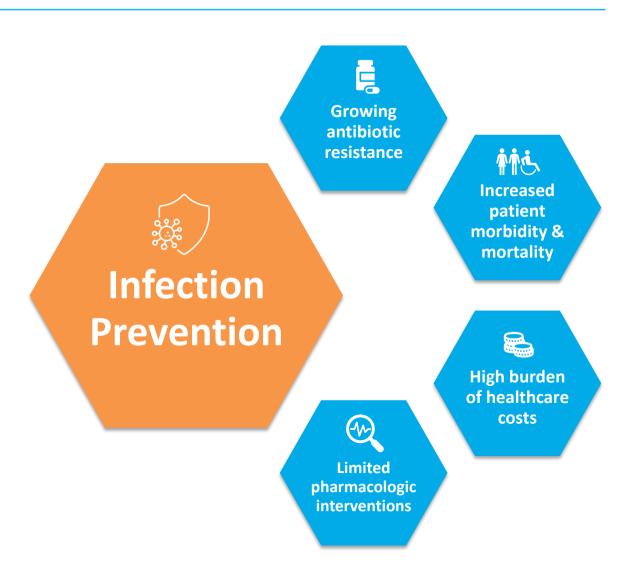


Strong partnering strategy diversifies and de-risks pipeline development with two active partnerships



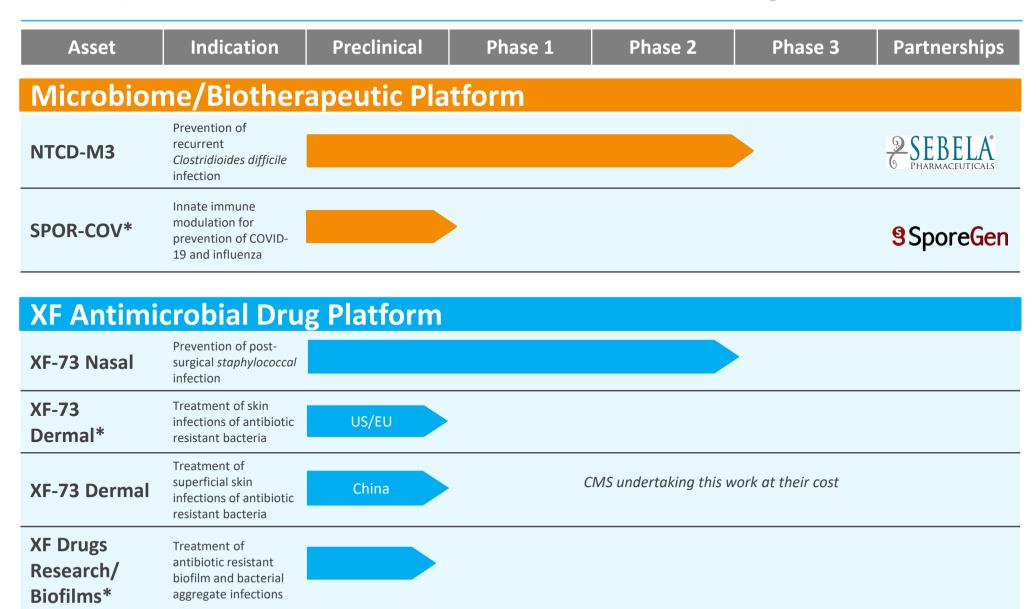
# Focused on Infection Prevention & Antimicrobial Stewardship

- AMR is a public health concern with significant burden on the global economies
  - Expected to reach \$1 trillion annually by 2050
- AMR caused ~1.27 million deaths worldwide in 2019
  - Expected to reach 10 million by 2050
- Destiny is developing viable, breakthrough anti-infectives to address infection prevention





# Rich Pipeline of De-risked Assets - two Products Entering Phase 3 Studies









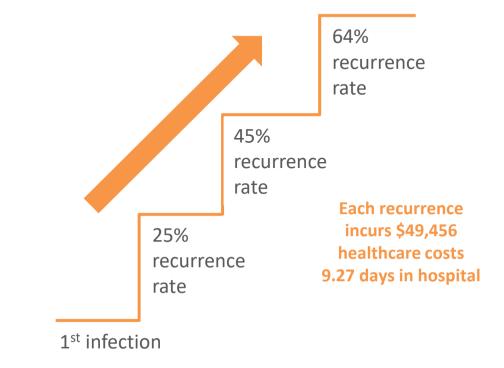
NTCD-M3

Biotherapeutic for prevention of *C. difficile* infections



#### NTCD-M3: Prevention of *C. difficile* Infection Recurrence

- Clostridium difficile infection (CDI) is a bacterial infection of the large intestine
- CDI recurrence risk escalates with each episode and is linked to increased morbidity and mortality
- CDI has profound economic impact on both the healthcare system and patients
  - ~500K cases of CDI in US/yr
  - 29,000 deaths US/yr
  - \$6 billion healthcare burden US/yr
  - Estimated target peak sales per year for NTCD-M3 is >\$500 million



\$38,876 healthcare costs 7.3 days in hospital

	Total costs per patient	Days in hospital
1 episode	\$38,876	7 days
4 episodes	\$187,244	37 days

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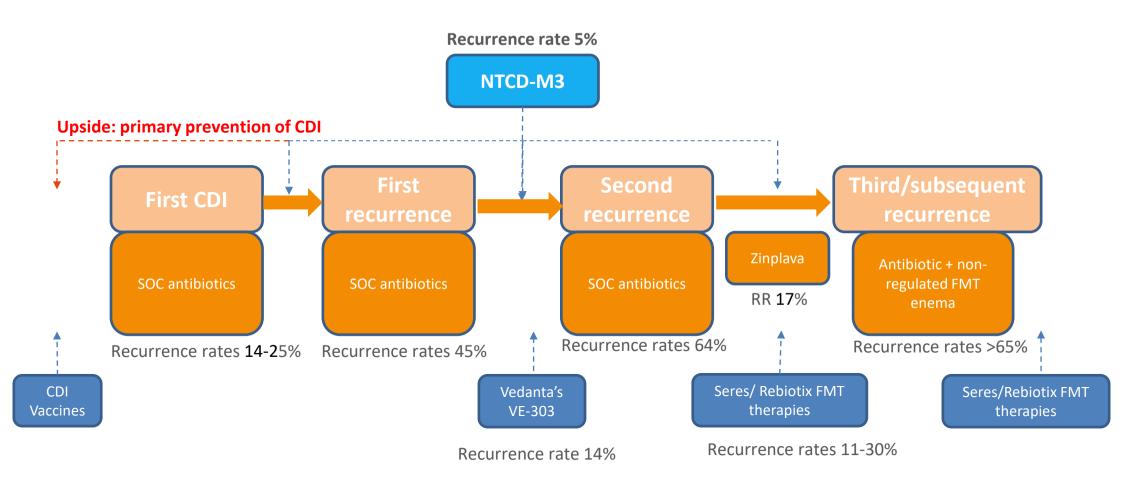


#### NTCD-M3: Harnesses the Microbiome to Prevent *C. diff* Infections

- Naturally occurring non-toxigenic strain of C. difficile bacteria (REA type M3) isolated from an asymptomatic patient in US by Professor Dale Gerding
- Effective in preventing toxic strains of C. difficile proliferating in the colon after antibiotic treatment
  - Can be used after any antibiotic treatment
  - Once daily oral treatment for 7 days
  - Low cost of goods, long shelf life
- Temporarily colonizes human gut without causing any symptoms; restores gut microbiome a few weeks after treatment
- Demonstrated 'game changing' recurrence rate of 5% vs. 30% in placebo in Ph 2 trial
  - Marketed and development stage products have recurrence rates of 11-25%
- Preparing for global Phase 3 study in USA and Europe
  - Expect commencing enrollment towards the end of 2023



#### NTCD-M3: Potential Breakthrough in Prevention of CDI Recurrence



Recent U.S. CDI study supports the use of NTCD-M3 after all major 1<sup>st</sup> line antibiotics

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#### NTCD-M3: Development Plan

#### Study Design

- Planned Phase 3 study design approved by MAA and EMA
  - 700 patients (adults treated with antibiotics for 1<sup>st</sup> episode or 1<sup>st</sup> recurrence)
  - Primary endpoint: Rate of recurrence of CDI at 8 weeks post-treatment
  - Dosing: once daily for 7 days
- Phase 3 trial anticipated to commence in 2024 with expected first approval
   2027
- Partnered with Sebela for US rights and to fund the Phase 3 study through commercialization. DP retains US/ROW rights (ex-China)

#### Manufacturing

- Finalizing the manufacturing and formulation of NTCD-M3 clinical trial material
  - Process development ongoing to produce oral capsule product for Phase 3
  - FDA agreed to simple disintegration test to demonstrate equivalence between Phase 2 and Phase 3 product
  - Expected to have capsules ready for Phase 3 H2 2023



# NTCD-M3- Building a \$500m peak sales opportunity

Clinical data demonstrating 5% recurrence rate after primary episode or first recurrence with a simple oral product will give a broad label 'to reduce recurrence of *C. difficile* infection'

Broad label with a simple, cost-effective oral capsule product will enable uptake in primary episode and first recurrence patients which are not served with alternative preventative products

- Primary episode (453K episodes in US)
- First recurrence (113K episodes in US)

#### Benefits are

- Ability to use NTCD-M3 after any standard of care antibiotic
- Single strain bacteria enables simpler, cost-effective manufacture which translates into competitive price
- Simple administration 1 oral capsule per day for 7 days

'Line extension' if NTCD-M3 is developed for primary prevention of *C. difficile* infection

 Use in elderly patients admitted to hospital or on broad spectrum antibiotics

Could be used to prevent people from getting *C. difficile* infection altogether as it can protect the gut microbiome while the gut is disrupted by antibiotics and enable a return to normal function.

Total US market size= 566,000 episode per year NTCD-M3 share of this with appropriate price = \$300m US peak sales US/ EU= \$500 million peak sales

Total US market size secondary prevention & primary prevention = \$600m US peak sales





XF-73 Nasal

Nasal gel for post-surgical *S. aureus* infection prevention



# XF-73 Nasal: S. aureus Decolonization to Prevent Post-surgical Infection

- Staphylococcus aureus is a bacteria on human skin and in the nose that can cause serious infections in surgical wounds
- Patients at high risk for infection:
  - Have had surgery or stay in healthcare facilities
  - Have medical devices in their body or inject drugs
  - Close contact with infected patient



- MSSA surgical site infection costs over \$130k vs. MRSA costs over \$160k
- 15 days extra hospital stay for patients with wound infections
- Economic burden of post-surgical *S. aureus* infection
  - 1 in 3 people are nasal carriers (~up to 12x higher risk of post-surgical infection)
  - ~40 million US surgical patients at risk
  - Annual cost of complications is ~\$10 billion
  - Peak sales for prevention of post-surgical infections is ~\$1 billion







# XF-73 Nasal: Eradication of *S. aureus* to Prevent Post-Surgical Infections

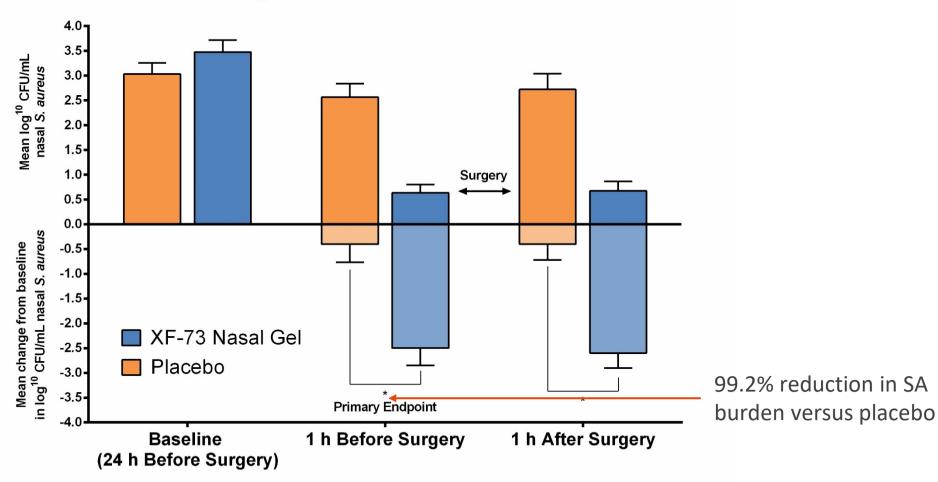
- XF-73 (exeporfinium chloride) is a highly novel mechanism with compelling clinical profile
  - Demonstrated 99.5% eradication of S. aureus in 24 hours in Phase 2b study
- Highly bactericidal with potent intrinsic anti-microbial activity against S. aureus after 1 day dosing
- Antibiotic-sparing because fewer infections mean less antibiotic needed to treat postsurgical infections
- Fast bactericidal mechanism reduces threat of resistance\*
- Safe, targeted, topical gel delivery for nasal decolonization of *S. aureus* 
  - Acute usage and minimal systemic absorption limits side effect potential
- Low cost of goods, long shelf life
- Granted Fast Track designation by FDA and QIDP status with anticipated market exclusivity to late 2030s

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

# XF-73 Nasal: Met the Primary Efficacy Endpoint in Phase 2 Study





Error bars represent the standard error of the mean (SEM)  $\,$ 

\*Difference in mean change from baseline log<sup>10</sup> CFU/mL nasal *S. aureus* (XF-73 - Placebo); p<0.0001



# XF-73 Nasal: Compelling Advantages Over Competitors

	Mupirocin*	XF-73	Chlorhexidine/other nasal antiseptics	
Pre-op dosing	5 Days	1 Day	Single use	Reduces timeframe needed to treat prior to surgery
Efficacy	<b>Not</b> All Strains	All Strains	Toxic to human cells	Targets the entire SA spectrum
Resistance Build Up	Yes	No	Yes	Expands target patient populatio
	.00			
Administration	Nasal Ointment	Nasal Gel	Ointment/swab	Positive effect on compliance
Tolerability	Irritant	Non-irritant	Irritant	Well-tolerated – positive impact on compliance
Indication	Off Label in US	Phase 3	No clinical data/claims	Superior efficacy and safety profi Increases potential for adoption onto hospital formulary

<sup>\*</sup> Mupirocin used off label in the US in the surgical setting to decolonize *S. aureus* in the nose but used on label in EU

#### XF-73 Nasal: Development Plan

#### Study Design

Phase 3 studies in breast surgery (being finalized following Scientific Advice from FDA)
and emergency orthopedic fracture surgery demonstrating a reduction in
post-surgical infections

- Studies anticipated to commence in 2024 with potential approval in 2027
- Seeking partners to co-fund the Phase 3 study through commercialization

#### Manufacturing

 Process development and final formulation for Nasal gel for Phase 3 studies is underway and planned to be completed by end 2023

Low cost of goods and long shelf life



# XF-73 Nasal – Building a \$1 billion peak sales market

Clinical data supporting XF-73 in reducing post-surgical infections in breast surgery, and orthopedic surgeries will give XF-73 a broad surgery label

Broad label 'for nasal decolonization in high-risk surgeries to prevent post-surgical infection' will enable uptake in the following patient groups (7.5 million procedures in US alone):

- High risk surgeries, S. aureus carriers
- High risk surgeries, Universal decolonisation (not double counting the S. aureus carriers
- Expedited surgeries (expedited and emergency fracture surgery)

Uptake in favour of mupirocin or nasal antiseptics because:

- Has a label specifically to reduce post-surgical infection
- Improved compliance due to short treatment course
- Lack of resistance
- Better tolerability

'Line extensions' if a further study covered repeat use, this could open up

- Use in ICU patients (9 million)
- Dialysis/ repeat procedures patients (0.5 million)

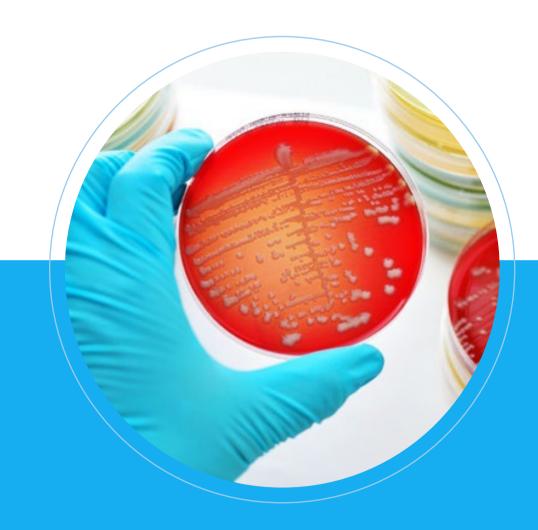
If universal decolonisation of all surgeries (34 million excluding the high-risk surgeries) became a recommendation then this would add further to the market opportunity

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Total US market size= 7.5
million procedures
XF-73 share of this with
appropriate price = \$400m US
peak sales
US/EU/ROW = \$1 billion peak
sales

Total US market size
(excluding high risk
surgeries)= 34m surgeries
plus 9m dialysis patients
XF-73 share of this with
appropriate price = \$1 billion
US peak sales





# **Preclinical Programs**



#### XF-73 Dermal: Treatment of Skin Infections

- Novel dermal formulation for treatment of antibiotic resistant skin infections associated with open wounds / broken skin
- Encouraging preclinical data demonstrating:
  - superficial skin and full thickness wound infection in multiple murine and porcine models of both
  - minimal systemic exposure indicating a superior safety profile
  - Clinically-enabling GLP study, sponsored by NIAID (c.£800k funding) expected to begin in H1 2023
- Well funded program
  - Granted Innovate UK/China-UK AMR award
  - Dermal toxicology studies are sponsored by NIAID
- Additional XF-73 Dermal superficial skin infection programme is ongoing in China led and funded by partner, CMS



# SPOR-COV<sup>TM</sup>: Nasal Spray to Prevent against Influenza and/or COVID-19

- SPOR-COV<sup>™</sup> is a novel formulation of the bacteria Bacillus with potential rapid protective action against COVID-19 and influenza
- Preclinical studies demonstrated boost in innate immunity:
  - Nasal dosing delivered 100% protection against flu viral infection in mice
  - Potentially stimulates various components of the immune system pathway
  - Conducting further preclinical studies in influenza and COVID-19 models
- SPOR-COV is a research collaboration with SporeGen Ltd. (leading Bacillus experts)
- Awarded £0.8 million by UK COVID-19 in 2020 to deliver a product candidate in 2022
- Out-licensing discussions underway



# Building a highly valuable infection prevention portfolio



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