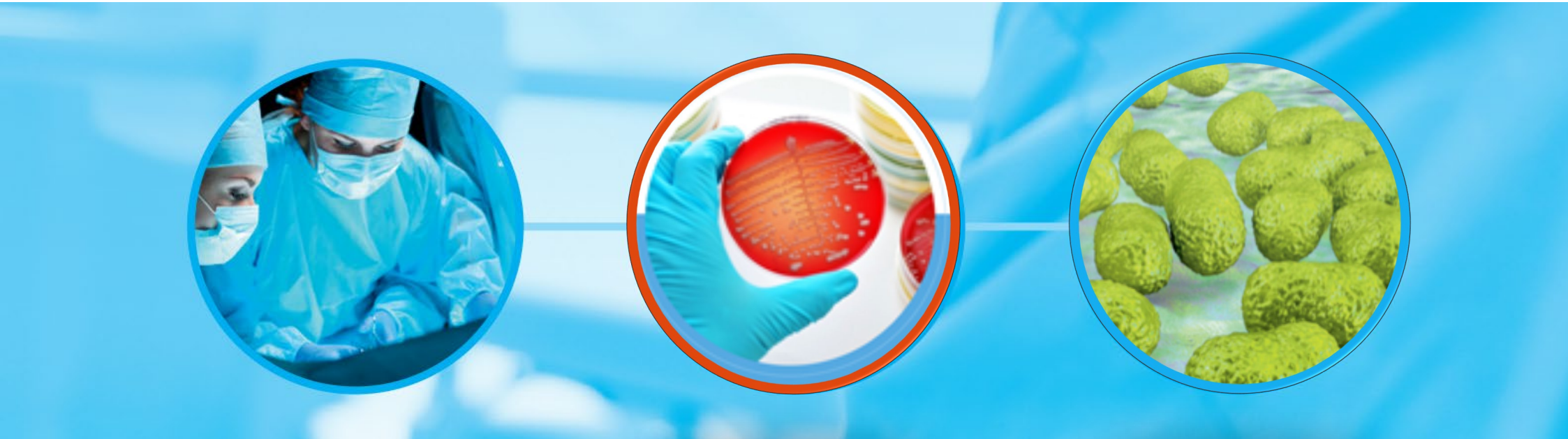
Destiny Pharma

Developing Novel Medicines that Prevent Serious Infections

XF-73 Nasal Gel Reports Positive Phase 2b Study Results

LSE AIM Listing: DEST

March 29th 2021



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Presentation contents

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  - XF-73B07 study design
  - Analysis sets
- **EFFICACY/SAFETY**
  - Primary endpoint
  - Secondary endpoints
  - Conclusions
- **NEXT STEPS**
- **SUMMARY OF XF-73 PRODUCT OPPORTUNITY**
- **Q&A**

This presentation contains information based on preliminary data from the XF-73B07 study.

Though it is not expected that the final data will change the main conclusions of this presentation, there remains a small possibility that final data will change either the values presented or conclusions drawn.

At a glance: **Two clinical assets heading to Phase 3**

Two late-stage clinical assets addressing areas of high unmet need:

- XF-73 to prevent post-surgical infections (Fast Track and QIDP)
- NTCD-M3 to prevent *C. difficile* recurrence

Assets targeting large markets with clear differentiation from competition:

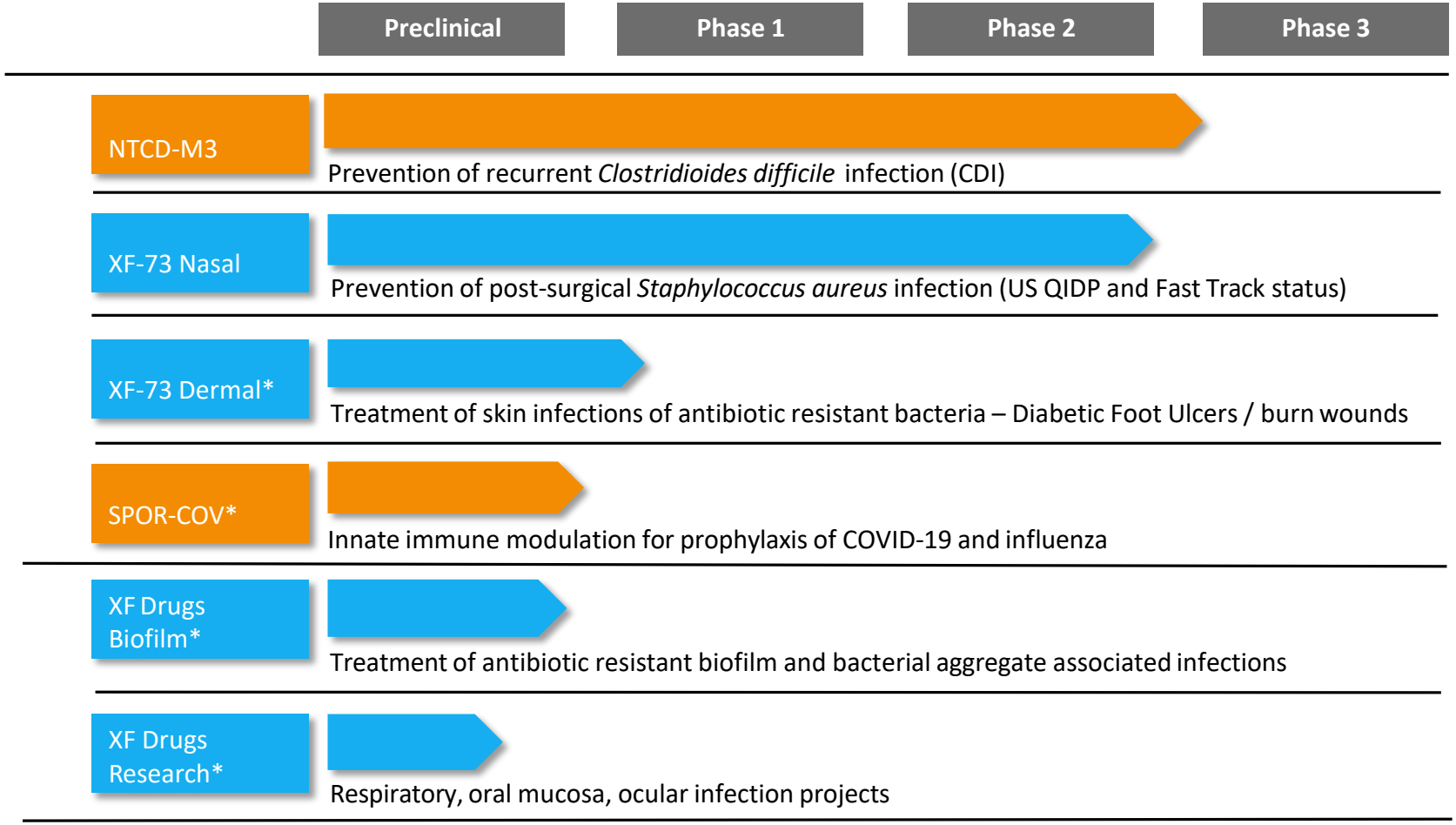
- XF-73 label would be first approved product in indication
- NTCD-M3 shown 95% prevention of CDI recurrence in Phase 2

Earlier Pipeline, well funded by grants, focused on:

- COVID-19 prevention
- XF drug products to treat/prevent MDR bacterial infections

Cash runway to Q4 2022 after fund-raise of £10.4 million in Q4 2020

Pipeline of novel medicines to prevent infections



SPOR-COV is collaboration with SporeGen Ltd
NTCD-M3 in-licensed in 2020
China regional rights to the XF platform licensed to China Medical Systems
* Grant supported projects >£2.5m received. Working in partnership with University groups and medical schools.

Small molecule XF projects
Microbiome/Biotherapeutic projects

XF-73 – nasal *S. aureus* decolonisation to prevent post-surgical Infection

High economic burden of post-surgical infections

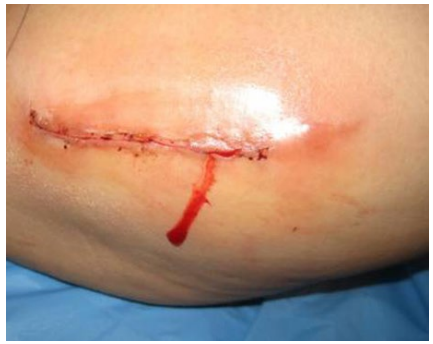
1 in 3 people are S. aureus carriers

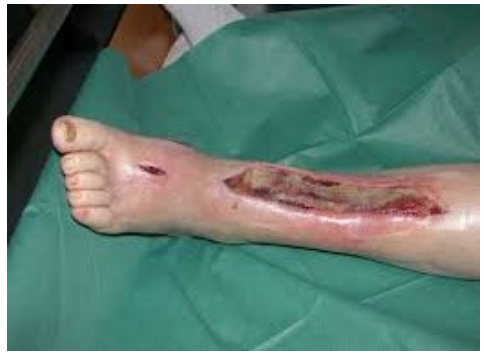
Carriers have 10x higher risk of post-surgical infection

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

Annual cost of complications in US due to post-surgical infections ~$10 billion

Target market for prevention of post-surgical infections $1 billion (US)





Hospital stay increases by **15 days** for patients with wound infections

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

Summary of XF-73 nasal: Targeting a significant market opportunity with no approved products in US

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XF-73 (exeporfinium chloride) is a dicationic porphyrin derivative small molecule with intrinsic antibacterial properties – highly novel mechanism, compelling clinical profile

XF-73 exhibits potent intrinsic anti-microbial activity against S. aureus that is rapidly bactericidal, and due to this, S. aureus/ MRSA appears unable to generate resistance to XF-73

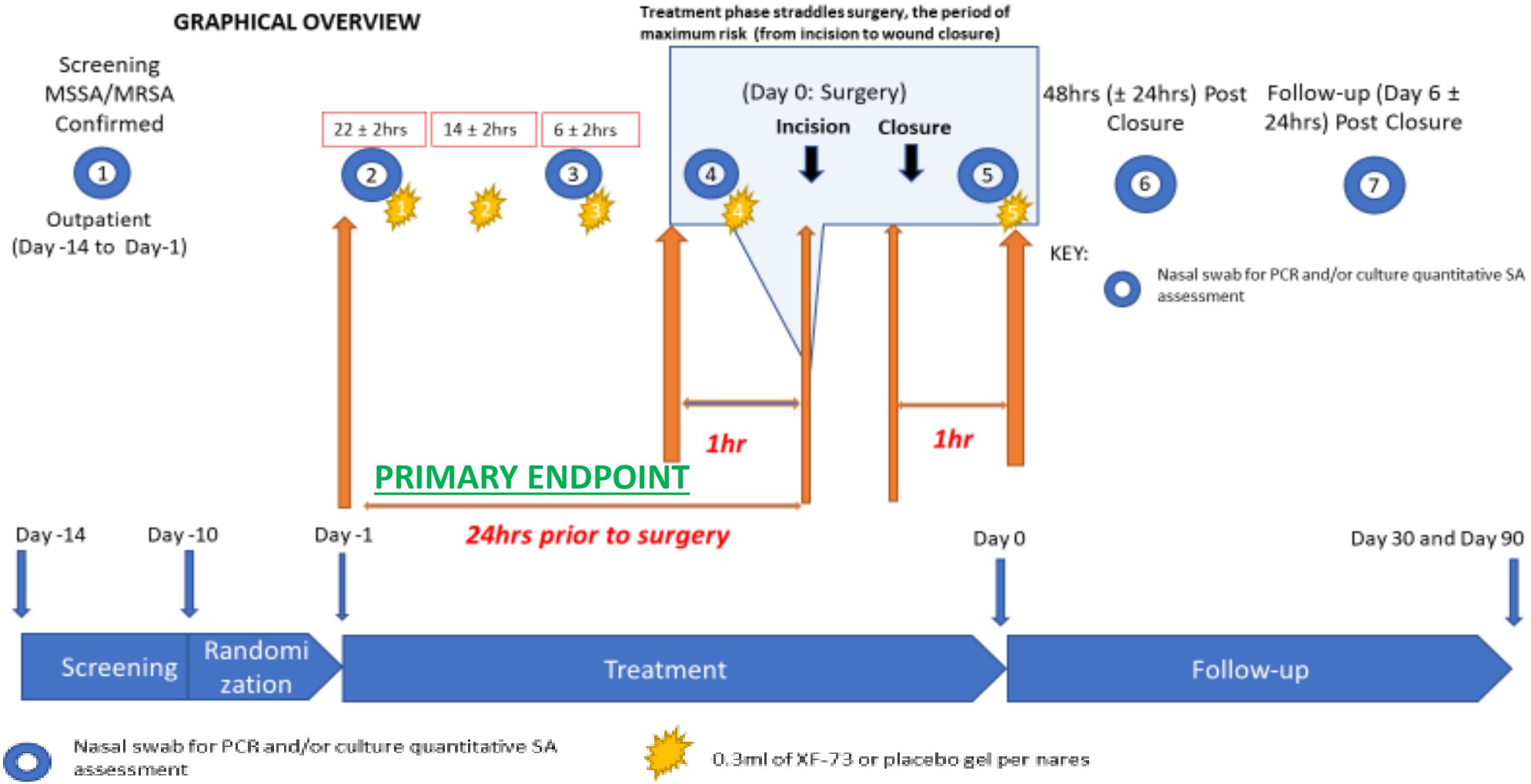
Targeted, topical delivery for nasal decolonization of S. aureus – acute use, minimal systemic absorption limits side effect potential

Phase 2b trial completed – positive results announced 29th March 2021
Phase 3 plan – FDA meeting scheduled to discuss plan Q2 2021
XF-73 has Fast Track status and QIDP

XF-73 and the XF platform – strong patent estate and QIDP status provides anticipated market exclusivity to late 2030s

XF-73 Phase 2b study design overview

XF-73 Phase 2b, multi-centre, randomized, double-blind, parallel group, placebo-controlled study conducted in patients undergoing surgical procedures at risk of post-operative staphylococcal infections.



Efficacy: Primary endpoint met

Analysis of Change in nasal *S. aureus* log10 (CFU/mL) from Baseline to 1 hour Pre-Surgery (Microbiological Intent-to-Treat Analysis Set)

STATISTIC	XF-73 (N=43)	PLACEBO (N=40)
n	43	40
Adjusted Mean Change from Baseline	-2.5	-0.4
SE	0.35	0.37
Difference in Mean (XF-73 Nasal-Placebo)	**- 2.1**	
95% CI	**-2.7; -1.5**	
p-value	<0.0001	

Primary endpoint of study met with high statistical significance.

Efficacy: AUC secondary endpoint also positive

Analysis of Nasal *S. aureus* (CFU/mL) Area Under the Curve (log10-transformed) from Baseline (Microbiological Intent-to-Treat Analysis Set)

VISIT	STATISTIC	XF-73 (N=43)	PLACEBO (N=40)
1 HOUR BEFORE SURGERY	n	43	40
	Adjusted treatment Mean	4.4	5.0
	SE	0.15	0.16
	Difference in Mean (XF-73 Nasal- Placebo)	-0.6	
	95% CI	-0.8, -0.3	
	p-value	<0.0001	

The AUC analysis confirms highly significant activity of XF-73 in reducing *S. aureus* nasal burden versus placebo in the 24 hours prior to surgery.

Efficacy conclusion – very strong Phase 2b data supporting XF-73 TPP

- XF-73 reduced the mean nasal burden of *S. aureus* in patients undergoing open chest open heart surgery by **2.5 log (99.5% reduction)** in the 24 hours immediately before surgery in the micro-ITT population. The effect was maintained during surgery, considered the period when the risk for infections is the highest.

- XF-73 showed 2.1 log (99.2%) greater reduction than placebo in the same patient population and this difference in reduction of nasal burden of *S. aureus* was **statistically significant (p<0.0001)** in both the micro-ITT and per protocol populations.

- A significantly higher reduction of burden of nasal *S. aureus* in XF-73 arm compared to placebo arm in the 24 hours before surgery was also observed when the data was analyzed by AUC. This higher reduction was also seen when analyzing the percentage of patients reaching a specific log value over time.

Safety: XF-73 was safe and well tolerated

- None of the AEs reported during the study were considered related with study drug by the investigators.
- The adverse events profile of XF-73 is similar to placebo and reflect the clinical events expected from the co-morbidities of a population undergoing open chest open heart surgery and the associated surgical intervention.
- There were no clinically significant changes in the nasal examinations of patients carried by ENT specialist pre and post study treatment in the XF-73 or placebo arm.
- Compared to baseline, there were no important decreases in post study treatment smell test scores between patients in XF-73 or placebo arms.

Next steps for XF-73 clinical development

- Destiny Pharma will meet with regulators including FDA to discuss Phase 3 study design
- Target H2 2022 to start Phase 3 study
- Share the Phase 2b positive data with existing and new potential partners
- Publish data in peer reviewed journal
- Positive result adds to background efficacy and safety data for other XF programmes

Guidelines support need for XF-73 nasal product

"Perform topical intranasal decolonization prior to surgery" (Highest level recommendation)

For enhanced recovery after surgery it is recommended that topical therapy be applied universally to all cardiac surgical patients, not only *S. aureus* carriers.

Guidelines for Perioperative Care in Cardiac Surgery: Enhanced Recovery After Surgery Society Recommendations (Engelman et al 2019)

JAMA The Journal of the American Medical Association

New Asian guidelines recommend decolonization of S. aureus in surgical patients to prevent surgical site infections

Guidelines warn of issue of antibiotic resistance highlighting the need for new approaches

APSIC Guidelines for the Prevention of Surgical Site Infections (Ling et al 2019)

APSIC ASIA PACIFIC SOCIETY OF INFECTION CONTROL

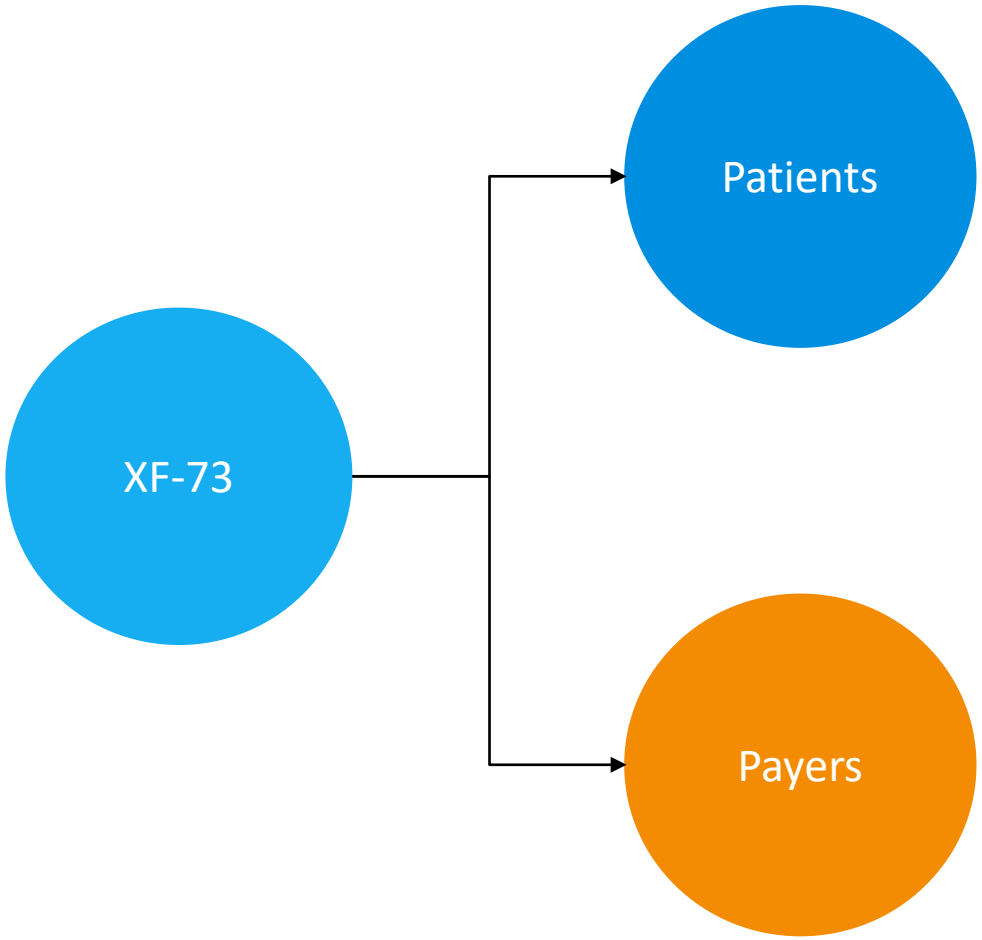
Global mupirocin-resistant S. aureus prevalence has increased to 7.6% and mupirocin-resistant MRSAs significantly increased to 13.8%

Monitoring of mupirocin-resistance development remains critical

Mupirocin resistance in Staphylococcus aureus: A Systematic Review and Meta-analysis (Dadashi et al 2019)

JOURNAL OF GLOBAL ANTIMICROBIAL RESISTANCE

XF-73 nasal offers a potential step-change with benefits to patients and payers



- Ease of use - Dosing over 24 hours instead of 5 days
- Self administration possible – topical gel in nose
- In hospital, cost absorbed under DRG so no/limited co-pay
- No resistance to XF-73 so improved efficacy
- Reduced risk of a *S. aureus* post-surgical infection, therefore improved outcome possible
- No/limited systemic exposure so good safety profile

- Hospital use so cost absorbed under surgical DRG payment
- Improved outcomes if fewer post-surgical infections
- Shorter hospital stay, fewer re-admissions
- Lower secondary healthcare costs
- Universal decolonization (good safety profile) would negate need and cost of PCR tests to identify carriers

XF-73 on track to deliver compelling Target Product Profile

Ideal nasal S. aureus product attributes	XF-73 TPP claims	Evidence	
Easy to apply, safe gel	Specifically designed for nose. Non-irritant, no side effects. Good compliance.	Seven clinical studies including P1 dermal sensitivity/irritancy. Plus latest P2 safety data	✓
Fast acting targeting all *S. aureus* strains and killing for period of risk.	All antibiotic strains of *S.aureus* including MRSA/biofilms. Sub-15 minute kill. Novel MOA.	Extensive microbiology updated on regular basis. Several published papers. Phase 2b shows high efficacy after 3 doses in 24 hours.	✓
Easy to use in hospital environment.	Fits into existing protocols with high patient/medical staff compliance	Phase 2b trial data and feedback. Market research studies.	✓
Stable, low cost product	Stable gel stored at room temperature. Mature production process.	Multi-kg process established. Pricing tested by market research. Low COGS forecast.	✓
Addresses AMR threat	Does not create resistance/superbugs. S. aureus/MRSA not resistant to XF-73	Published “passage” studies supported by peer reviews and testing of clinical samples	✓