BiomX

Revolutionizing the Treatment of Serious Infections Through Phage Therapy

Corporate Presentation / August 2024

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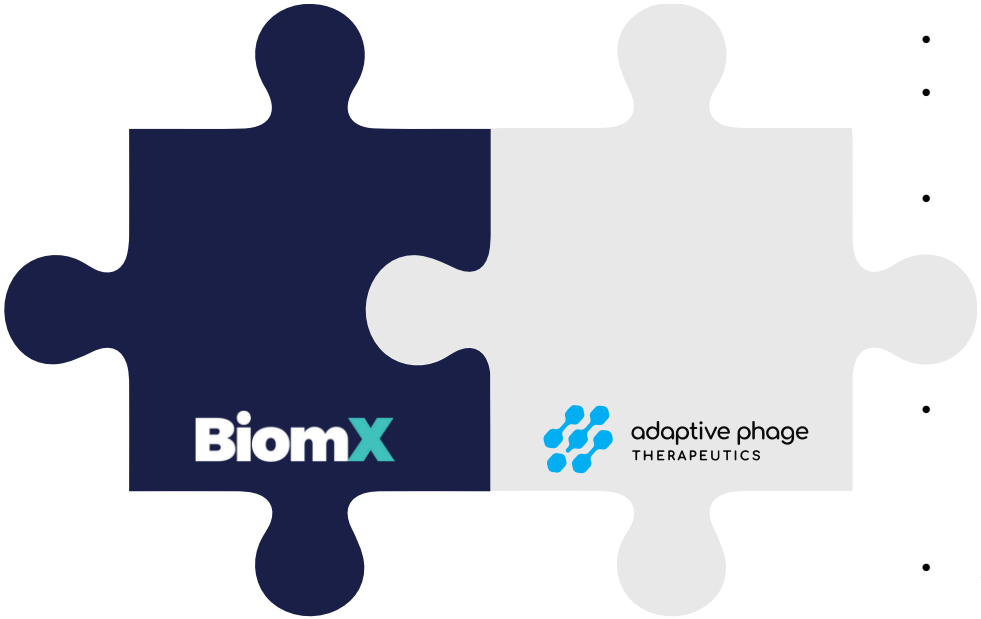
Acquisition of APT creates a leading phage company with an advanced clinical pipeline

On March 18, 2024, BiomX announced closing of the acquisition of Adaptive Phage Therapeutics (APT)



- **Multiple clinical readouts:** Two Phase 2 programs expected to read out in 2025
- **Extensive clinical experience:** ~80 compassionate use cases, multiple clinical studies & INDs
- **Top tier investor base:** Deerfield, AMR Fund, Orbimed and the CF Foundation
- **Attracted significant non-dilutive government funding:** >$40M received from Defense Health Agency, NIH and other
- **Large phage collection/bank:**
  - 185 phage cleared for investigational use by regulatory agencies or institutional review boards, targeting 8 bacterial species
  - 100's of phage targeting multiple bacteria
- **Advanced CMC capabilities:** GMP certified facilities (upstream, downstream fill & finish), capacity of up to 40L, multiple formulation types (topical, inhalation, IV, oral)
- APT selected for Fierce Biotech's **2023 Fierce 15** list for 15 most innovative and truly fierce biotechs

Combined pipeline provides two significant clinical inflection points in indications with high unmet need

Unmet need in cystic fibrosis ('CF')

- In CF patients, *Pseudomonas aeruginosa (PsA)* lung infections are a leading cause of morbidity and mortality
- Prolonged antibiotic treatments lead to significant resistance, creating a large unmet need - estimated 17,000 CF patients in the US and Western Europe with chronic *PsA* infections. Potential commercial opportunity of > $1.5 billion worldwide[1]

BX004 – our lead program

- In a Phase 1b/2a study, 3 out of 21 (14.3%) patients in the BX004 arm converted to sputum culture negative for *PsA* after 10 days of treatment compared to 0 out of 10 (0%) in the placebo arm[2]
- BX004 showed signals of improvement in pulmonary function vs. placebo, in relative FEV1 improvement (5.67% at Day 17, 1 week after EOT) and PRO in patients with reduced lung function[3]
- Phase 2b readout expected 3Q25

Unmet need in Diabetic Foot Osteomyelitis ('DFO')

- DFO patients represent the majority of 160K lower limb amputations in diabetic patients annually in the US[4]
- Treating DFO patients infected with *S. aureus,* the most common pathogen, represents a potential commercial opportunity of > $2 billion worldwide[4]

BX211 (formally an APT program)

- Numerous compassionate cases provide justification for approach
- Targeting S. aureus in a personalized approach
- Phase 2 ongoing, readout expected in 1Q25

Financing and investors

- Publicly traded **(NYSE American: PHGE)**
- $32.7 million cash and cash equivalents as of June 30, 2024
- On March 18, 2024, announced closing of the acquisition of APT and concurrent financing of $50 million led by Deerfield and AMR Action Fund and including Orbimed, CF Foundation and Nantahala Capital, among other investors

1. See slide 35
2. In patients that had quantitative CFU levels at study baseline
3. FEV1 or ppFEV1 – percent predicted forced expiratory volume, EOT – End of treatment, PRO – Patient reported outcome, reduced lung function - Predefined group with Baseline FEV1<70%
4. See slides 30 and 36

Strong leadership and scientific team

Management

Jonathan Solomon - Chief Executive Officer, Director
Former co-Founder and CEO Proclara

Merav Bassan, PhD - Chief Development Officer
20 years drug and clinical development; former at Teva

Assaf Oron - Chief Business Officer
Former EVP business development at Evogene

Marina Wolfson, CPA - Chief Financial Officer
Former Bioview, Ernst & Young

Inbal Benjamini-Elran – Chief HR Officer
Former HR roles at Teva and Herzog Law

Michael Billard – General Manager US
Former roles APT and MedImmune

Board of Directors

Russell Greig, PhD Chairman of the Board
Former president of GSK Pharma International

Susan Blum - Director
Chief Financial Officer of Melinta Therapeutics, LLC.

Jesse Goodman, MD,MPH - Director
Former Chief Scientist of the FDA

Jonathan Leff - Director
Partner on the Biotherapeutics team, Deerfield

Greg Merril - Director
Former founding CEO of Adaptive Phage Therapeutics

Alan Moses, MD - Director
Former Global Chief Medical Officer of Novo Nordisk

Eddie Williams - Director
Former special advisor to the CEO of Ascendis Pharma, Inc.

Scientific Team

Prof. Rotem Sorek
Head of microbial genomics group at Weizmann Institute
Phage genomics and CRISPR research

Prof. Eran Elinav
Principal investigator at Weizmann Institute
Immune system and intestinal microbiome interactions

Carl R. Merril, MD, Capt Usphs (Ret)
NIH Emeritus Scientist
Internationally recognized expert in bacteriophage science

Prof. Eitan Kerem
Former Chairman of Pediatric Pulmonology Unit, Hadassah Medical Center
World leader in CF care and research

Pipeline

Program	Indication	Phage Discovery	Preclinical	Phase I	Phase II	Phase III
BX004[1]	Cystic Fibrosis					Ph2b Topline Expected Q3 2025
BX211	Diabetic Foot Osteomyelitis					Ph2 Topline Expected Q1 2025 and Q1 2026

Potential additional indications:

- Prosthetic Joint Infections (PJI)
- Non-Cystic Fibrosis Bronchiectasis (NCFB)
- Nontuberculous mycobacteria (NTM)

1. Granted Orphan Drug Designation and Fast Track by the FDA

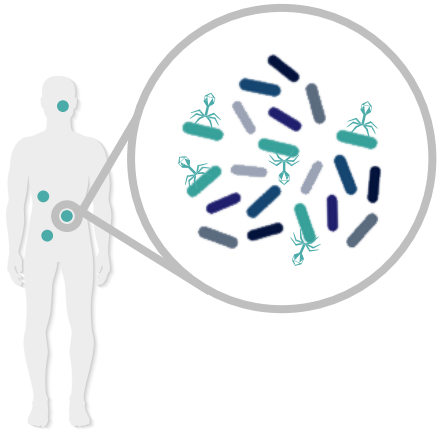
Introduction To

PHAGE

Phage: Nature's precision tool to target bacteria

1. SPECIFIC

Each phage binds only to specific bacterial strains



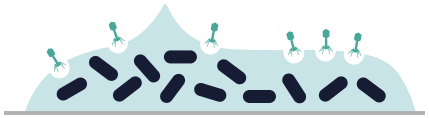
2. KILLING MECHANISM ORTHOGONAL TO ANTIBIOTICS

Lysin proteins burst bacterial cell wall from within

3. BREAKDOWN BIOFILM

Phage can breakdown biofilm

(a polysaccharide mesh secreted by bacteria)



4. AMPLIFY

Phage components multiply and assemble within bacterial cell

5. SAFETY PROFILE

100s of compassionate use cases with no significant side effects to date

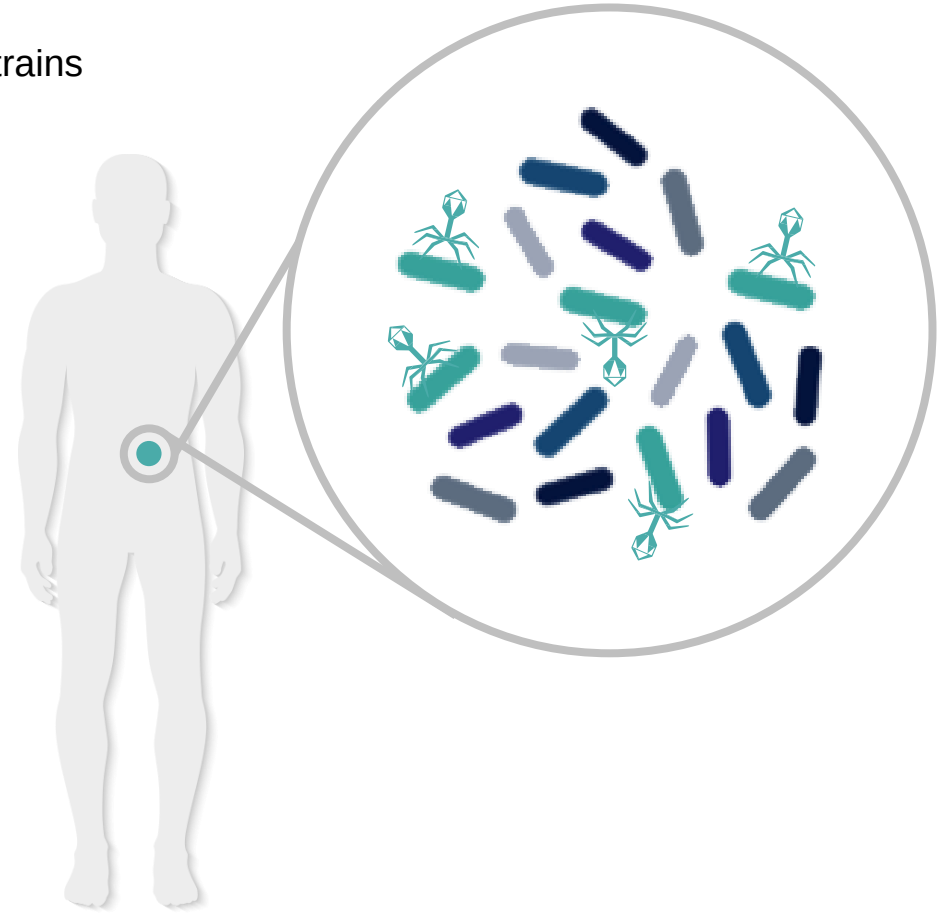
Kortright et al. (2019), Cell Host & Microbe

Key challenges in developing phage therapies

- **Host range -** Narrow specificity to a subset of bacterial strains
- **Resistance -** Bacterial defense systems (e.g. CRISPR)
- **CMC –** Manufacturing (e.g. purity, stability)

And many other considerations

- Phage titer
- Biofilm breakdown
- Absence of toxic genes
- Other



Phagoburn study The Lancet, inf..Dis.2019 Jan;19(1):35-45.doi: 10.1016/S1473-3099(18)30482-1.
Nestle study: E.BioMedicine 2016 Jan 5;4:124-37. doi: 10.1016/j.ebiom.2015.12.023.
Patterson case: Antimicrob Agents Chemother 2017 Sep 22;61(10):e00954-17. doi: 10.1128/AAC.00954-17.

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Complementary approaches taken by BiomX for phage treatment

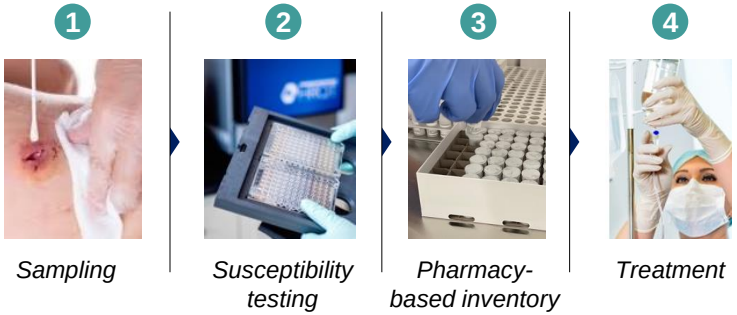
Fixed phage cocktail

Applicable where a 3-5 phage cocktail can:

- Target a broad host range of various bacterial strains across patients
- Address multiple resistance mechanisms that may develop

Personalized phage treatment

- Enables rapid entry into clinical proof of concept, prior to fixed cocktail design
- Could be applied to polymicrobial infections
- Applicable in cases where bacterial diversity hinders fixed cocktail development

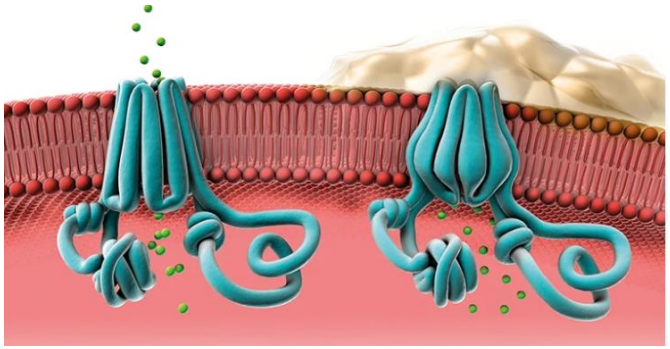


BX004

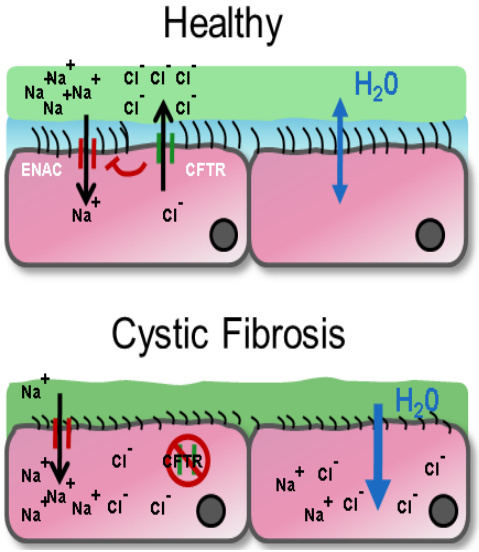
Targeting the Unmet Need in
CYSTIC FIBROSIS

CF is an inherited disease caused by a mutation on the CFTR protein

- The CFTR protein is present on epithelial cells throughout the body. It is a chloride ion channel involved in maintaining water and ion homeostasis on cell surfaces
- The disease causes severe damage to the lungs, digestive system and other organs with > 80% of deaths from respiratory failure
- 105K individuals are estimated to live with CF worldwide, with 33k in the US alone



Normal (left) and abnormal CFTR proteins (right)



Light blue – periciliary layer

Green – mucus layer

In CF lungs, mutations cause thick and sticky mucus that provides environment for bacteria to infect and propagate. In the less hydrated periciliary layer, the cilia are flattened and the ability to clear bacterial infection is reduced.

CF Foundation estimates across 94 countries (https://www.cff.org/intro-cf/about-cystic-fibrosis)
Plackett, Nature 2020
Gibson et al., 2003; Stuart et al., 2010

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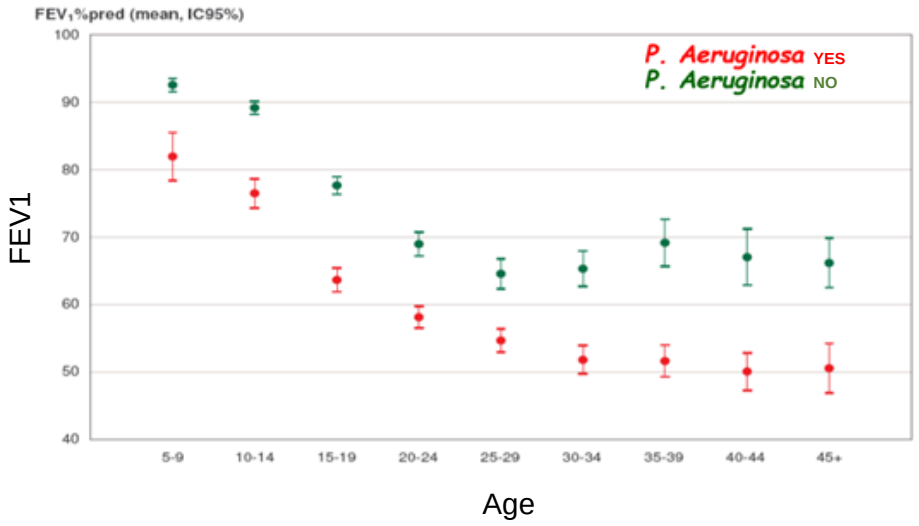
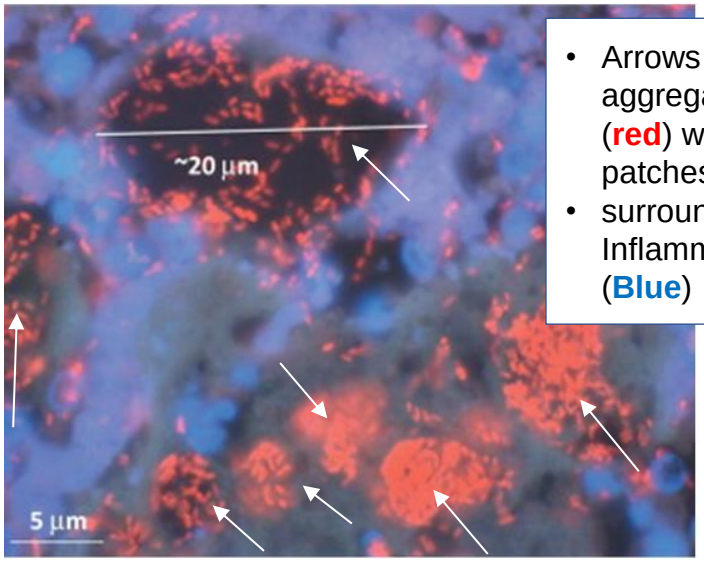
Pseudomonas aeruginosa (*PsA*) bacteria are associated with decreased lung function (FEV1) and damaged lung epithelium

PsA colonization associated with lower FEV1 at all ages[1]



PsA forms biofilm patches in the lungs[2]



- Arrows show aggregates of PsA (**red**) within biofilm patches
- surrounded by Inflammatory cells (**Blue**)

PsA bacteria and biofilm lead to persistent inflammation causing tissue damage and eventually necrosis of lung tissue

1. Kerem et al., ECFS unpublished data, 2013
2. Bjarnsholt at al., Trends in Microbiology 2013

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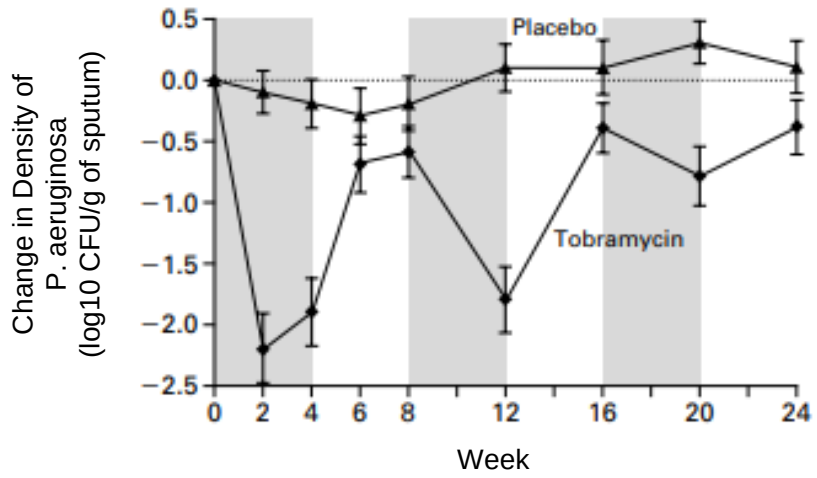
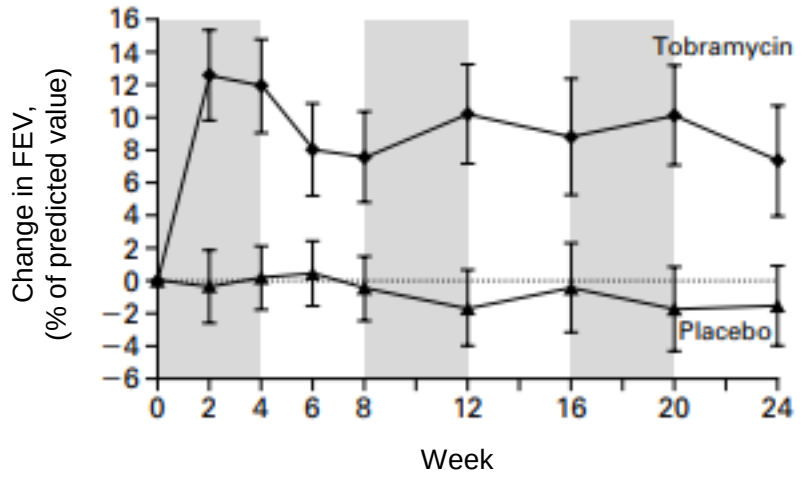
Antibiotics were effective 2 decades ago in treating *PsA* infections

Tobramycin showed (study conducted 1995-96) up to **2.2 log bacterial reduction** and **8-12% FEV1 improvement** (compared to placebo)

Phase 3 Efficacy and Safety Study of Tobramycin Inhaled Solution (1995-96)*



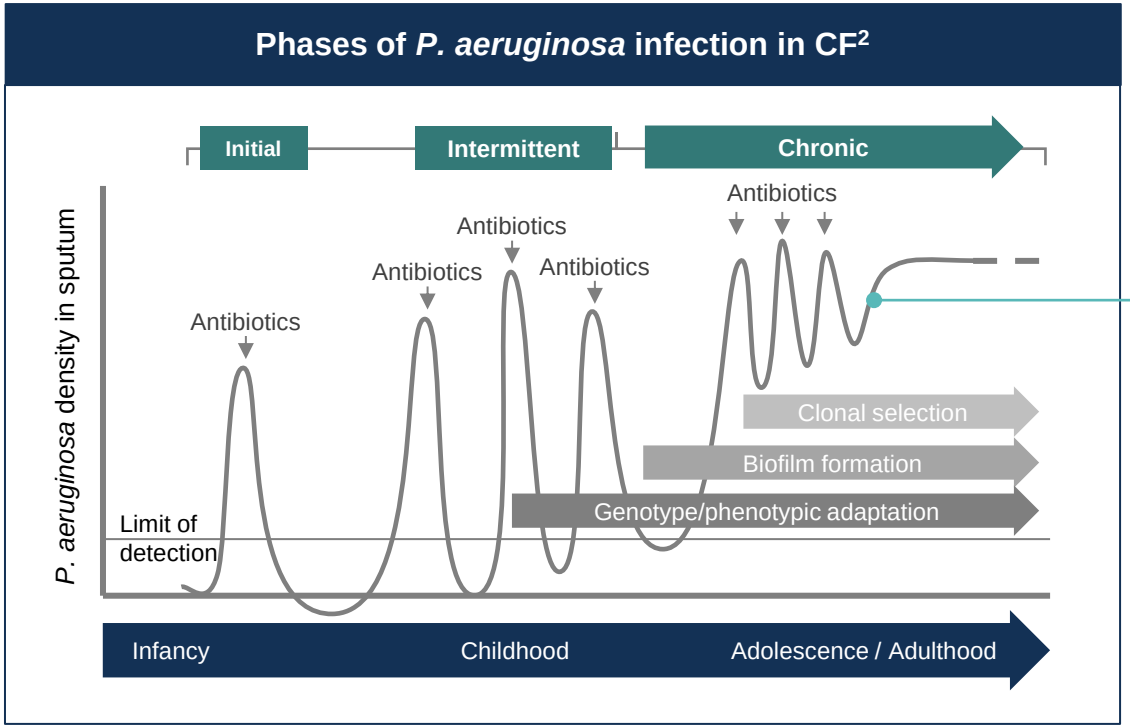


Over the last 2 decades, with the rise of antibiotic resistance, benefits of inhaled antibiotics have diminished

*n=520; 52% >18 yrs; treated in 28 day on/off cycles
B.W. Ramsey et al., (N Engl J Med 1999;340:23-30.

Chronic *PsA* infections have become a persistent problem due to antibiotic resistance driving morbidity and mortality in CF

- Chronic pulmonary infections and the resulting robust but ineffective inflammatory response, culminating in respiratory failure, are the primary causes of death in CF patients
- After prolonged and repeated antibiotic courses, increased resistance to antibiotics has lowered efficacy, creating a large unmet need for CF patients suffering from chronic *PsA* - Estimated at **17,000 patients in the US and Western Europe**[1]



Lack of antibiotic efficacy driven by:

1. *PsA* strains with multidrug resistance (MDR)

2. Formation of biofilm => making infection harder to treat

1. CFF Annual Data Report 2019, ECFS patient registry report, 2020
2. Nicole M. Bouvier et al., 2016

BX004 – BiomX's proprietary phage cocktail targeting *PsA* has the potential to treat CF patients with chronic *PsA* lung infections

BX004

- **Product** – Proprietary phage cocktail targeting *PsA*
- **Patient population** – CF patients with chronic *PsA* lung infections
- **Delivery** – Nebulized
- **Key features** – Potentially effective on antibiotic resistant strains, enables breakdown of biofilm
- **Potential impact:**
  - Suppression/eradication of *PsA* (CFU in sputum)
  - Improved lung function (FEV1)
  - Fewer exacerbations, hospitalizations
  - Increased efficacy of antibiotic treatment
  - Reduce oral, inhaled and IV antibiotic treatments

Numerous compassionate treatments of CF patients with phage provide strong rationale for the development of BX004

11 CF patients treated for *P. aeruginosa* [1-4]

- Indication - *P. aeruginosa* AMR lung infections
- Location – 8 Yale University, 2 Georgia, 1 San-Diego
- Administration – 10 nebulized, 1 IV phage

Yale cases:

- eIND path for 8 CF patients
- Nebulized phage
- 7-10 days, single or multiple rounds
- **Post phage therapy *P. aeruginosa* CFU titers decreased significantly (2.2 ± 0.76 log reduction)**
- **Outcome - FEV1% increased in a range of 0 to 8.9%**

14 CF patients treated for Mycobacterium (20 patient total) [5]

- Indication - Non-tuberculous Mycobacterium infections. Lung infections in all CF patients
- Location – San Diego (UCSD)
- Administration – 20 IV, certain patients also received nebulized/ topical/ other routes

UCSD cases:

- eIND path for all patients
- IV phage (+ additional nebulized phage for certain patients)
- Twice daily for ~6 months (though a favorable outcome required improvement within 8 weeks)
- **Outcome - Favorable clinical or microbiological responses in 11/20 patients (for 5 patients infection resolved)**

Results demonstrate the potential to decrease bacterial burden and improve clinical outcome

1. Kutateladze et al., 2008
2. Kvachadze et al., 2011
3. Law et al., 2019
4. Stanley et al., 2020
5. Dedrick et al. 2022

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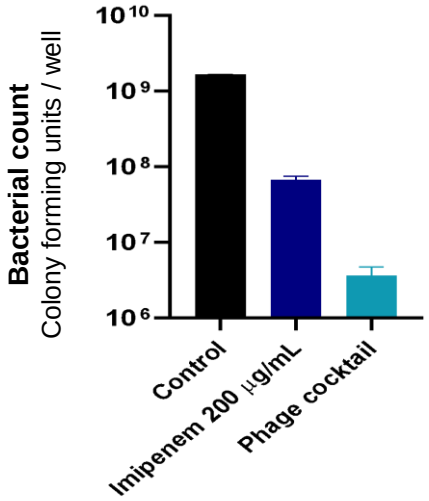
BX004 has demonstrated *in vitro* penetration of biofilm and activity on antibiotic resistant *PsA* strains

BX004 penetrates biofilm *in vitro*

**p-value <0.001



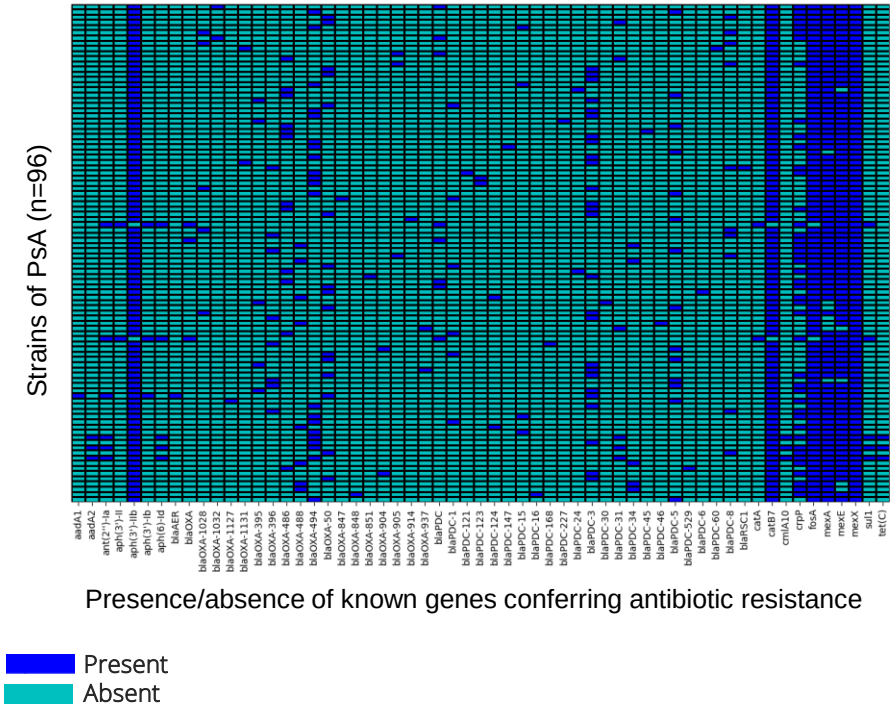
Control

BX004

Biofilm was grown from *PsA* for 24 hours and then treated with BX004 for 6 hours (control-untreated wells). Treatment with antibiotics not shown
Crystal violet – Used for biomass staining of biofilm. Staining substantially reduced following treatment with BX004

BX004 active *in vitro* on antibiotic resistant *PsA* strains

BX004 was active in killing all 96 strains described below displaying multiple antibiotic resistant genes



BiomX internal results

Phase 1b/2a study Part 1 – Study design

Part 1 (n=9)

Objectives

- Safety, PK and microbiologic/clinical activity

Endpoints

- Safety and tolerability (Primary endpoint)
- Decrease in *PsA* burden
- Sputum pharmacokinetics
- FEV1 (forced expiratory volume)
- CFQ-R (CF Questionnaire-Revised) and CRISS

Study Population

- CF patients with chronic *PsA* infection
- Physician choice of inhaled antibiotic regimen (continuous or alternating or cycling); on tobramycin, aztreonam or colistin during study drug
- No restriction on CFTR modulators

9 Subjects

- 7 received nebulized BX004 phage therapy
- 2 received nebulized placebo
- 7 days duration (3 ascending, 4 multiple dosing)

Key Design Features

- Single ascending dose followed by multiple doses

Completed

Study design informed by input from the CF Foundation

Phase 1b/2a Part 1 results - Highlights

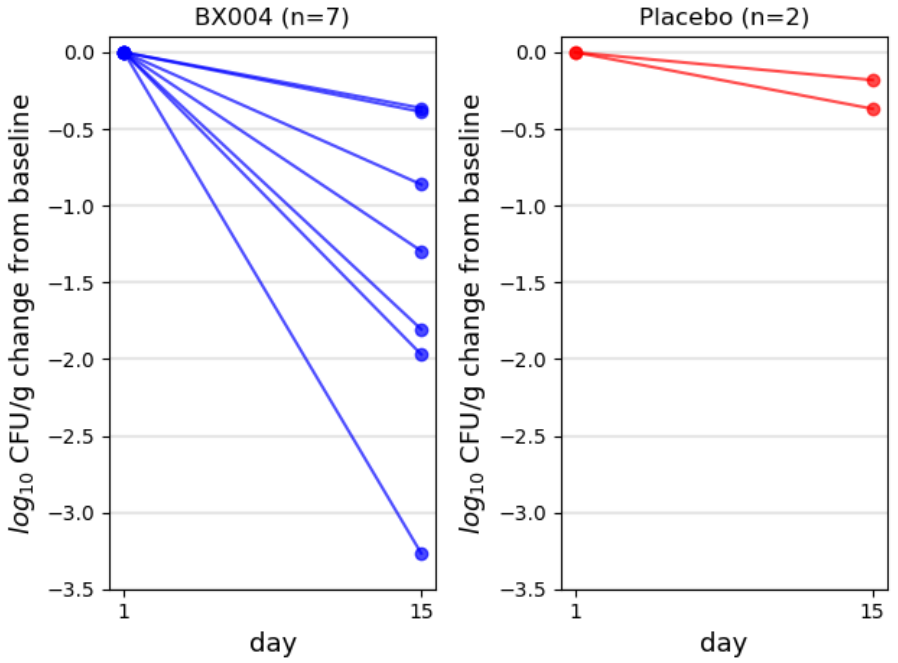
- Study drug was safe and well-tolerated

- Mean *P. aeruginosa* CFU[1] reduction at Day 15 (compared to Baseline): -**1.42 log_{10} CFU/g** (BX004) **compared to -0.28 log_{10} CFU/g** (placebo) on top of standard of care inhaled antibiotics

- Phage were detected in all patients treated with BX004 during dosing period, including, in several patients, up to Day 15 (one week after end of treatment)

- During the study period, no evidence of treatment-related phage resistance was observed in patients treated with BX004 compared to placebo

- As expected, likely due to short course of therapy, no effect on % predicted FEV1[2]



	BX004	Placebo
n	7	2
Mean (SD)	**-1.42 (1.03)**	**-0.28 (0.13)**
Max, Min	-3.27, -0.37	-0.37, -0.18

1. CFU– Colony forming units
2. FEV1 (or ppFEV1) – percent predicted forced expiratory volume in 1 second

Phase 1b/2a study Part 2 – Study design

Phase 1b/2a – Part 2 (n=34)

Objectives

- Safety and efficacy

Endpoints

- Primary endpoint - Safety and tolerability
- Decrease in *PsA* burden
- Sputum pharmacokinetics
- FEV1 (forced expiratory volume)
- CFQ-R (CF Questionnaire-Revised) and CRISS

Study Population

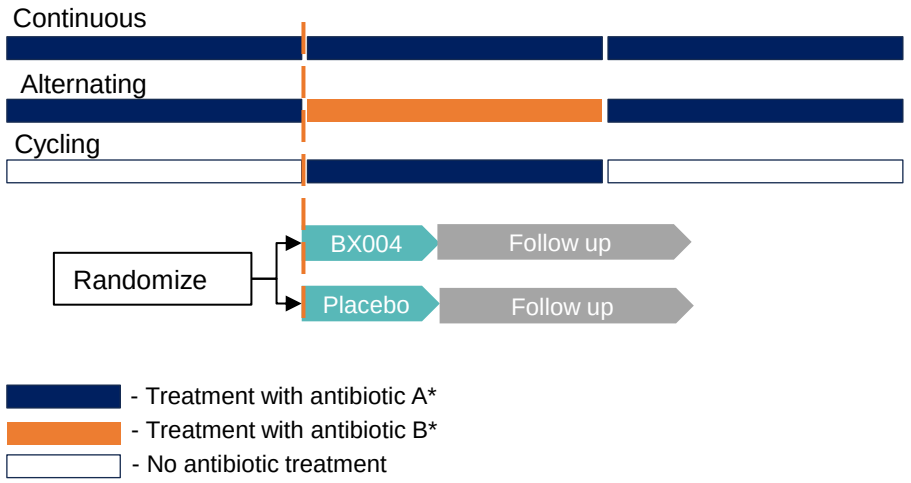
- CF patients with chronic *PsA* infection
- Physician choice of inhaled antibiotic regimen (continuous or alternating or cycling) on tobramycin, aztreonam or colistin
- No restriction on CFTR modulators

34 subjects

- 23 received nebulized BX004 phage therapy
- 11 received nebulized placebo
- 10 days duration of treatment

Ongoing safety follow-up

Treatment aligned with antibiotic standard of care



*Tobramycin or Aztreonam or Colistin

Study design informed by input from the CF Foundation

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Phase 1b/2a study Part 2 – Highlights

- Study drug was well-tolerated, no related SAE[1]s or related APE[1]s to study drug were observed
- In the BX004 arm, 3 out of 21 (14.3%) patients converted to sputum culture negative for *P. aeruginosa* after 10 days of treatment compared to 0 out of 10 (0%) in the placebo arm[3]
- BX004 showed signals of improvement in pulmonary function vs. placebo : Relative FEV1[2] improvement (5.67%) and CF Questionnaire-Revised respiratory[2] (8.87 points) at Day 17 (1 week after EOT[2]) in subgroup of patients with reduced lung function[4]
- In full population, BX004 vs. placebo *P. aeruginosa* levels were more variable. In a prespecified subgroup of patients on SOC[2] inhaled antibiotics on continuous regimen, BX004 vs. placebo showed bacterial reduction of 2.8 $\log_{10}$ CFU/g at EOT[2], exceeding Part 1 results
- Alternating/cycling background antibiotic regimen likely associated with fluctuations in *P. aeruginosa* levels potentially confounding the ability to observe a *P. aeruginosa* reduction in this subgroup
- During the study period, based on current available data, no evidence of treatment-related phage resistance was observed in patients treated with BX004 compared to placebo
- Plans to advance the BX004 program to a larger, Phase 2b trial, subject to regulatory feedback and availability of sufficient funding

We believe this better-than-expected clinical effect in a short treatment duration de-risks planned P2b study

1. SAE – Serious Adverse Event, APE – Acute Pulmonary Exacerbation
2. FEV1 (or ppFEV1) – percent predicted forced expiratory volume in 1 second, CF Questionnaire-Revised Respiratory – a PRO (Patient reported outcome) for respiratory parameters in CF aptients, EOT – End of treatment, SOC – standard of care
3. In patients that had quantitative CFU levels at study baseline
4. Predefined group with Baseline FEV1<70%

BX004 showed greater conversion (bacterial culture turned negative) in treatment over placebo

- In the BX004 arm 3 out of 21 (14.3%) patients converted to sputum culture negative for *P. aeruginosa* after 10 days of treatment (2 already after 4 days)[2]

Patient	Duration of PsA infection (years)	Baseline *PsA*[1] in sputum (CFU/g)
1	**18**	**$2.40x10^3$**
2	**13**	**$5.60x10^7$**
3*	**35**	**$1.09x10^7$**

*Subject had negative sputum culture for *P. aeruginosa* at D4, D10, D28, D38, and at most recent standard of care clinic visit (D63)

- In the placebo arm 0 out of 10 (0%)[2]

- In addition, in Part 1 of the study, one subject in the BX004 arm (1/7: 14.3%) who was persistently positive for *P. aeruginosa* for at least 13 years had a 3.3 log reduction at D15 later converted to sputum negative

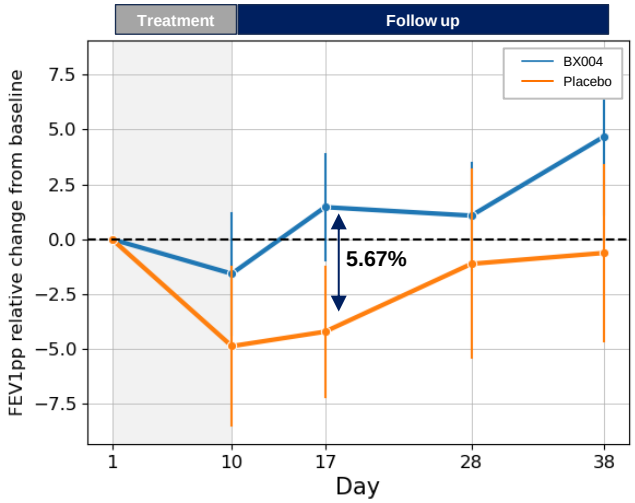
1. PsA – Pseudomonas aeruginosa, CFU/g – Colony forming units per gram
2. In patients that had quantitative CFU levels at study baseline

BX004 shows meaningful clinical improvement after 10 days of treatment in multiple clinical readouts

Clinical improvements were observed on both objective & patient reported outcomes

- Clinical readouts in patients with reduced baseline lung function (predefined group, ppFEV1 of <70%)

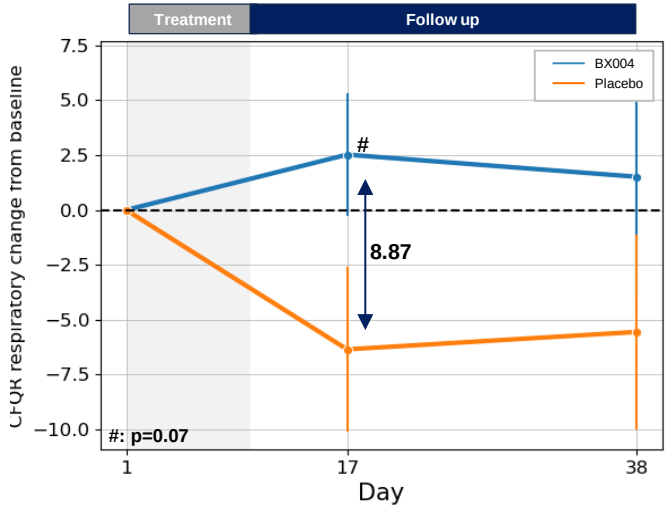
ppFEV1



ppFEV1 change from Baseline: Mean(SE)

	BX004 (N=12)[2]	Placebo (N=8)[2]	Difference
D10	**-1.57 (2.64)**	**-4.86 (3.39)**	**3.29**
D17	**1.46 (2.33)**	**-4.21 (2.78)**	**5.67**
D28	**1.07 (2.32)**	**-1.12 (3.96)**	**2.19**
D38	**4.68 (3.28)**	**-0.62 (3.65)**	**5.3**

CFQR[1] (respiratory)



CFQR respiratory change from Baseline: Mean(SE)

	BX004 (N=12)[3]	Placebo (N=8)[3]	Difference
D17	**2.52 (2.61)**	**-6.35 (3.45)**	**8.87**
D38	**1.51 (5.1)**	**-5.56 (4.05)**	**7.07**

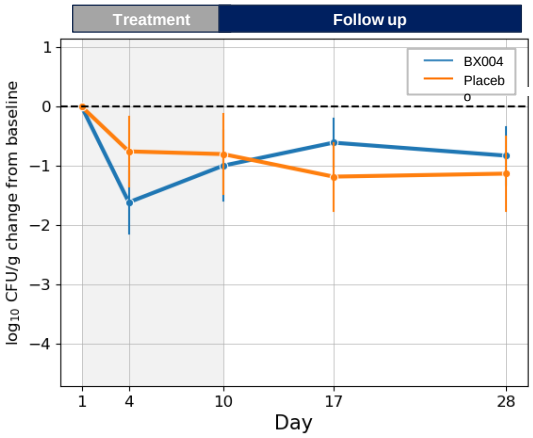
1. PRO (Patient reported outcome) - CF Questionnaire-Revised for respiratory parameter
2. 2. BX004: D38 N=7, Placebo: D28 N=7, D38 N=6
3. 3. BX004: D17 and D38 N=11, Placebo: D17 and D38 N=7

In a prespecified subgroup on continuous antibiotic standard of care, BX004 vs. placebo showed bacterial reduction of 2.8 log at end of treatment

- Reduction of *P. aeruginosa* assessed on all patients and those on continuous standard of care inhaled antibiotic regimen

PsA Bacterial reduction (CFU/g)[1]

All study population



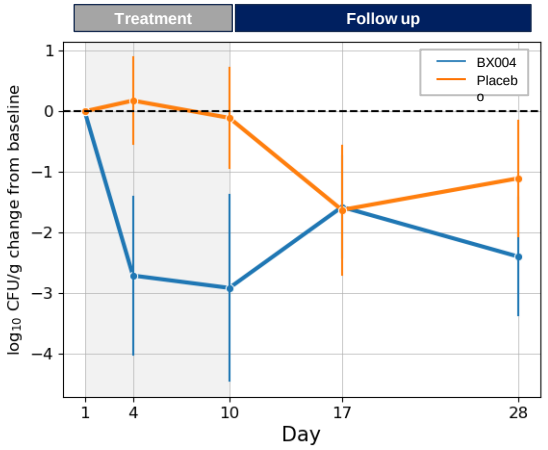
In full population, BX004 vs. placebo bacterial levels were variable

CFU/g log change from Baseline: Mean (SE)

	BX004 (N=21) [2]	Placebo (N=10) [2]	Difference
D4	**-1.61 (0.51)**	**-0.75 (0.55)**	**-0.86**
D10	**-1.0 (0.57)**	**-0.8 (0.64)**	**-0.2**
D17	**-0.61 (0.4)**	**-1.18 (0.54)**	**0.57**
D28	**-0.83 (0.47)**	**-1.13 (0.59)**	**0.3**

PsA Bacterial reduction (CFU/g)[1]

Continuous antibiotic SOC[1]



Prespecified subgroup on continuous antibiotic SOC showed bacterial reductions which exceeded Part 1 results

CFU/g log change from Baseline: Mean (SE)

	BX004 (N=7)[3]	Placebo (N=5)	Difference
D4	**-2.71 (1.21)**	**0.18 (0.64)**	**-2.89**
D10	**-2.91 (1.4)**	**-0.11 (0.73)**	**-2.8**
D17	**-1.58 (0.77)**	**-1.63 (0.95)**	**0.05**
D28	**-2.4 (0.9)**	**-1.1 (0.85)**	**-1.3**

1. PsA – Pseudomonas aeruginosa, CFU/g – Colony forming units per gram , SOC – Standard of care
2. BX004: D10 N=20, Placebo: D4 and D10 N=9
3. BX004: D10 N=6

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BX004 Phase 2b study targeting *PsA*

Phase 2b – Preliminary design*

Objectives

- Improvement in reduction of PsA burden observed by microbiology and in clinical outcome

Endpoints

- Decrease in *PsA* burden (including culture conversion/eradication)
- FEV1 (forced expiratory volume)
- CFQ-R (CF Questionnaire-Revised), CRISS (Chronic Respiratory Infection Symptom Score)
- Safety and tolerability

Study Population

- CF patients with chronic *PsA* infection
- Physician choice of inhaled antibiotic regimen
- No restriction on CFTR modulators

Approximately 60 patients

- 2:1 randomization, Treatment : Control
- Treatment duration: 2 months

Key Design Features

- Multi-centered, double blind, placebo control

Topline results expected in Q3 2025

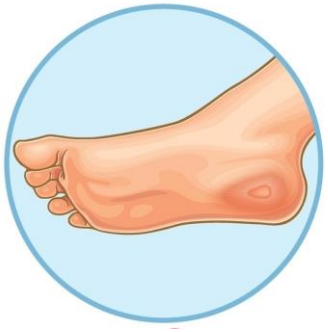
*Subject to discussions with FDA, additional analysis of Phase 1b/2a Part 2 data and further consultation with the CF Foundation

BX211

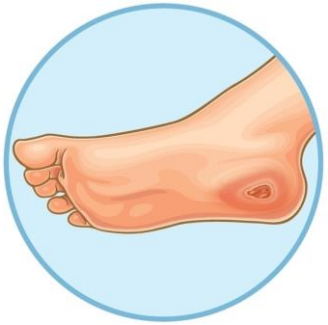
Targeting the Unmet Need in
Diabetic Foot Osteomyelitis (DFO)

High unmet need in DFO

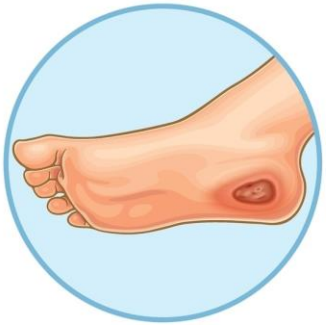
- DFO is a bacterial infection of the bone in patients with diabetes that is caused by bacteria spreading from adjacent infected soft tissue



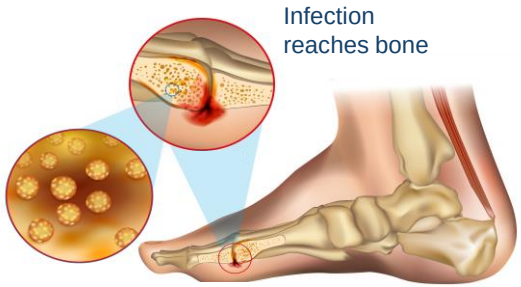
1. Superficial ulcer



2. Ulcer deepens extending through subcutis, and becomes infected



3. DFO – Ulcer and infection further penetrate and reach bone, displaying destruction of periosteum



Staphylococcus aureus is the most common bacteria present in DFO

Standard of care

- Hospitalization and off-loading (removing all pressure from foot, reducing patient mobility)
- Debridement and/or antibiotic therapy, typically 4-6 weeks of IV/oral antibiotics

30%-40% of DFO cases result in amputation

Truong 2022; Giurato, 2017

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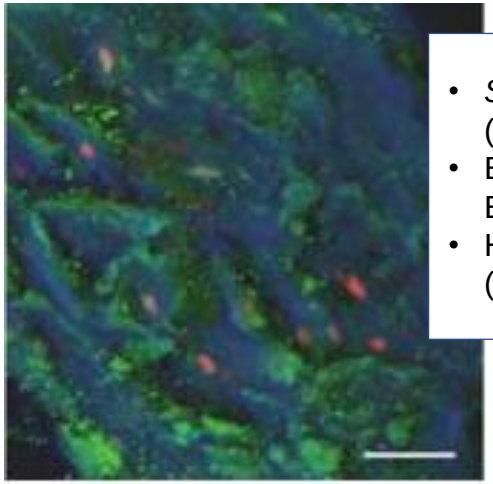
Biofilm and antibiotic resistance among key drivers of treatment failure

Key drivers of treatment failure:

- Biofilm - *S. aureus* inhabiting biofilms are 10 to 1,000 fold more resistant to antibiotics, compared to planktonic cells
- Poor blood supply limits effective concentration of IV/oral antibiotics
- Antibiotic resistance

- *S. aureus present in* ~50% of DFO cases
- While other organisms are often present, *S. aureus is* considered the main pathogenic species, due to its rapid doubling time and arsenal of virulence factors

S. aureus forms biofilm patches in diabetic foot ulcers



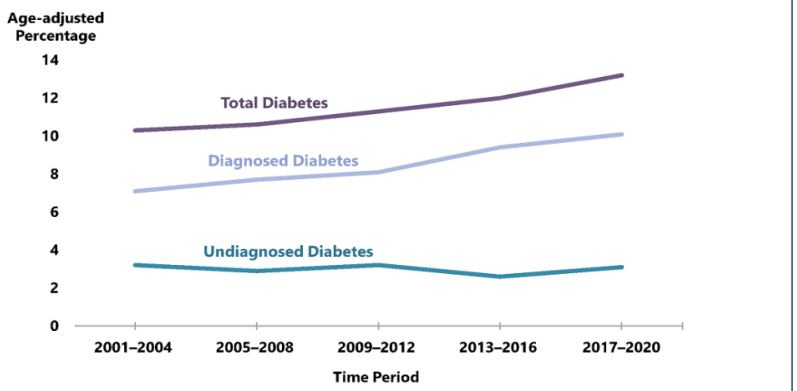
- *S. aureus* bacteria (**green**)
- Bacterial biofilms, EPS (**blue**)
- Host cell nuclei (**red**)

Confocal laser scanning microscopy of soft tissue from patient with diabetic foot ulcer infected by *S. aureus*

Eleftheriadou, 2010
Lesens 2011
Neut 2011
Oates 2012
Kavanagh 2018
Sharma 2023

Amputations in diabetic patients are an enormous burden to the health system

Trends in age-adjusted prevalence of diabetes among adults, US



Notes: Diagnosed diabetes was based on self-report. Undiagnosed diabetes was based on fasting plasma glucose and A1C levels among people self-reporting no diabetes. Time period 2017–2020 covers January 2017 through March 2020 only.
Data sources: 2001–March 2020 National Health and Nutrition Examination Surveys.

~160K Incidence

Lower limb amputations, diabetic patients annually, US

~$50K Cost

Amputation costs (direct), per patient, US

~$8bn Annually

Diabetic amputations cost the US healthcare system

- ~85% of amputations in diabetic patients are due to DFO
- Undergoing an amputation increases five-year mortality rate from 30% to ~50%
- An episode of lower limb amputation is a major risk factor for subsequent amputations

(1) CDC National Diabetes Statistics Report, 2020 (2) Nilsson, 2018 (3) Cesar, 2022 (4) Armstrong, 2020 (5) Waibel, 2024 (6) APMA publication, 2014 (7) Winkler, 2022

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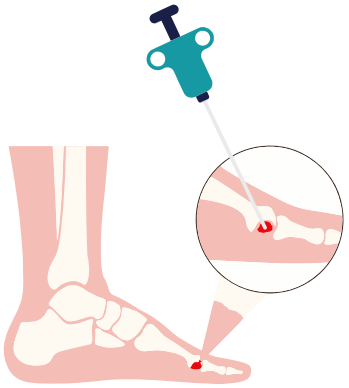
BX211 phage treatment for DFO patients with *S. aureus*

- **Product** – Phage treatment targeting *S. aureus.* Phage, originating from a ‘phage-bank’, are personally matched for each patient
- **Patient population** – DFO patients with *S. aureus infection*
- **Delivery** – IV + topical
- **Treatment -** On top of standard of care
- **Key features** – Potentially effective on antibiotic resistant strains, enables breakdown of biofilm, improves penetration
- **Potential impact:** (1) Prevent amputations (2) Shorten time to healing

1

Biopsy



2

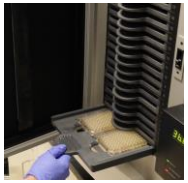
Culture

Bacterial culture

3

Match phage to *S. aureus* isolate

Proprietary **Phage Susceptibility Test** (**PST**) platform

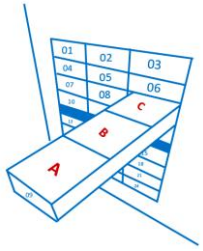


- Planktonic activity
- Biofilm activity
- Other

4

Phage therapy accessed at hospital

Phage-bank ‘ATM-like’ dispensing system



Therapy ready

BiomX

Multiple compassionate treatments of DFO patients demonstrate potential for phage treatment

12 DFO cases (*S. aureus)*

9 patients

- Single phage against *S aureus*
- Topical application or injection to bone, surrounding tissue
- 3-7 weekly applications
- Olympia, Washington

3 patients

- Administration – Direct application
- 6-45 days of application
- Jerusalem, Israel

Outcome (in 11 out of 12 patients)

- **Clearance of soft tissue infection and DFO**
- **Wound healing**
- **Prevented amputation**

11 Osteomyelitis cases (not DFO, various bacteria)

No. of cases	Bacteria	Treatment
1	*A.baumanii* and *K. pneumonia*	IV, 11 days
5*	*P. aeruginosa*	IV 2 weeks or direct application, 7-12 days
2	*P. aeruginosa* and *S. epidermidis*	Direct application, 7-10 days
1	*E.faecalis*	Direct application, 7 days
1	*S.agalactiae* and *S aureus*	Direct application, 9 days
1*	*S.aureus*	IV

Outcome - at least 8 reported as clinical recovery

* For 5 of the 6 cases phage provided by APT

Fish 2017, Fish 2018, Suh 2022, Onallah 2023

BX211 Phase 2 for DFO - Study design

Phase 2 in DFO

Objectives
- Improvement in clinical outcome

Primary Endpoints
- Percent area reduction of study ulcer through Week 13

Secondary Endpoints
- Time to complete ulcer healing
- Time to 85% CRP reduction

Exploratory Endpoints
- Percentage of subjects with amputation-free survival at Weeks 26 and 52
- Percent decline from baseline in ESR and CRP at Weeks 26 and 52
- Microbiological eradication of the target pathogen
- Safety and tolerability

Study Population
- Patients with Diabetic Foot Osteomyelitis due to *S. aureus*

Approximately 45 patients

- 2:1 randomization, Treatment : Control
- Treatment duration: 12 weeks (IV & topical)

- **Key Design Features**
- Multi-centered, double blind, placebo control
- Topline readouts after all patients complete 13 weeks (readout 1) and 52 weeks (readout 2)

Topline results from week 26 expected in Q1 2025,
and from week 52 expected in Q1 2026

Appendix

BX004 addressable market of > $1.5 billion worldwide

	BX004	References/Comments
Patient population (US)	~8,000	Number of CF patients with chronic PsA infections[1]
Potential effect on *PsA* CFU in lungs	Suppression/eradication of *PsA* (CFU in sputum)	Magnitude observed under Tobramycin Phase 3 study was ~1.5-2 log[2]
Potential impact on lungs	Improved lung function (FEV1)	Magnitude observed under Tobramycin Phase 3 study was 8-12%[2]
Potential pricing in the US	$100K - $120K annually per patient	Benchmarks (cost annually per patient): Trikafta: $300K, alternating antibiotics treatment, Tobi Podhaler and Cayston solution: $80K, Arikayce for MAC: $100-120K[3]
Market potential	**~$1 Billion in the US alone** (worldwide $1.6 billion)[4]	US patient population times potential pricing

1. CFF 2019 Patient Registry Annual Data Report
2. See slide on Tobramycin study
3. Trikafta and Arikayce – Publicly announced pricing, First Databank, Jan. 8, 2021, public pricing information. for alternating Tobi Podhaler and Cayston solution assumes 65% compliance
4. Assumes rest of the world outside US comprises 40% of total market (Vertex annual report, publicly available pricing for Vertex drugs)

BX211 addressable market of >$2B worldwide

	BX211	References/Comments
General patient population	160,000	Lower limb amputations (LLA), diabetic patients annually, US[1]
Assumed relevant population for BX211 treatment	40,000 (25% of 160,000)	Deductions due to[2]: - 85% of amputation are due to DFO - 50% positive for of S. aureus - 60% not urgent amputations, enabling biopsy and treatment 85% X 50% X 60% = 25%
Pricing	$25,000	Based on 50% of the saved $50K amputation costs[3]
Relevant market for BX211, US	**$1 Billion**	40K times $25K
Relevant market for BX211, Worldwide	**>$2 Billion**	ROW is over $1 billion, based on the following: . Annual incidence of LLA in the OECD is 3-4 higher than the US[4] Assuming OECD pricing is 50% of US pricing.

(1) CDC National Diabetes Statistics Report, 2020 (2) Brooks, 2021; Giurato, 2017, Lesens, 2014 (3) Nilsson, 2018; Brooks, 2021 (4) Hughes, 2020; OECDiLibrary Diabetes care report,2017

Thank you

BiomX