## PHAXAM

# Building a Global Leader in AMR Infections Therapies

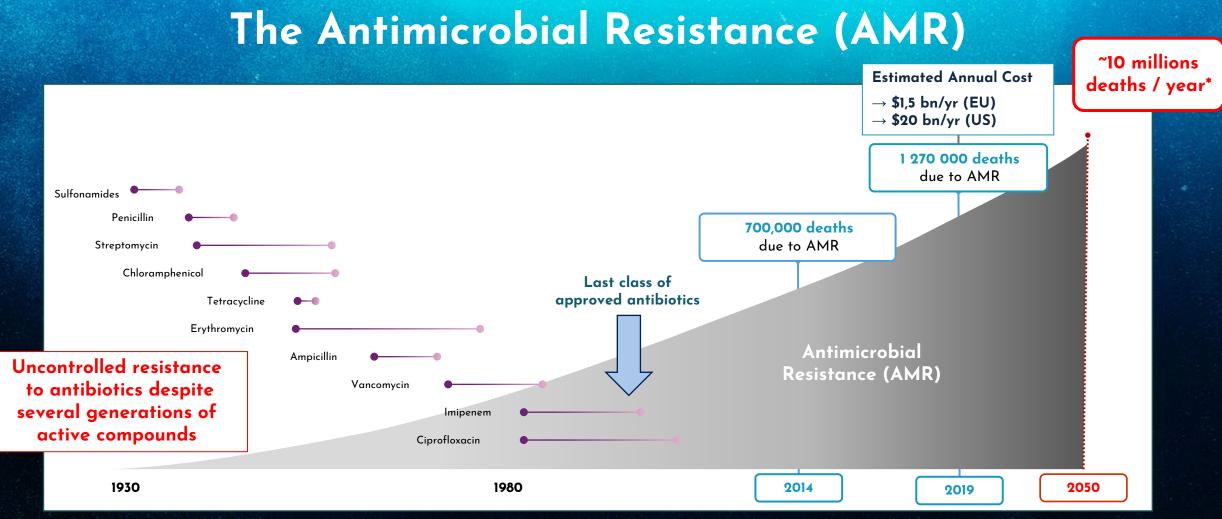
May 2024

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## Agenda

Global Context
 PHAXIAM Differentiation
 Development Strategy
 Communication & Financing



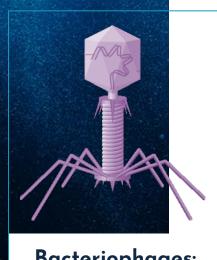
There is a CRITICAL NEED to address Antimicrobial Resistance

May 2024

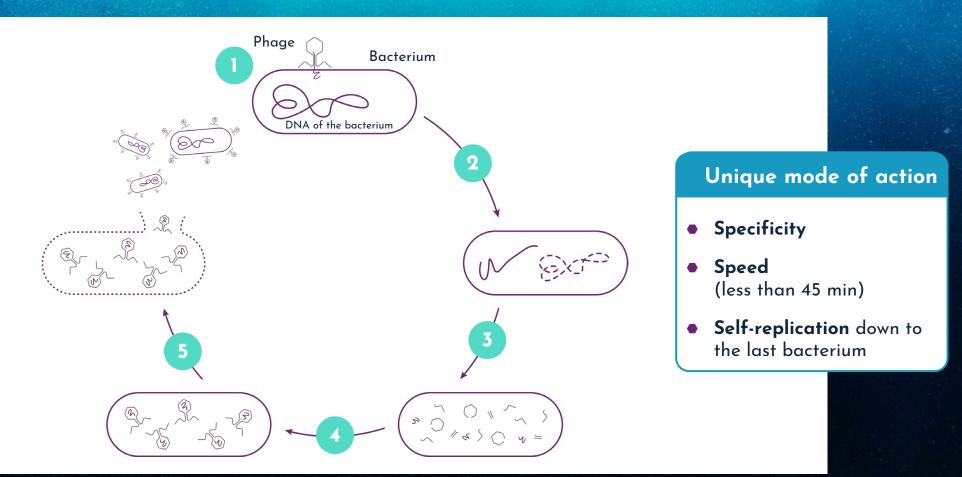


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## Phage Therapy, a Solution for Resistant Infections



Bacteriophages: viruses, natural predators of bacteria



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Phage Therapy allows SIMPLE, EFFECTIVE and WELL-TOLERATED treatments

## The Strong Momentum of Phage Therapy

INCREASING IMPACT of difficult-to-treat resistant infections Rising concern among public authorities and medical community

High safety and promising clinical benefits from REAL-LIFE treatments Increased probability of success from early clinical evidence

Active collaboration with REGULATORY AGENCIES Strong support / Clear development guidelines / Accelerated paths

> GMP STANDARDIZATION & CMC developments Robust GMP processes / Well characterized phages

Better understanding of resistance mechanisms NEW TOOLS to address potential emergence of phage resistance



CRITICAL NEEDS FOR ALTERNATIVE TECHNOLOGIES

PROMISING REAL-LIFE CLINICAL DATA

ATTRACTIVE REGULATORY CONTEXT

MATURITY OF THE TECHNOLOGY

SOLUTIONS TO POTENTIAL RESISTANCE

Phage Therapy is a TOP-10 INNOVATION to be developed according to the 2023 World Economic Forum



#### **Reinforced interest in Phage Therapy** Major Commitment from Top Tier US investors in March 2024



Purchase agreement with a \$50M financing led by Top tier investor base, incl. Deerfield and Orbimed

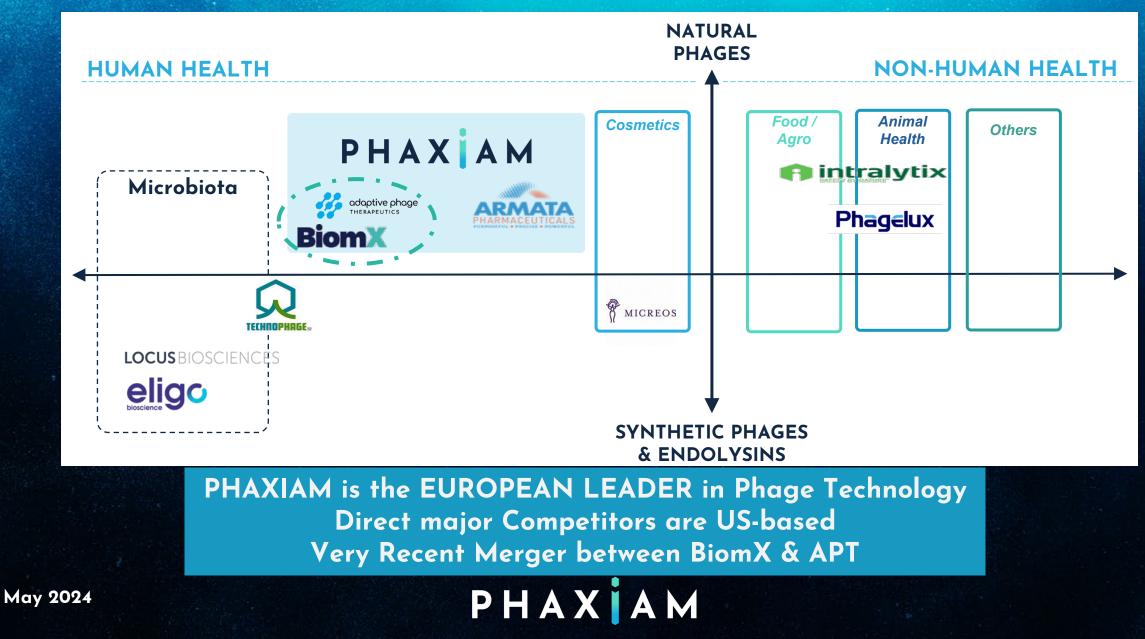


Armata Pharmaceuticals has recently announced a \$35M refinancing with Innoviva

Growing attractiveness of the phage-therapy field to leading investors



#### **Competitive Landscape**



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## Key Technology Assets for PHAXIAM Treatments

- **SELECT phages to maximize breadth of repertoire** Internal PHAXIAM Technology and Expertise
- 2 PRODUCE large scale GMP batches of high purity Internal PHAXIAM process development Capabilities and Expertise Industrial partnership to produce "off-the-shelf" GMP-grade phages
- 3 **TEST PHAGOGRAM for a precision therapy** PHAXIAM proprietary IVD Test
- DISTRIBUTE personalized therapeutics to patients' bed Supply chain in place with a few days leadtime







Discovery, Screening, Characterization, GMP production, Testing, Distributing

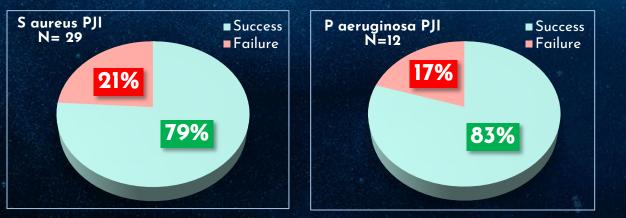


#### 2- PHAXIAM Differentiation

## **Real-life Clinical Data From ~100 Treated Patients**

STRONG SUPPORT from Regulatory Authorities & >15 hospitals

- SEVERAL ROUTES OF ADMINISTRATION TESTED, including local, intravenous, nebulisation, ...
- 7 DIFFERENT INDICATIONS TREATED with a majority of PJI



#### PROMISING CLINICAL ACTIVITY RESULTS

(First 77 patients evaluated) 2020-2024

- EXCELLENT RESULTS observed in reported cases: safety + clinical benefit
- Several PUBLICATIONS

~ 80% CONTROL RATE of infection @3months for PJI Patients (n=42) VERY PROMISING Data in « hard to treat » population (very severe infections - 2<sup>nd</sup>/3<sup>rd</sup> line antibiotics)



## AAC\* Regulatory Status from French Authority (June 2022)



COMPASSIONATE ACCESS AUTHORIZATION (AAC) SOURCE OF REVENUES To be extended to OTHER AAC\* INDICATIONS Process towards an EARLY ACCESS AUTHORIZATION To be extended to ORPHAN STATUS

An Important First Step for MARKET ACCESS in EUROPE

PHAXAM

\*Compassionate Access Authorization

#### **Corporate Strategy**

#### POSITION THE COMPANY AS A GLOBAL LEADER



ΡΗΑΧΙΑΜ

May 2024

#### An Ambitious Clinical Development Strategy

#### **Target High-Value Indications**

Severe Resistant Infections with High unmet medical needs high mortality rate / high budget impacts -> claim high pricing

#### Accelerate the Path to Global Registration

Launch the 1<sup>st</sup> global randomized Phase 2 study at international scale in PJI\* Leverage on potential Early access pathway (after Phase 2)

#### **Diversify Portfolio**

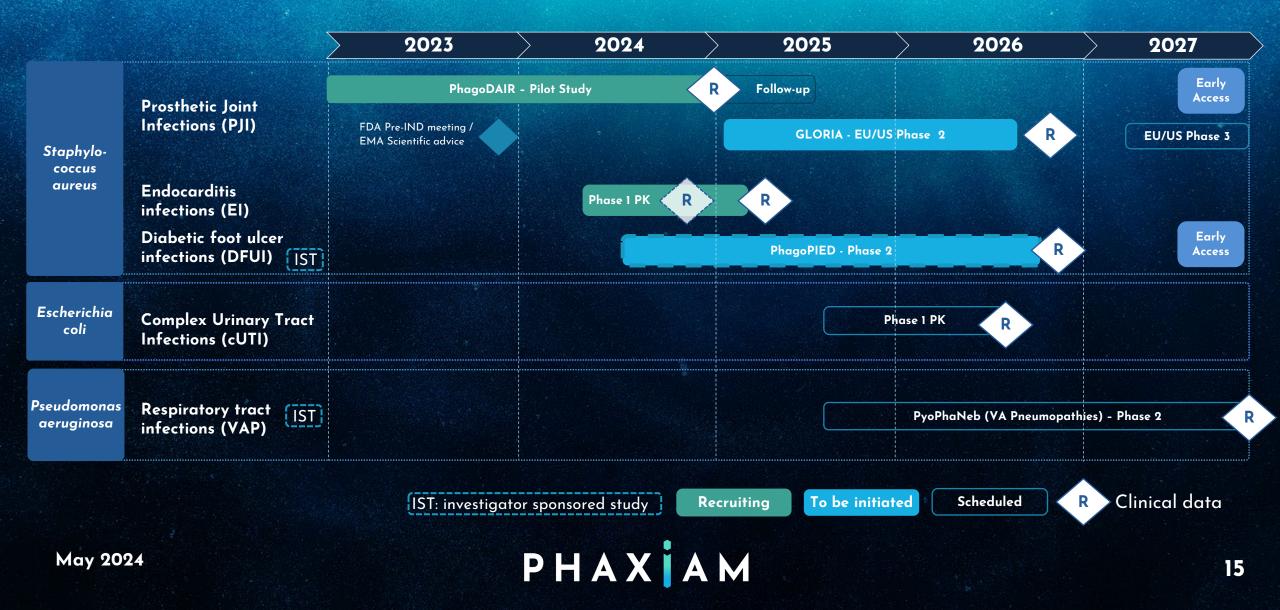
Target several Life-Threatening Infections (Endocarditis, VAP\*\*, ...) Target several Virulent & Resistant Bacteria (E. coli, P. aeruginosa, ...)

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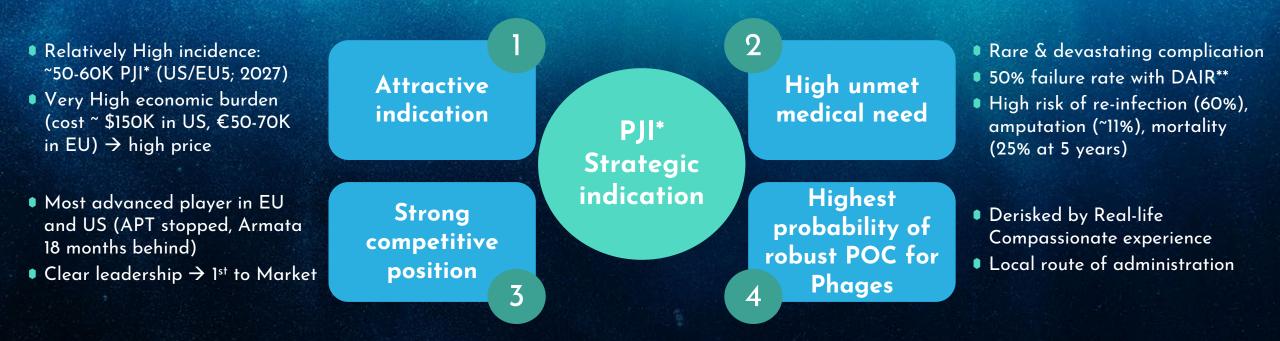
\* Prosthetic Joint Infections
 \*\*Ventilated-acquired Pneumopathies

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## **A Balanced Clinical Portfolio**



## PJI, a strategic indication for PHAXIAM

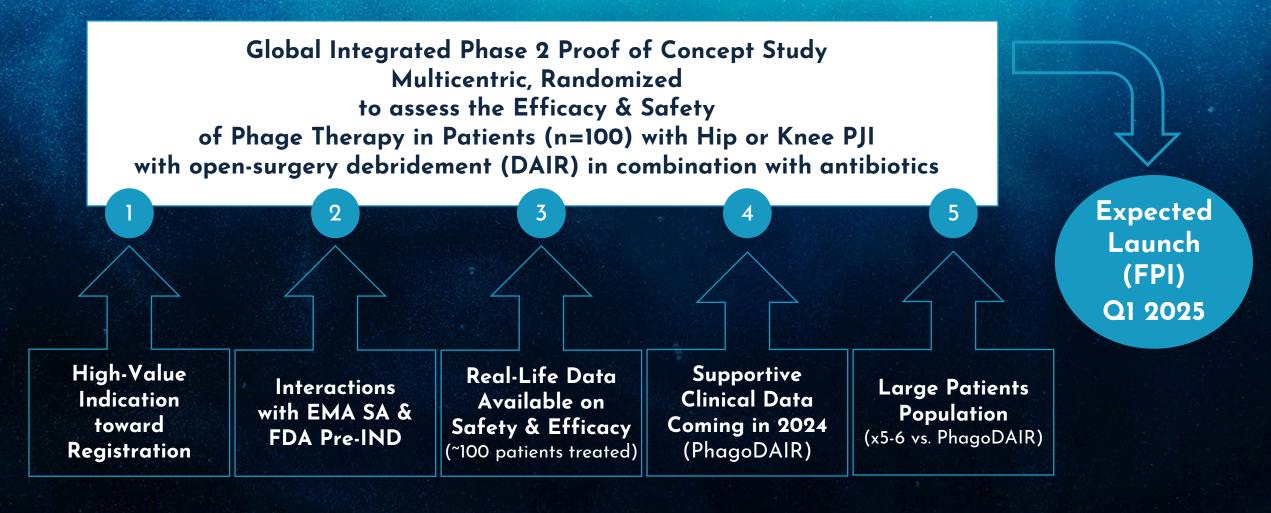


Unique and leadership position in the strategic PJI indication



\* Prosthetic Joint Infection (PJI)
 \*\* SOC = Debridement, Antibiotic, Implant Retention

## First Global (EU/US) PJI Phase 2 Study (GLORIA)



## **Preparation of the GLORIA study**

Positive and consistent feedback from the FDA (pre-IND meeting) and EMA (scientific advice)

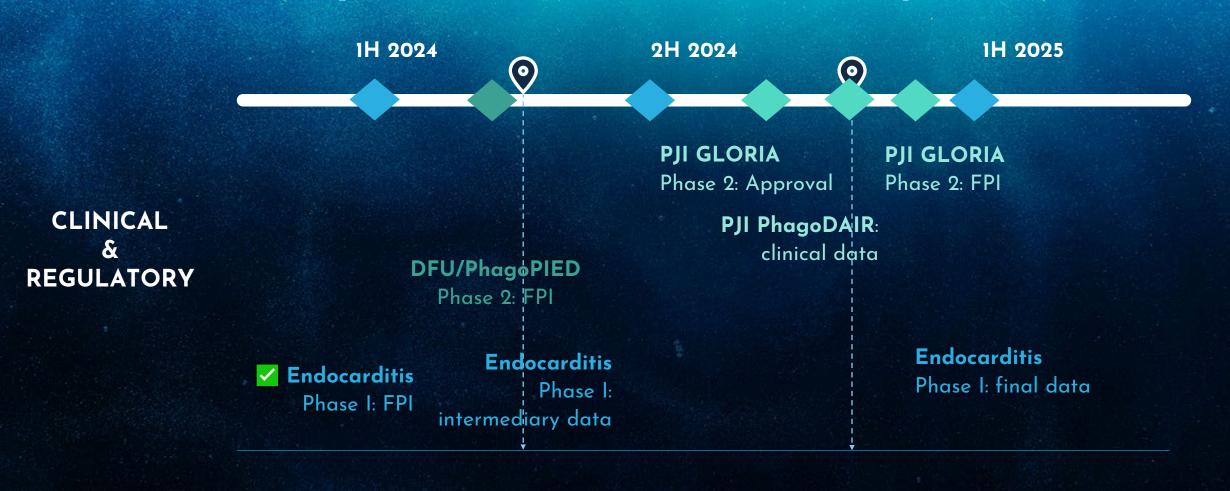
- Global CRO selection in final steps
- Sites selection ongoing: ~40 sites and countries (FR, ESP, GER, NLD, ITA, UK, US)
- Launch of the clinical study in Q1 2025, clinical results expected in H2 2026

Progress in line with our objectives



#### **4-** Communication & Financing

## **Expected Major Clinical Catalysts**



**4-** Communication & Financing

#### **Financial Position**

Cash position as of March, 2024: €5.8m Cash Runway into August 2024 Reviewing options to further extend cash Runway





## Key Messages

Concern is growing about **AMR Infections**, the "New Global Pandemics" **Phage Therapy** is the Therapeutic Solution for Multi-resistant Bacterial Infections

- A new momentum for Phagotherapy with an increased interest from financial investors
- Ambitious strategy by focusing on High-Value Indications targeting Life-Saving Therapeutics according to Pharma standards
- De-risked Clinical Strategy with real-life demonstrated Clinical Efficacy and Safety
- Performing Sales, First-to-Market anticipating Market access in 2027 (Early Access Pathway)
- Secured and in place GMP-Manufacturing (Pharma standards) & Logistics Capabilities
- Environmental-friendly technology
- Robust execution Capabilities



# Thanks PHAXIAM

#### **4-Capabilities**

## **Experienced & Complementary Leadership Team**



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**Appendixes:** Capabilities

#### Leading Phage Therapy Platform

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Leading Edge in Clinical Development Regular Interactions with Regulatory Agencies & HTA agencies Strong internal R&D, CMC & GMP Capabilities **Proprietary PHAGOGRAM® IVD Solution** Large Phage Bank for the most critical bacterial Infections Strong IP with 87 patents filed



Developments within a regulatory framework validated by key health authorities







Network of prestigious scientific partners



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**Appendixes:** Capabilities

#### Manufacturing & Logistics strategic capabilities

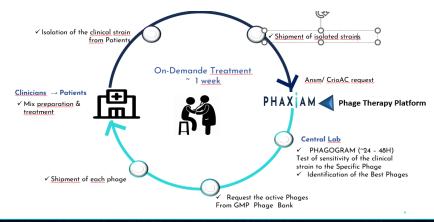


**Pharmaceutical supply chain mastered** to ensure robust and short lead time clinical supply (clinical studies, AAC, ....)

#### **Major achievements**



- > 35 GMP clinical batches produced
- Low Manufacturing COGS
- Available capacity till early market launch
- Short supply lead time (> 1 week)



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Manufacturing & Logistics Capacities Fit to Address future Clinical Demand

PHAXIAM

May 2024

#### **Appendixes: Merger Rationale**

## PHAXIAM, a new company

🖢 Nasdao



HQ in Lyon, Office in Boston Listed on Euronext, Nasdag

ERYP LISTED



Leader in red blood cell-based therapeutics



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- Late-stage clinical experience in oncology
- Phase 3 trial in second-line pancreatic cancer did not meet its primary endpoint (Q4 2021), following which Ervtech:
- Launched strategic partnering process
- Sold its US manufacturing facility
- Restructured, keeping core R&D, QA and support teams
- Focused preclinical programs on promise of extracellular vesicles (EV) for drug delivery



HQ in Nantes, Office in Paris Listed on Euronext ALPHE EURONEXT Growth

Leading European player in phage therapy against resistant bacterial infections, a major global health issue

Phase 2 trial ongoing: enrolment on track, Ē data expected Q1 2024

- > 65 patients already benefited from 0 B compassionate treatments with
  - · Systematic & strong support of the Health Authorities
  - · Encouraging clinical efficacy and tolerability observed in reported cases to date
- Large & robust IP portfolio
- Ambitious development strategy

#### **Appendixes: Merger Rationale**

Many synergies to leverage

Experienced in late-stage clinical development

RDD & Manufacturing capabilities (proteins engineering)

> US presence & experience

Nasdaq / Euronext dual listing 01 ACCELERATION OF AN AMBITIOUS GLOBAL CLINICAL PLAN

02 COMPLEMENTARY PLATFORMS AND EXPERTISES

03 COMPLEMENTARY & SYNERGISTIC MANAGEMENT AND INFRASTRUCTURE

> 04 ENHANCED FINANCING CAPABILITIES & ACCESS TO INVESTORS IN US / EU

Ongoing Ph2 PJI trial & established clinical development plan

Phage RD & manufacturing capabilities

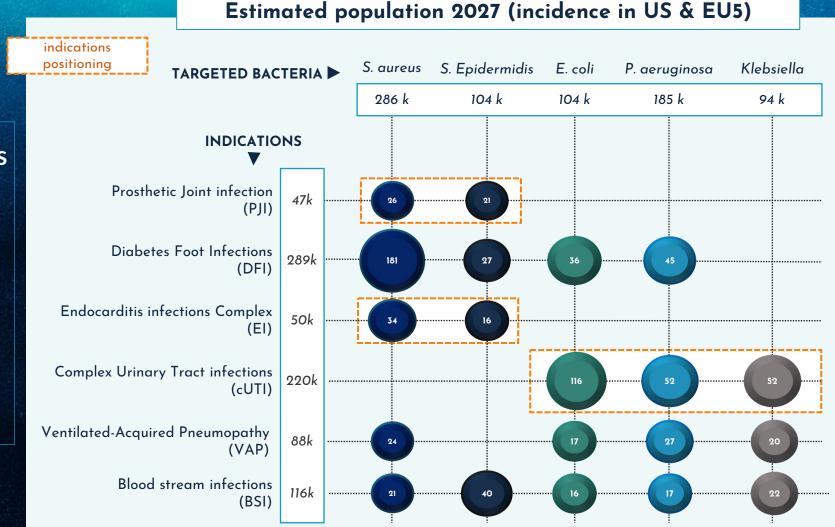
Initiation of partnership discussions

- Development beyond ID Human Health: one health, cosmetics
- Phagogram IVD solution

**Appendixes: Development Strategy** 

## **Targeting High-value Resistant Infections**

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Life-Threatening Conditions

Potential Orphan Status Indications

The most severe Hospital-Acquired and Resistant Infections

#### **Appendixes: Development Strategy**

## **Additional Clinical Studies**

TRIALS	STATUS AND PROGRESS
Endocarditis Infections (EI) Staph. aureus Phase I PK	<ul> <li>Demonstration for IV indications before Registration Study</li> <li>Resistant infections in cardiac chambers and valves</li> <li>IV-administered Phages</li> <li>Key milestones : First Patient-In, April 2024</li> </ul>
Complex Urinary Tract Infections (cUTI) E. coli Phase I PK	<ul> <li>Demonstration for intra-bladder administration before Registration Study</li> <li>cUTI with resistant E. Coli infections in the bladder</li> <li>Phages administered locally into the bladder</li> <li><u>Key milestones</u> : ANSM study validation in April 2024</li> </ul>