# Focused on Growth and Innovation

## “Patients are at the heart of what we do”

**Investor presentation**

January 06, 2024

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# Executive summary

# Experienced leadership team

**David Veitch** CEO

Joined: 2014

Previous roles: Bristol-Myers Squibb; SmithKline Beecham

**Adesh Kaul** CFO

Joined: 2009

Previous roles: POLYPHOR; Genedata solutions in-silico

**Marc Engelhardt MD, Ph.D.** CMO

Joined: 2010

Previous roles: NOVARTIS; BRACCO

**Gerrit Hauck Ph.D.** CTO

Joined: 2018

Previous roles: SANOFI

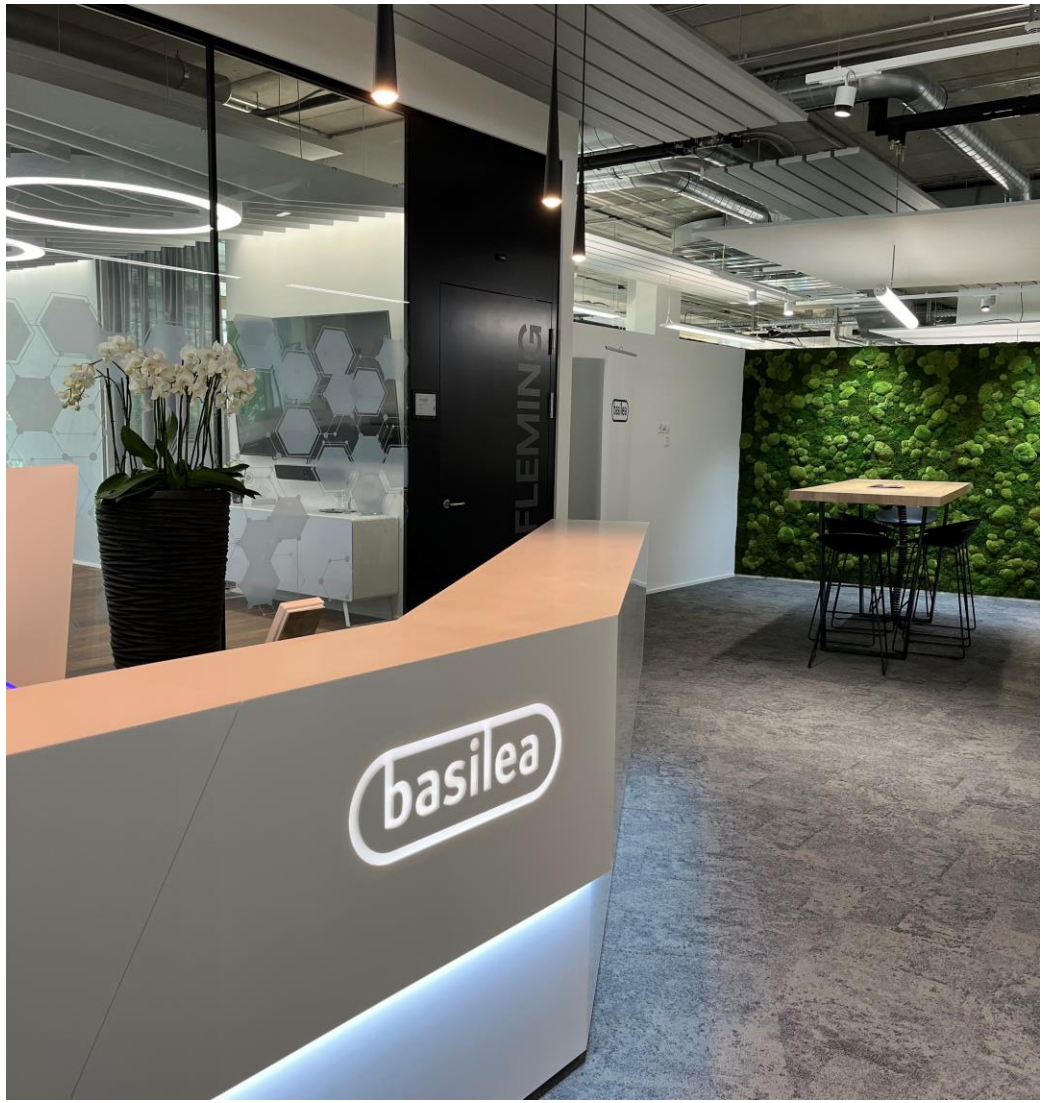
**Laurenz Kellenberger Ph.D.** CSO

Joined: 2000

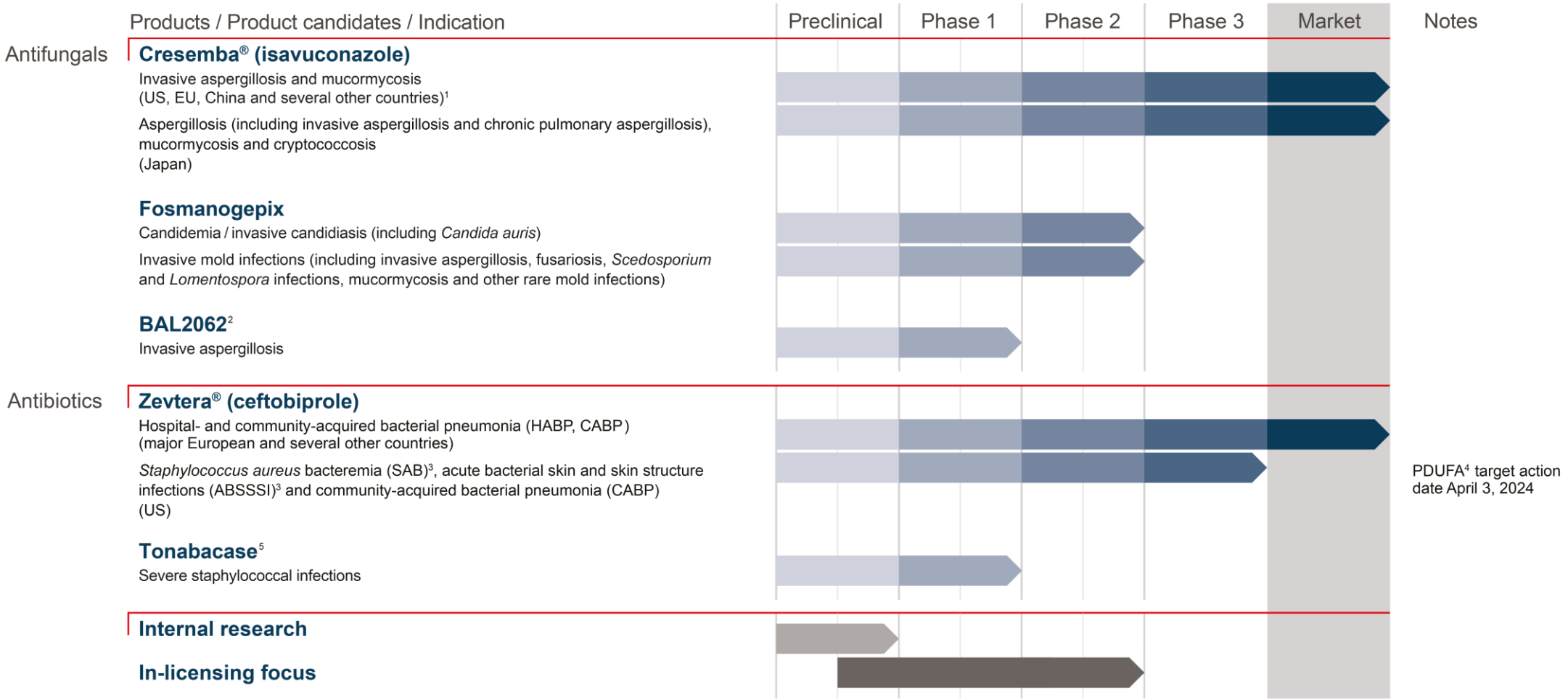
Previous roles: UNIVERSITY OF CAMBRIDGE; Roche

# At a glance

- Focus on the treatment of severe bacterial and fungal infections
- Recognized ability to establish and manage partnerships in both the development and commercial phase
- Cresemba® and Zevtera® – two revenue generating hospital anti-infective brands
- Commercial products complemented by preclinical and clinical programs, including
  - **Fosmanogepix**, a phase-3-ready broad-spectrum antifungal
  - **BAL2062**, an antifungal for the potential treatment of invasive aspergillosis
  - **Tonabacase**, an endolysin antibacterial for the potential treatment of severe staphylococcal infections
- Profitable biotech company listed on SIX Swiss Stock Exchange, SIX: BSLN
- Located in the Basel area life sciences hub, Switzerland

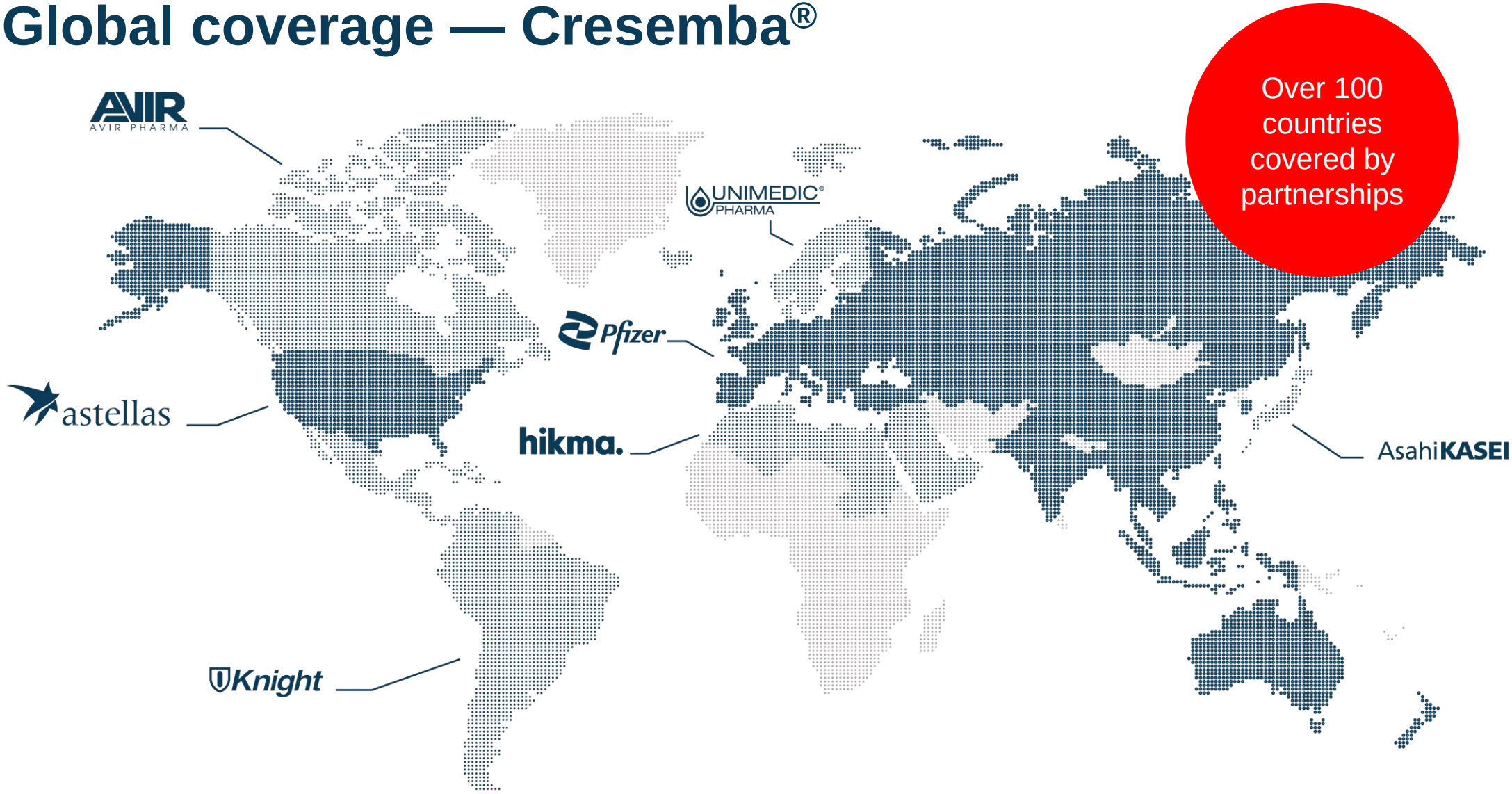


# Potential for sustainable growth and value creation




1 The registration status and approved indications may vary from country to country.
2 Formerly GR-2397
3 Phase 3 program was funded in part with federal funds from the US Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA).
4 The Prescription Drug User Fee Act (PDUFA) target action date indicates the date for the FDA to complete its review of the NDA.
5 Exclusive option to in-license upon completion of preclinical profiling

# Global coverage — Cresemba®



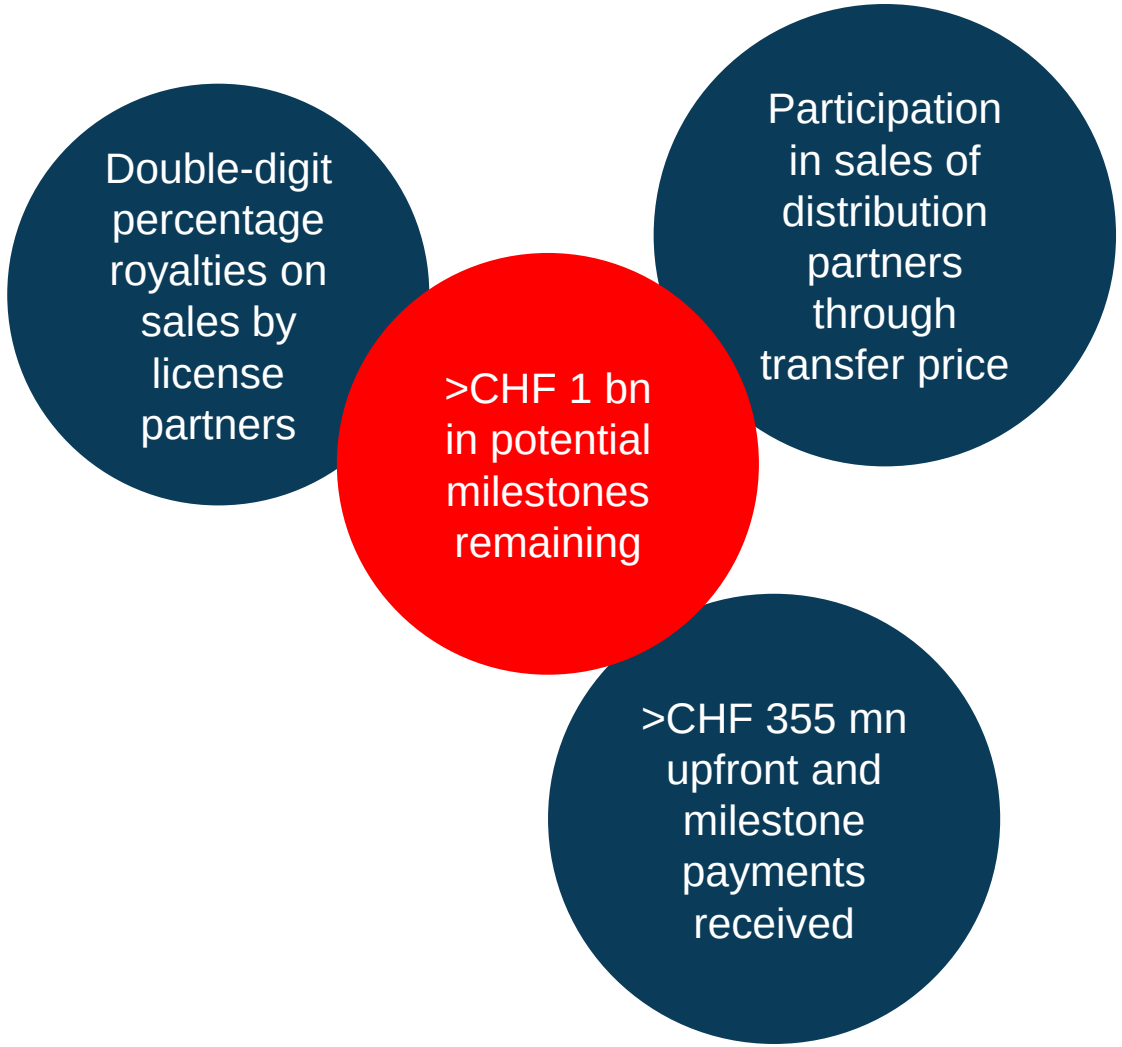
# The company we keep — Established strong partnerships

## License partners

| | |
|---|---|
| Pfizer<br>Europe (excl. Nordics), China Asia-Pacific, Russia, Turkey and Israel (Cresemba®) | astellas<br>US (Cresemba®) |
| AsahiKASEI<br>Japan (Cresemba®) | CR Gosun<br>China (Zevtera®) |

## Distribution partners

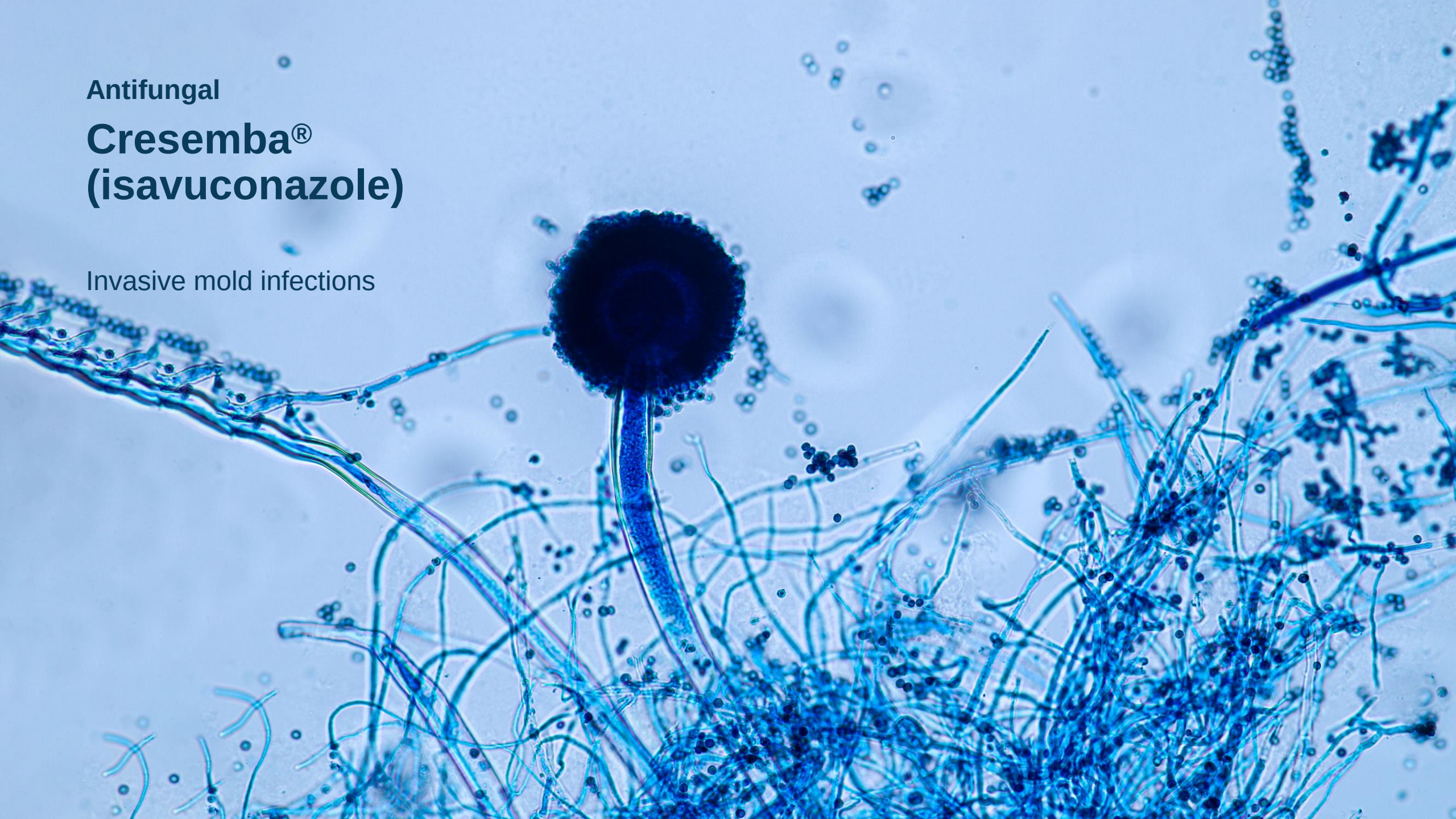
| | | |
|---|---|---|
| ADVANZ PHARMA<br>Europe (excl. Nordics), Israel (Zevtera®) | hikma.<br>MENA region (Cresemba® and Zevtera®) | Knight<br>LatAm (Cresemba® and Zevtera®) |
| UNIMEDIC PHARMA<br>Nordics (Cresemba® and Zevtera®) | AVIR PHARMA<br>Canada (Cresemba® and Zevtera®) | LANCET<br>Russia and the Eurasian Economic Union (Zevtera®) |



Antifungal

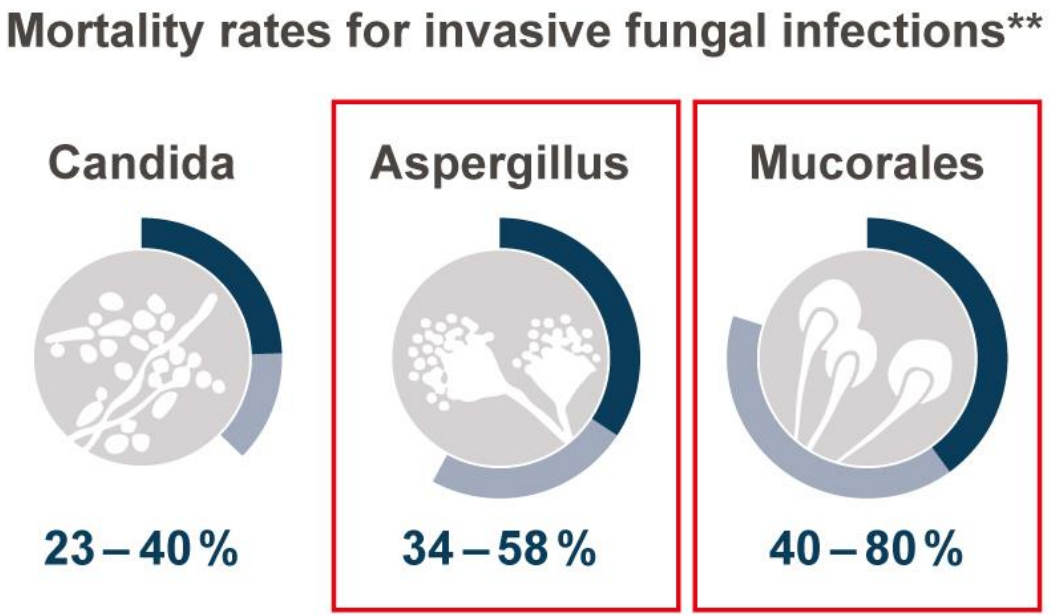
# Cresemba® (isavuconazole)

Invasive mold infections



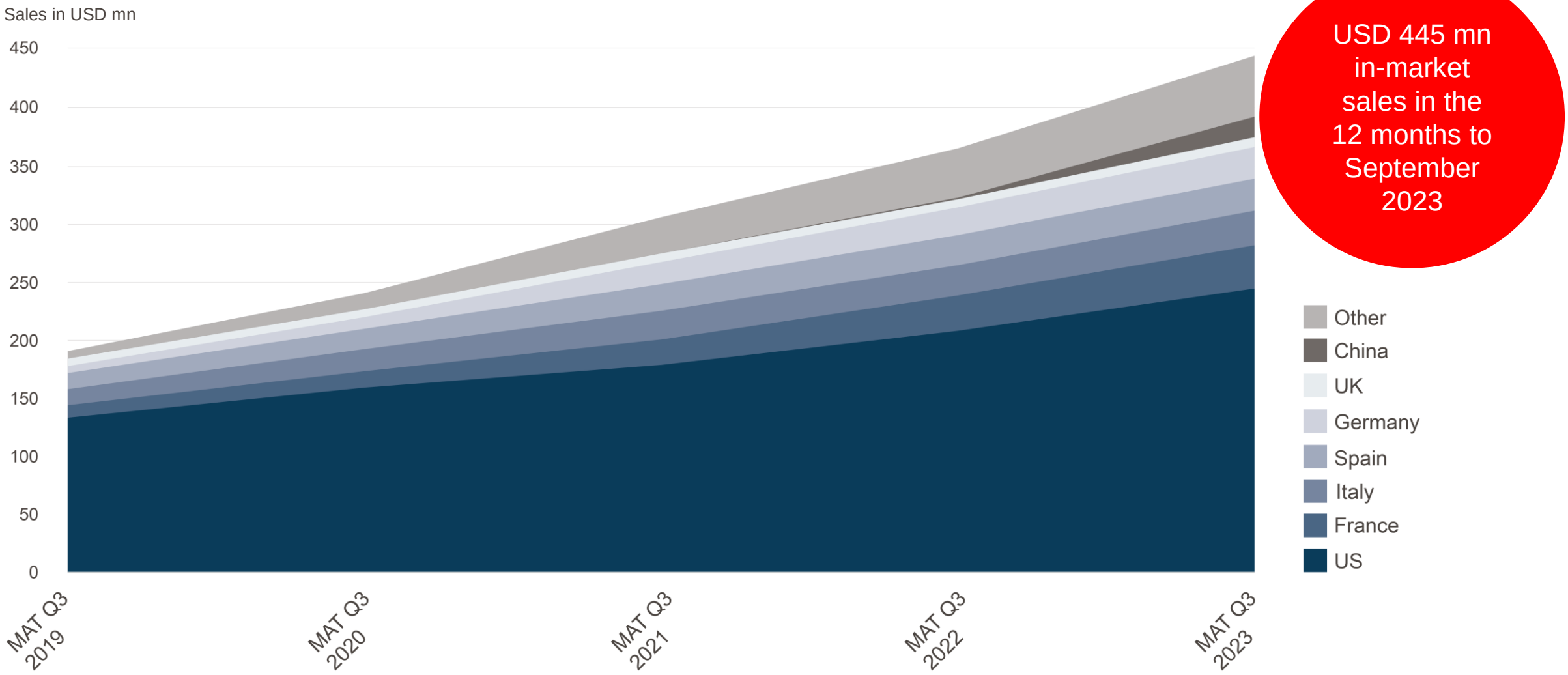
# The market — Invasive fungal infections

- Severe, potentially life-threatening infections mainly affecting immunocompromised patients
- An important cause of morbidity and mortality in cancer patients undergoing intensive chemotherapy regimens
- Rising number of immunocompromised patients (cancer and transplantations) driving therapeutic demand
- Mucorales infections on the rise – doubled from 2000 to 2013
- Limitations of current therapies (spectrum of activity, toxicity, effective plasma levels) drive the need for new agents




**Kullberg/Arendrup *N Engl J Med* 2015, Baddley *Clin Infect Dis* 2010, Roden *Clin Infect Dis* 2005, Greenberg *Curr Opin Infect Dis* 2004.

# Cresemba continues strong in-market sales uptake

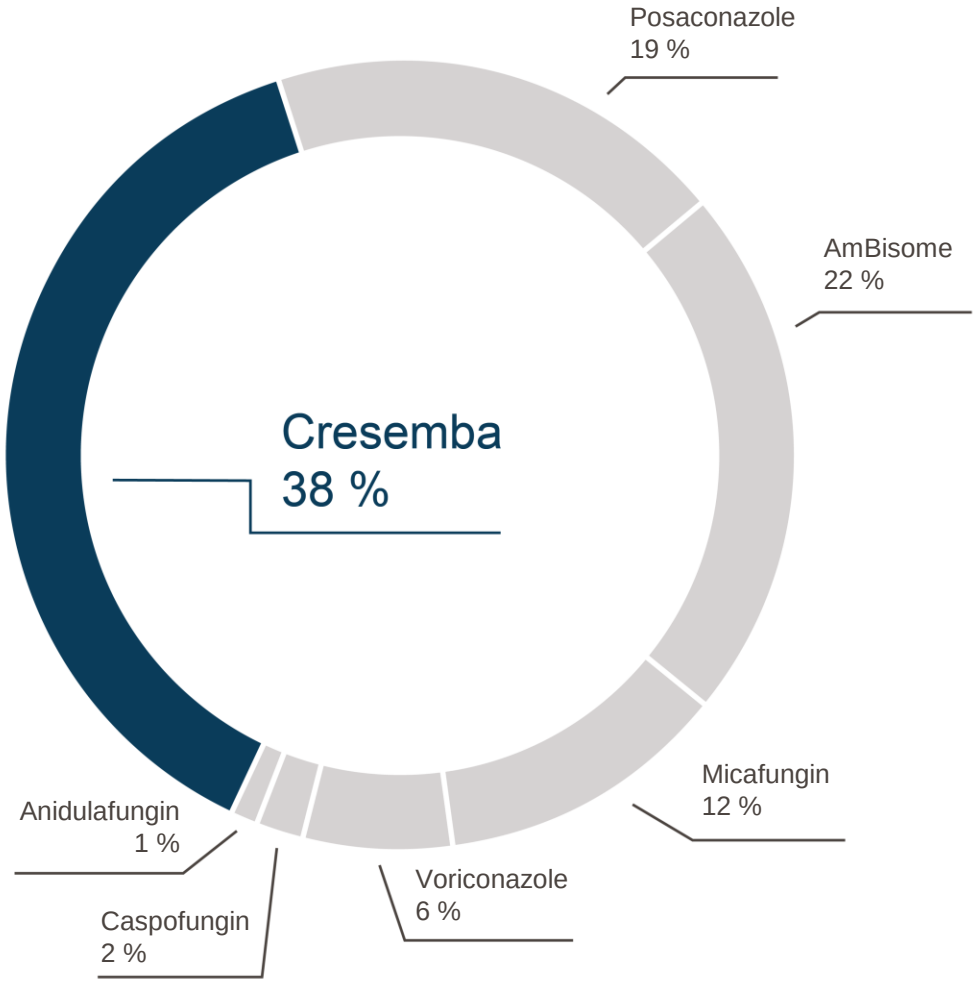



USD 445 mn in-market sales in the 12 months to September 2023

MAT: Moving annual total; Source: IQVIA Analytics Link, September 2023

# Cresemba has become the market leader in the US in terms of value

- Consistently increased market share among best-in-class antifungals* since launch to 38% by September 2023**




* Best-in-class antifungals: Cresemba (isavuconazole), posaconazole, voriconazole, AmBisome, anidulafungin, caspofungin, micafungin

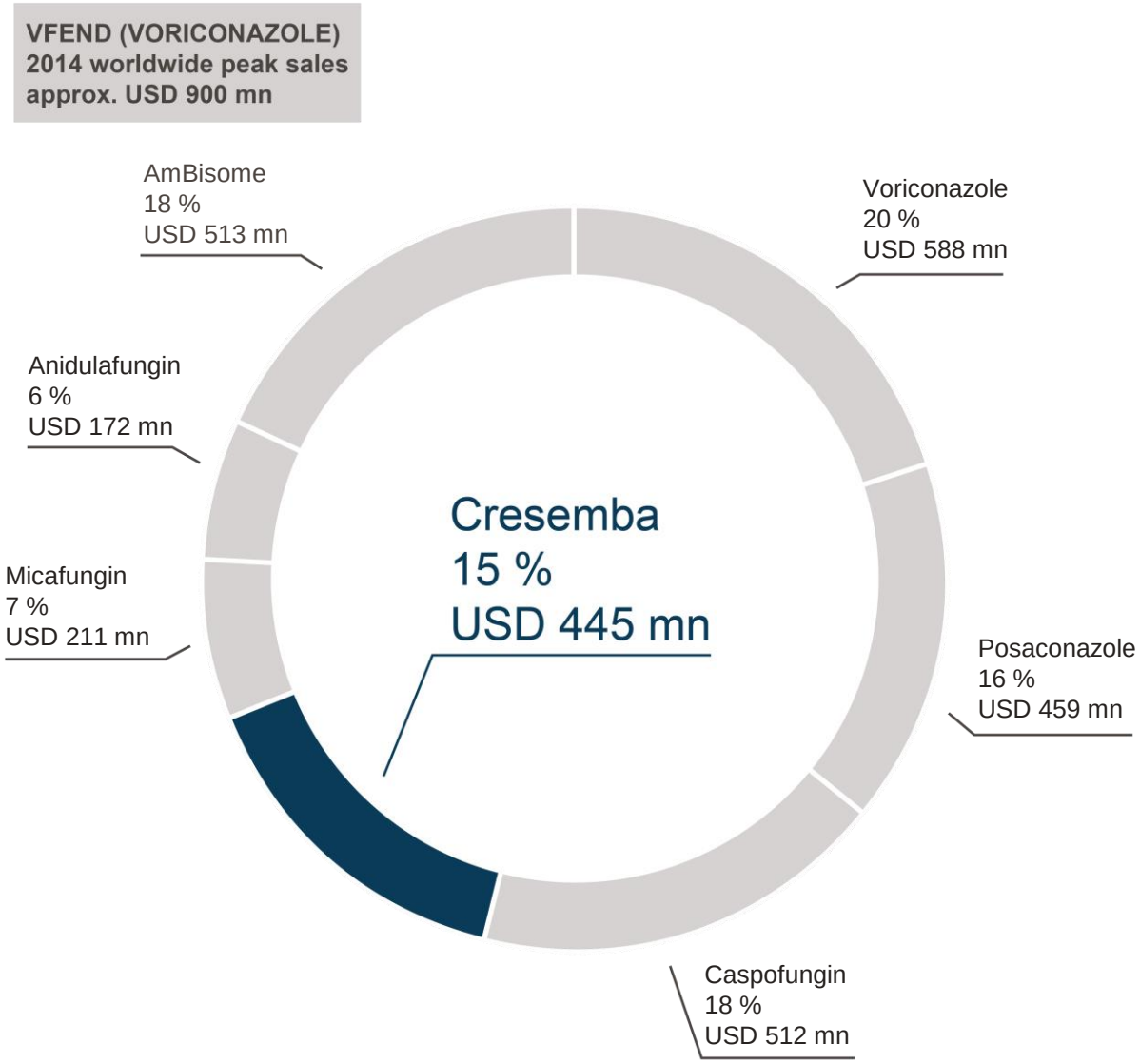
**Market share based on MAT Q3 2023, in-market sales reported as moving annual total (MAT) in US dollar; rounding consistently applied. Source: IQVIA Analytics Link, September 2023

# Global sales of best-in-class antifungals* by product

**USD 2.9 bn sales (MAT Q3 2023)**

Significant potential to increase Cresemba® (isavuconazole) global market share

- Launched in 71 countries
- Pediatric label extension in US granted in December 2023; market exclusivity extended to September 2027
- Pediatric label extension in EU anticipated in 2024; would lead to market exclusivity extension by two years to October 2027




* Best-in-class antifungals: Cresemba (isavuconazole), posaconazole, voriconazole, AmBisome, anidulafungin, caspofungin, micafungin

MAT: Moving annual total; Source: IQVIA Analytics Link, September 2023, rounding consistently applied

# Cresemba — Differentiated by spectrum, safety and tolerability

- Broad spectrum of activity against molds, including emerging molds (mucorales)
- Consistent plasma levels
- Statistically fewer drug-related adverse events and treatment-emergent adverse events (liver, skin, eye) in invasive aspergillosis patients vs. voriconazole in SECURE phase 3 study
- Can be administered without restriction in patients with renal impairment
- Manageable drug-drug interaction profile
- Once daily maintenance dose, i.v./oral treatment
- ECIL-6 guideline: Cresemba® recommended for the first-line treatment of invasive aspergillosis in leukemia and hematopoietic stem cell transplant patients. ECIL states that isavuconazole is as effective as voriconazole with a better safety profile.

Antifungal

# Fosmanogepix

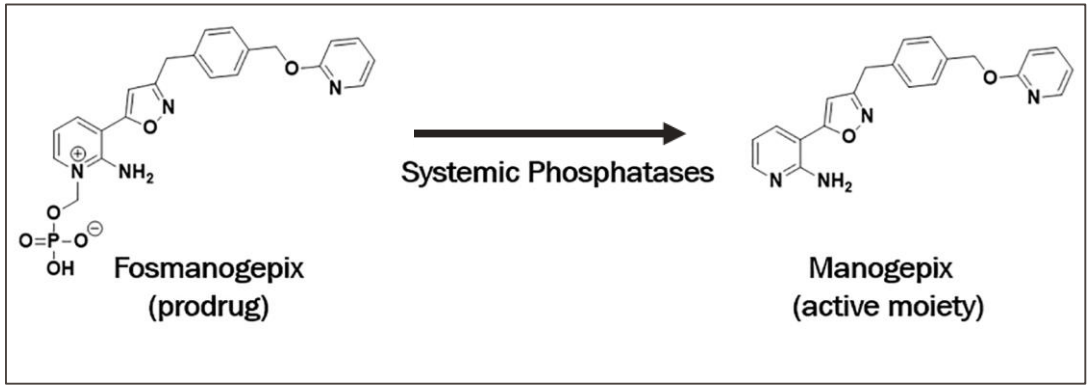
Invasive yeast and mold infections

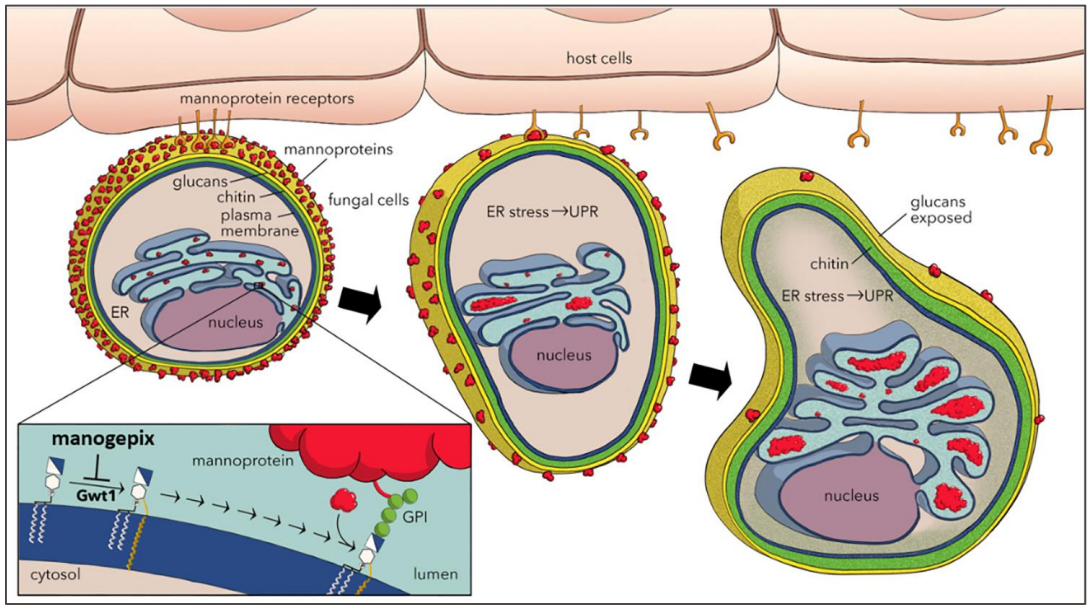
# Fosmanogepix – A highly attractive antifungal asset

- First-in-class, intravenous and oral antifungal with a novel mechanism of action
- Broad spectrum antifungal activity against yeasts, molds and dimorphic fungi, including *Candida auris*, azole-resistant *Aspergillus* spp. and *Fusarium* spp.
- Three successfully completed phase 2 studies for the treatment of
  - Candidemia, including *Candida auris*
  - Mold infections
- Phase-3-ready for yeast and mold infections with first phase 3 study in candidemia / invasive candidiasis expected to start mid-2024
- Potential to become our next lead commercial product and mid-term value driver
- Asset purchase agreement with Amplyx Pharmaceuticals, an affiliate of Pfizer; Pfizer maintains the right of first negotiation for commercialization

# Overview

- Fosmanogepix is the prodrug of manogepix
- Novel mechanism of action
- Inhibition of the protein Gwt1 impedes the production of cell wall mannoproteins, causing cell wall fragility, fungal cell death and decreased potential for biofilm formation
- Potent broad-spectrum activity against resistant yeasts, molds and dimorphic fungi, including azole-resistant phenotypes
- IV and oral availability enables treatment in both inpatient and outpatient settings
- US FDA fast track status, QIDP and orphan drug designations




Friedman DZP, Schwartz IS. Infect Dis Clin North Am. 2023;37:593-616.

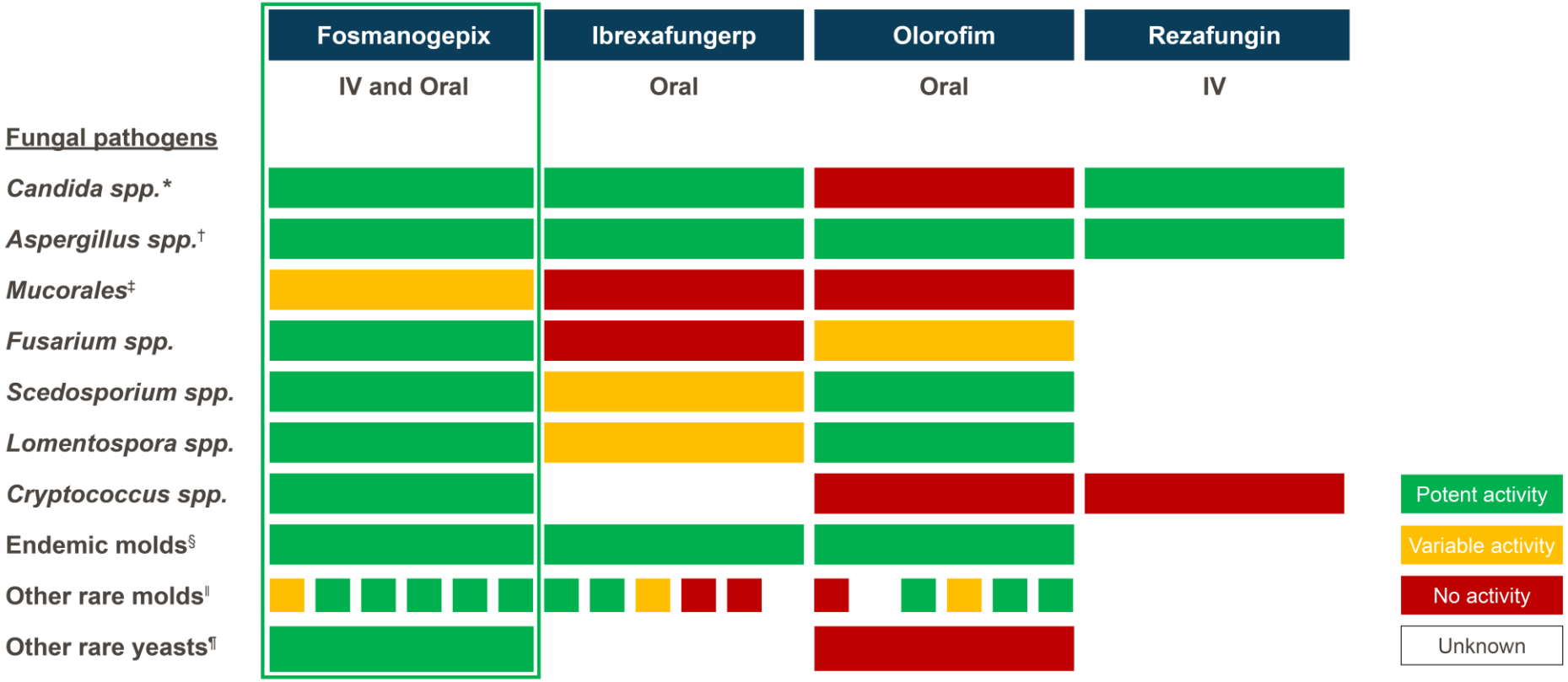
Shaw KJ, Ibrahim AS. J Fungi (Basel). 2020; 6:239

# Addressing high unmet medical needs

- Fast track status by the US FDA for invasive candidiasis, invasive aspergillosis, scedosporiosis, fusariosis, mucormycosis, cryptococcosis, and coccidioidomycosis
- Addressing emerging resistance issues in yeast infections including *Candida auris* and azole resistant *Aspergillus* spp.
- Potent activity against mold infections including difficult-to-treat *Fusarium* and *Scedosporium spp*.
- Wide tissue distribution enabling treatment of disseminated infections including CNS
- Favorable drug-drug interaction profile
- *In-vivo* synergism with liposomal amphotericin B and echinocandins may provide utility for the most difficult-to-treat infections

Hoenigl M, Sprute R, Egger M, at al. Drugs. 2021;81:1703-1729.
Winston DJ, Young PA, Schlamm HT, Schiller GJ. Clin Infect Dis. 2023:ciad309.
Gebremariam T, Gu Y, Alkhazraji S, et al. Antimicrob Agents Chemother. 2022;66:e0038022.

# Addressing high unmet medical needs (cont)



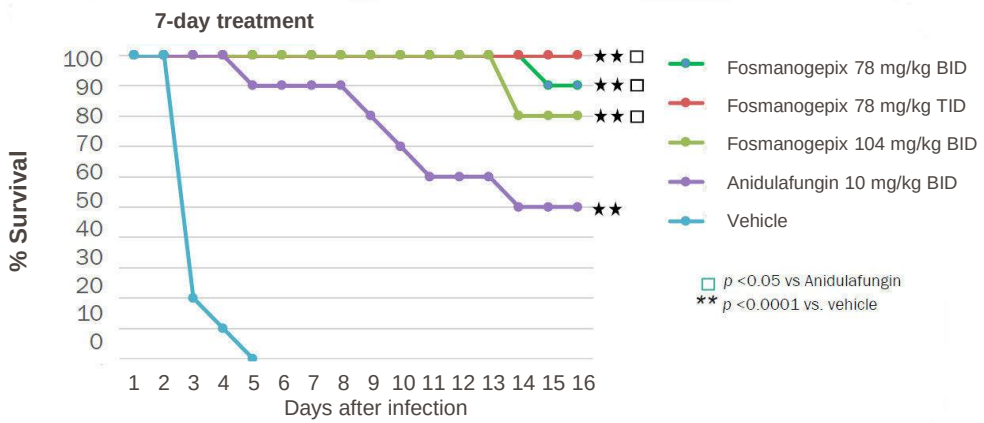

* including *C. albicans*, *C. auris*, *C. dubliniensis*, *C. glabrata*, *C. krusei*, *C. lusitaniae*, *C.parapsilosis*, *C. tropicalis*. Fosmanogepix not active against *C. krusei*.
† including *A. calidoustus*, *A. fumigatus* (including azole-resistant), *A. flavus*, *A. lentulus*, *A. nidulans*, *A. niger, A. terreus*, *A. tubingensis*.
‡ including *Cunninghamella spp.*, *Lichtheimia spp.*, *Mucor spp.*, *Rhizopus spp*.
§ including *Blastomyces dermatitidis*, *Coccidioides immitis*, *Histoplasma capsulatum*.
‖ including *Alternaria alternata*, *Cladosporium spp*. *Paecilomyces variotii*, *Purpureocillium lilacinum*, *Scopulariosis spp.*, *Rasamsonia spp*.
¶ including *Trichosporon asahii*, *Exophiala dermatitidis*, *Malassezia furfur*.

Adapted from Hoenigl M, Sprute R, Egger M, at al. Drugs. 2021;81:1703-1729.

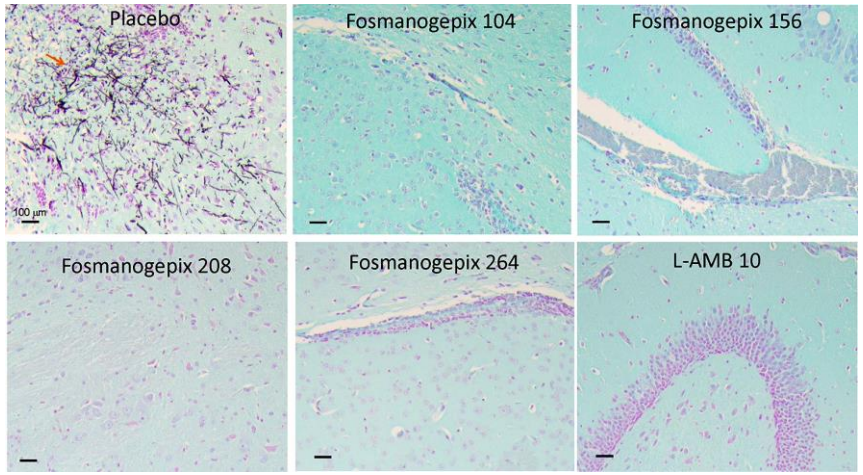
# Efficacy demonstrated in preclinical models

- Efficacy demonstrated in numerous *in-vivo* fungal infection models including azole/echinocandin-resistant isolates:
  - Disseminated and/or CNS infection models with various *Candida spp.* including *C. auris, Crytococcus neoformans and Fusarium solani*
  - Pulmonary infection models with *Aspergillus fumigatus, Aspergillus flavus, Coccidioides immitis, Lomentospora prolificans, Rhizopus spp.,* and *Scedosporium apiospermum*
- In addition to increased survival, reduction of fungal burden in lung, kidney, spleen, eye and brain was demonstrated in several animal models

**Efficacy of fosmanogepix in an immunocompromised murine model of disseminated *C. auris* infection**




**Efficacy of fosmanogepix in clearing CNS tissues in an immunocompromised murine model of disseminated *Scedosporium apiospermum* infection**




Shaw KJ, Ibrahim AS. J Fungi (Basel). 2020; 6:239.
Hager CL, Larkin EL, Long L, et al. Antimicrob Agents Chemother. 2018;62:e02319-17
Alkhazraji S, Gebremariam T, Alqarihi A, et al. Antimicrob Agents Chemother. 2020;64:e01735-19

# Completed clinical phase 1/2 program

| | |
|---|---|
| **Seven phase 1 studies in healthy subjects**<br>• Established dose range and safety/tolerability profile<br>• >90% oral bioavailability<br>• No significant food effect<br>• Broad tissue distribution to relevant target organs (mass balance study)<br>• Low propensity for CYP3A4 inhibition | **Fosmanogepix treatment up to 6 weeks** |
| **One phase 1 B study in neutropenic patients with AML**<br>• Consistent safety and tolerability profile | **Fosmanogepix treatment up to 2 weeks** |
| **Three phase 2 studies in patients with candidemia, candidemia with *C. auris*, and invasive mold infections**<br>• Proof of concept achieved based on survival and clinical success rates adjudicated by an independent review committee<br>• Safety and tolerability characterized by drug-related adverse events of headache, dizziness, fatigue, nausea and vomiting | **Fosmanogepix treatment up to 6 weeks** |
| **More than 300 subjects treated with fosmanogepix** | |


Shaw KJ, Ibrahim AS. J Fungi (Basel). 2020; 6:239.

Hodges MR, Ople E, Wedel P, et al. Antimicrob Agents Chemother. 2023;67:e0162322.

Vazquez JA, Pappas PG, Boffard K, et al. Antimicrob Agents Chemother. 2023;67(5):e0141922.

Pappas PG, Vazquez JA, Oren I, et al. J Antimicrob Chemother. 2023:dkad256

# Planned global phase 3 program

## Candidemia / Invasive candidiasis

- Randomized, double-blind, non-inferiority study
  - Approximately 450 patients
- Fosmanogepix IV (oral step-down fosmanogepix) vs caspofungin IV (oral step-down to fluconazole)
- Primary endpoints
  - FDA: Survival at 30 days
  - EMA: Overall response at end-of-study treatment
- Protocol and initial Health Authority approvals obtained
- Expected study start mid-2024

## Invasive mold infections (IMI)

- Randomized, open-label study including non-controlled salvage treatment arm
  - Approximately 200 patients
- Cohorts of invasive mold disease including IMI caused by:
  - *Aspergillus* spp.
  - *Fusarium* spp.
  - *Scedosporium* spp.
  - *Lomentospora prolificans*
  - Mucorales fungi, or
  - Other multi-drug resistant molds
- Fosmanogepix IV or oral vs best available therapy
- Endpoints include survival and overall response
- Expected study start end-2024

Antifungal

# BAL2062

Invasive *Aspergillus* infections

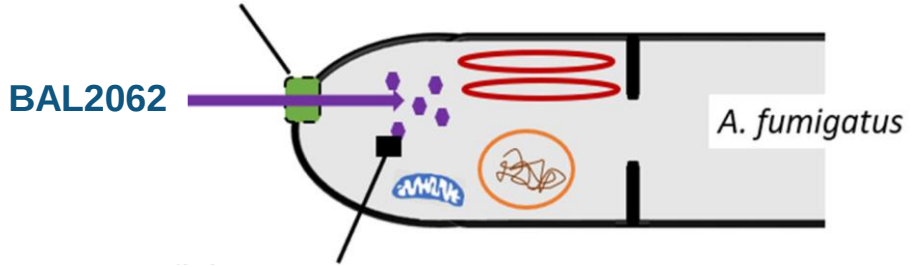
# Profile of BAL2062 (formerly GR-2397)

- First-in class antifungal with novel mechanism of action for intravenous administration
- Rapid fungicidal activity in vitro against *Aspergillus* spp.[1]
- Lack of cross resistance with marketed antifungal agents[2]
- Active against azole- and amphotericin B-resistant *Aspergillus* spp.[2]
- Active in invasive pulmonary aspergillosis animal models[1]
- Low propensity for CYP-450 mediated drug-drug interactions[2]

**BAL2062 – a siderophore antifungal agent**

**→ Uptake into fungal cells via iron transporter**

= similar principle as cefiderocol uptake into bacterial cells

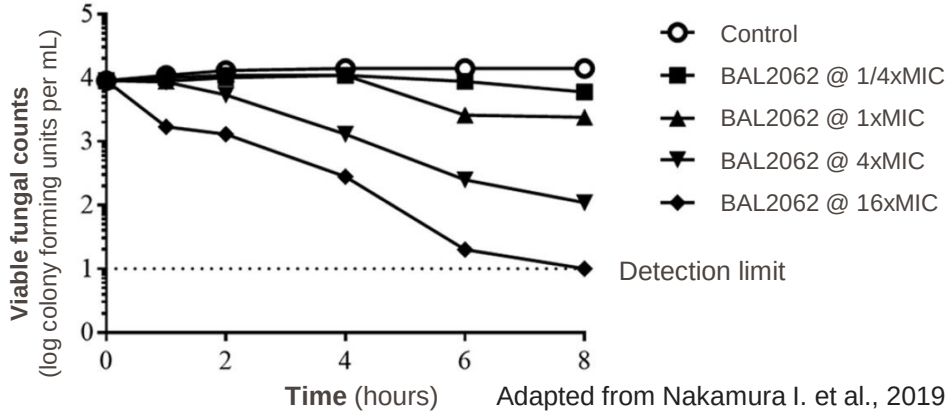



Adapted from Shaw KJ., 2022

[1] Nakamura I, Ohsumi K, Takeda S, et al. Antimicrob Agents Chemother. 2019;63:e02689-18.
[2] Shaw KJ. J Fungi (Basel). 2022; 8:909.

# Profile of BAL2062 (formerly GR-2397) cont.

- Clinical safety and tolerability demonstrated in phase 1 study[1]
- Potential for enhanced clinical efficacy addressing unmet medical needs in invasive aspergillosis and other invasive fungal infections
- Plan to start clinical phase 2 program in H1 2025 based on results from additional preclinical profiling studies
- QIDP, Orphan Drug and Fast Track designations granted from the FDA for invasive aspergillosis[2]




Rapid and potent in vitro fungicidal activity of BAL2062 against *A. fumigatus* 20025.

[1] Mammen MP, Armas D, Hughes FH, et al. Antimicrob Agents Chemother. 2019;63:e00969-19.
[2] Shaw KJ. J Fungi (Basel). 2022; 8:909.

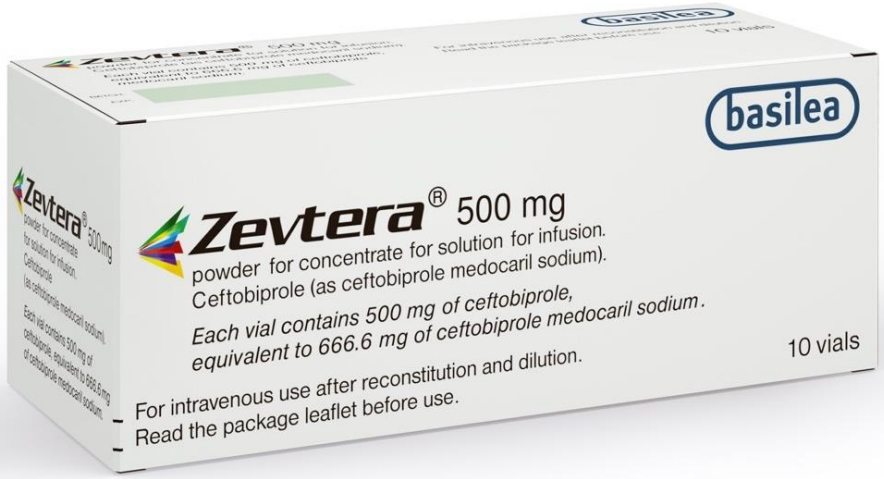
Antibacterial

# Zevtera® (ceftobiprole)

Severe bacterial infections

# Zevtera® — An introduction

- Broad-spectrum hospital anti-MRSA cephalosporin (including Gram-negative bacteria)
  - Rapid bactericidal activity
  - Potential to replace antibiotic combinations
  - Efficacy demonstrated in phase 3 clinical studies in SAB, ABSSSI and pneumonia[1, 2, 3]
  - Low propensity for resistance development[1]
  - Safety profile consistent with the cephalosporin class safety profile, demonstrated in both adult and pediatric patients[1, 2, 3, 4]
- Marketed in selected countries in Europe, Latin America, the MENA-region and Canada
- US FDA PDUFA target action date April 3, 2024



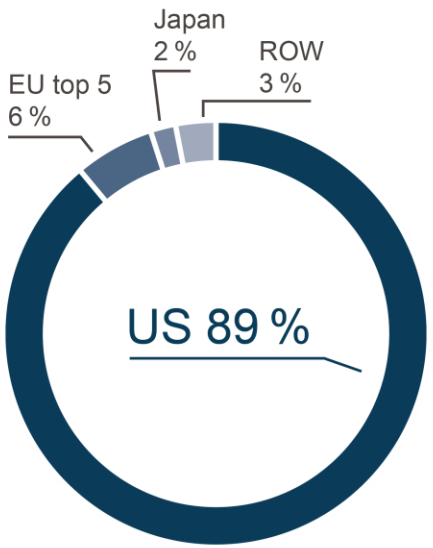

Approved in major European countries & several non-European countries for both hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated pneumonia (VAP), and community-acquired bacterial pneumonia (CABP). Not approved in the US

MENA: Middle East and North Africa

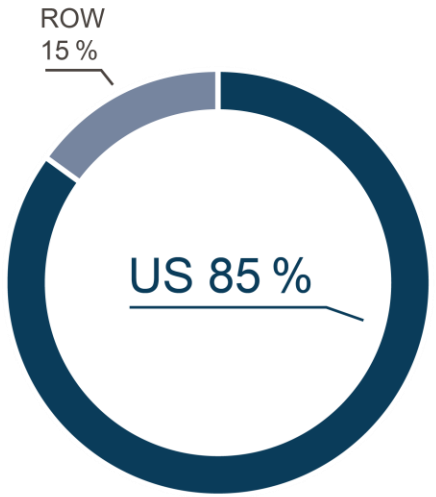

[1] Syed YY. Drugs. 2014;74:1523-1542 and Basilea data on file.
[2] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.
[3] Holland TL et al. N Engl J Med 2023;389:1390-1401.
[4] Rubino CM et al. Pediatr Infect Dis J. 2021;40:997-1003.

# The hospital anti-MRSA antibiotic market — A USD 2.4 bn market* with the US being the most important region

**Daptomycin sales by region (2015, before LOE)**




**Ceftaroline sales by region (MAT Q3 2023)**




* Vancomycin, linezolid, teicoplanin, daptomycin, tigecycline, telavancin, ceftaroline, dalbavancin, ceftobiprole, oritavancin and tedizolid (daptomycin and tigecycline are partial sales in the US in IQVIA data)

MRSA: Methicillin-resistant *Staphylococcus aureus*; LOE: Loss of exclusivity; ROW: Rest Of World; MAT: Moving annual total; Source: IQVIA Analytics Link, September 2023

# Ceftobiprole — Strategy for accessing the US market

- FDA accepted NDA submission for three indications:
  1. *Staphylococcus aureus* bacteremia (SAB)[1]
  2. Acute bacterial skin and skin structure infections (ABSSSI)[2]

     TARGET ABSSSI Study  ERADICATE SAB Study
  3. Previously completed phase 3 study in community-acquired bacterial pneumonia (CABP) as a third indication[3]

- PDUFA target action date April 3, 2024
- Phase 3 program largely funded by BARDA (~USD 112 million, or approximately 75 percent of the costs related to the SAB and ABSSSI phase 3 studies, regulatory activities and non-clinical work)
- Qualified Infectious Disease Product (QIDP) designation extends US market exclusivity to 10 years from approval
- Commercialization planned through partnership
  - Partnership expected prior to regulatory decision

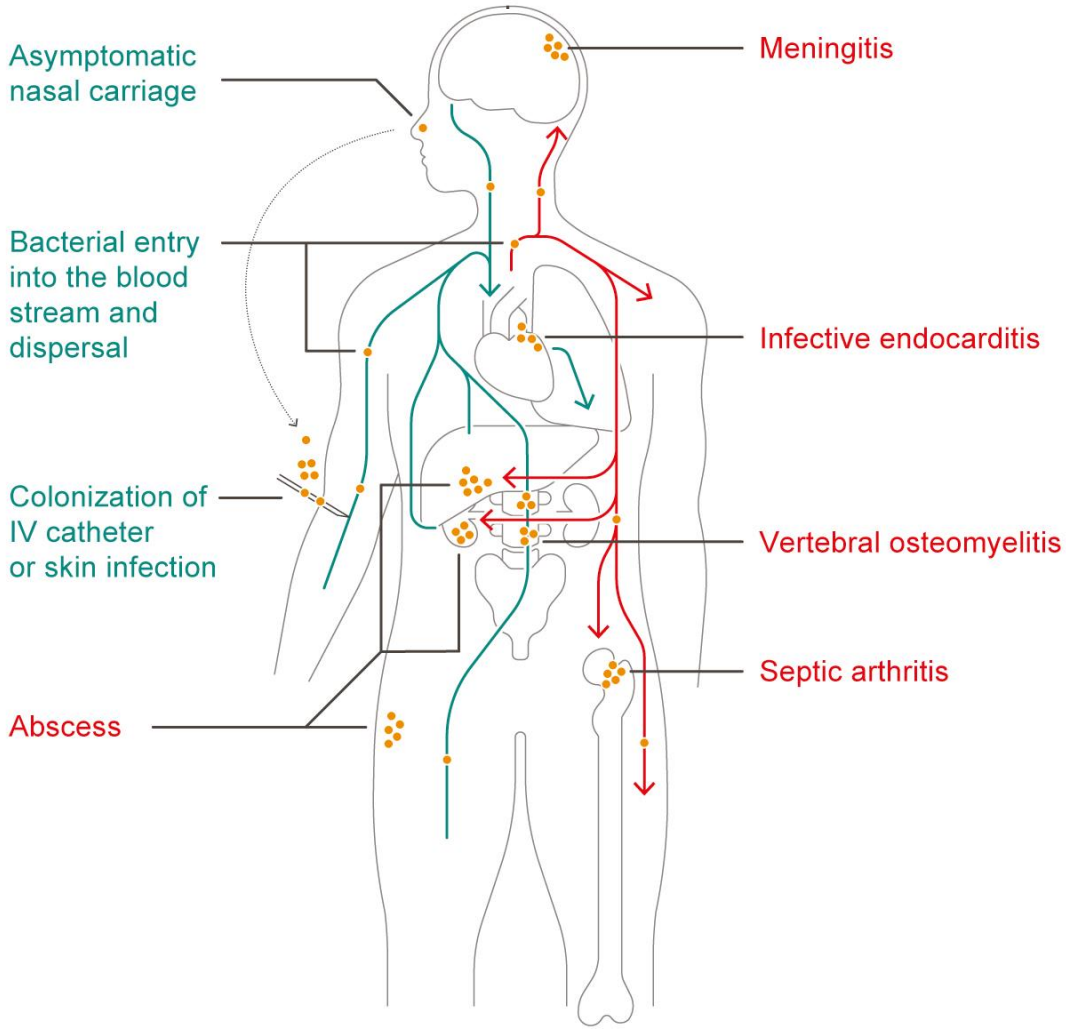
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY BARDA

[1] Holland TL et al. N Engl J Med 2023;389:1390-1401.
[2] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.
[3] Nicholson SC et al. International Journal of Antimicrobial Agents 2012 (39), 240-246.

# SAB – An area with high medical need

- Nearly 120,000 *S. aureus* bloodstream infections in the US (in 2017)[1]
- ERADICATE targets complicated SAB, characterized by concomitant or metastatic infections such as bone, joint or heart valve infections; persistent bacteremia; or bacteremia in patients on dialysis
- Substantial morbidity and approximately 20% 30-day mortality[2]
- Limited antibiotic treatment options with only two approved treatments for SAB in the US that cover both MSSA and MRSA, i.e. vancomycin and daptomycin

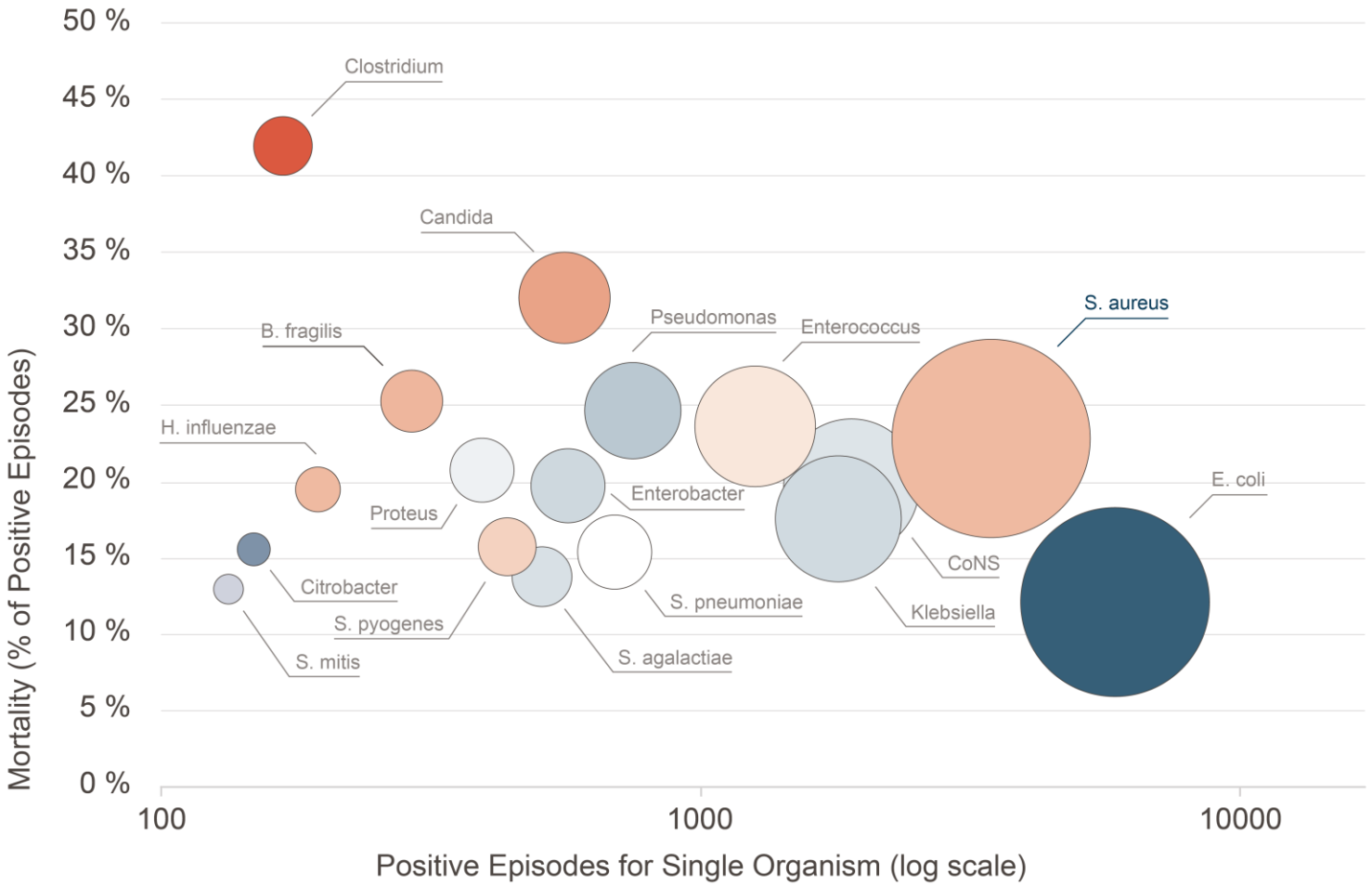
**Causes and consequences of SAB**




Adapted from Edwards AM et al. Trends Microbiol. 2011;19:184-190.

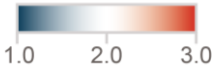
[1] MMWR, 2019;68:214–219.
[2] Hamed K et al. Future Microbiol. 2020;15:35-48.
MRSA: methicillin-resistant *Staphylococcus aureus*
MSSA: methicillin-susceptible *Staphylococcus aureus*

# SAB — Highest disease burden among bloodstream infections




- Circle areas reflect total number of deaths
- Color coding represents the risk of dying from the pathogen relative to a control

Adjusted Mortality OR




Adapted from: Verway M et al. J Clin Microbiol. 2022;60:e0242921.

# ERADICATE — The largest phase 3 registrational study conducted in SAB[1]

- ERADICATE is the largest phase 3 study conducted for registrational purposes of a new antibiotic treatment in *Staphylococcus aureus* bacteremia.
- The randomized, double-blind, multicenter phase 3 study was a global study performed in 60 study centers in 17 countries from August 2018 to March 2022.
- 390 patients were randomized to ceftobiprole or daptomycin, with or without intravenous aztreonam for coverage of Gram-negative pathogens, for up to 42 days of treatment.
- Patient characteristics in the 387 patients included in the modified intent-to-treat (mITT) population were balanced between the treatment groups.
- Primary objective of demonstrating non-inferiority compared to daptomycin was achieved, similar outcomes observed for secondary endpoints.

[1] Holland TL et al. N Engl J Med 2023;389:1390-1401.

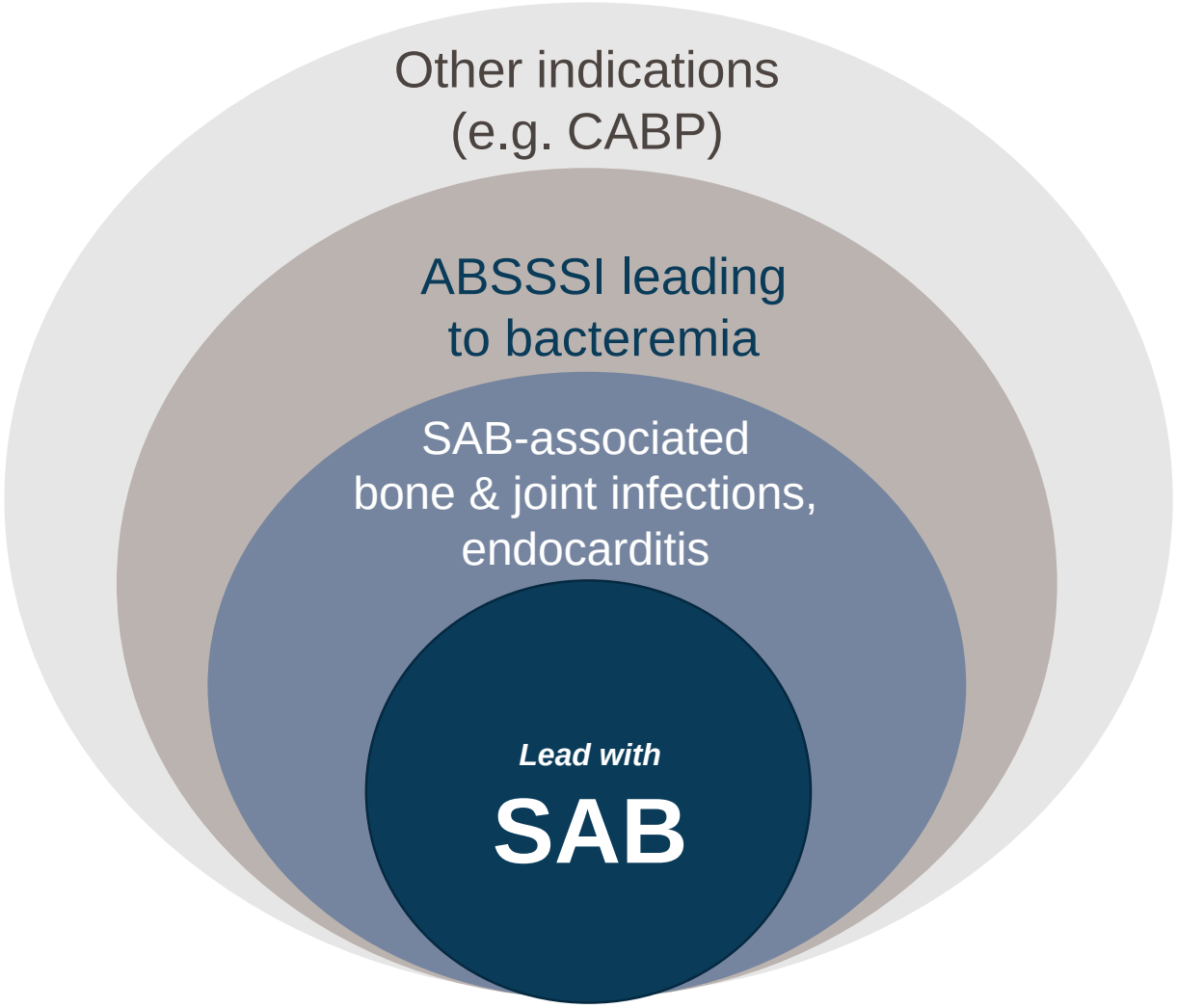
# Ceftobiprole — Place in therapy

- Excellent treatment option in difficult-to-treat patients presenting to the hospital with severe infections, especially when the clinician suspects involvement of Gram-positive pathogens including *Staphylococcus aureus*
- Single agent first-line bactericidal broad-spectrum therapy with proven efficacy in SAB, ABSSSI and CABP, enabling to treat these vulnerable patients effectively early in their disease to achieve recovery
- Ceftobiprole is differentiated versus competitors in various clinically important aspects, including:
  - The strong, bactericidal activity against MSSA and MRSA
  - A robust Gram-negative coverage
  - Efficacy demonstrated in pulmonary infections in phase 3 studies
  - The safety profile reflecting the cephalosporin class
  - The low propensity for resistance development

# Focused launch in area of highest unmet medical need with opportunities for broader utilization

**Patient numbers in the United States**

- *Staphylococcus aureus* bacteremia (SAB): 120,000 cases[1]
- Acute bacterial skin and skin structure Infections (ABSSSI): >600,000 hospitalizations per year[2]
- Community-acquired bacterial pneumonia (CABP): >1,500,000 hospitalizations per year[3]

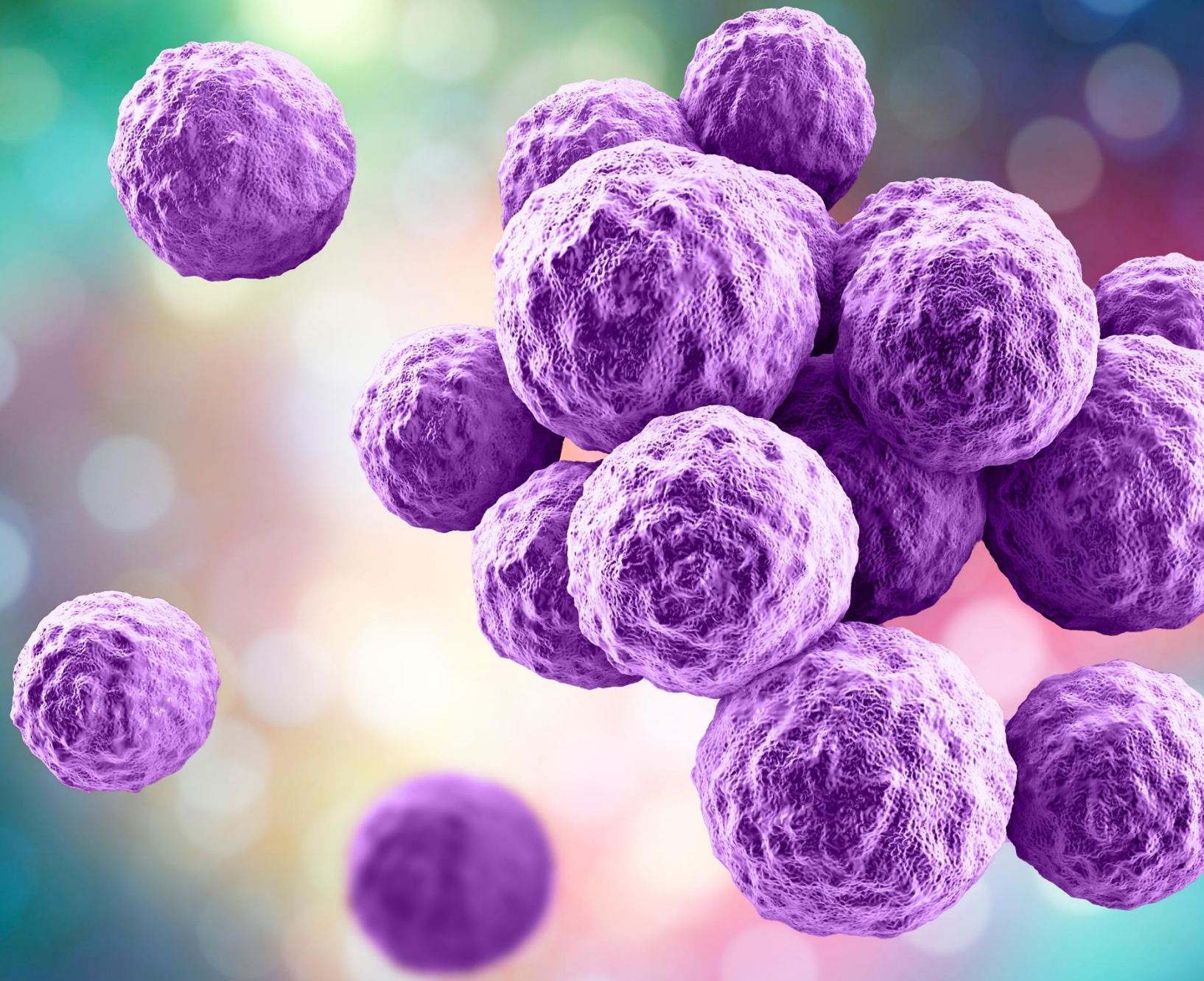



[1] Kourtis AP et al. MMWR Morb Mortal Wkly Rep. 2019;68:214-219.
[2] Edelsberg J et al. Emerg Infect Dis. 2009;15:1516-8.
[3] Ramirez JA et al. Clin Infect Dis. 2017;65:1806-1812.

Antibacterial

# Tonabacase

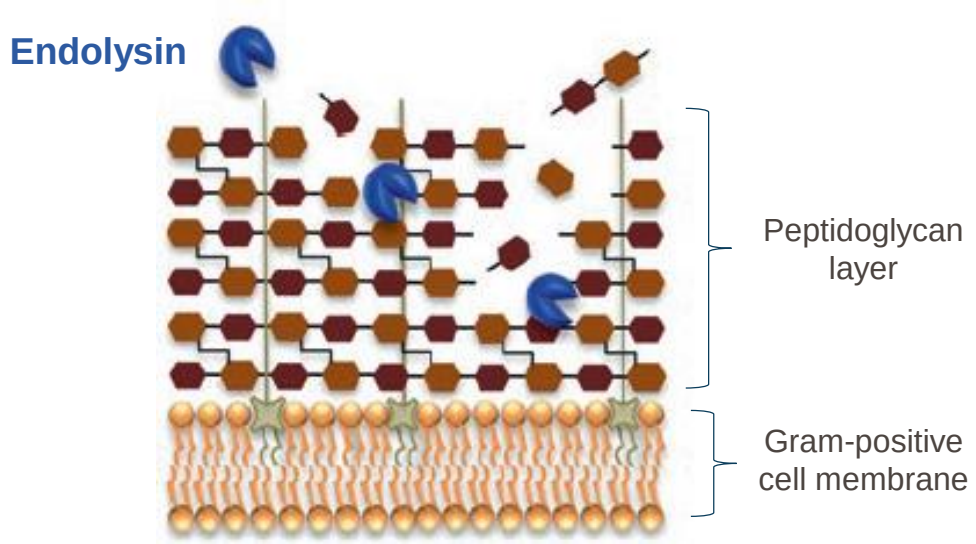
Severe staphylococcal infections



# Endolysins — Overview

- Endolysins are recombinant proteins from bacteriophages
  - Responsible for cell wall cleavage and bacterial cell lysis
- Pathogen-specific spectrum
- Advantages over conventional antibiotics[1, 2]
  - Rapid killing of bacterial cells
  - Effective against multidrug-resistant bacteria and biofilms
  - Low risk of resistance development
  - Minimal off-target damage preventing significant microbiome disruption
  - Synergy with standard-of-care antibiotics
  - Typically used in combinations

**Schematic representation of endolysin effects on Gram-positive bacteria**



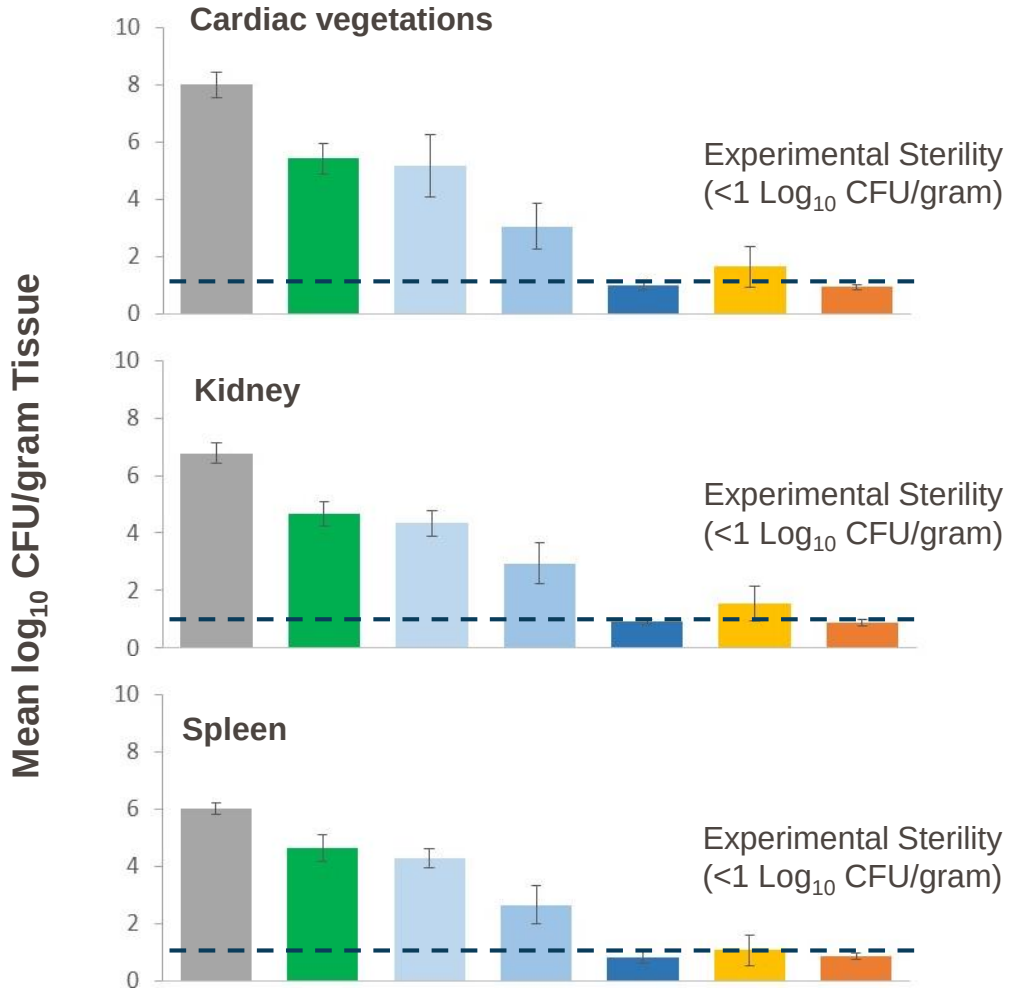

Reference: Dams D and Briers Y, 2019[3]

[1] Liu H, Hu Z, Li M et al. J Biomed Sci 2023 (30), 29
[2] Abdelrahman F, Easwaran M, Daramola O et al. Antibiotics 2021 (10) 124
[3] Dams D, Briers Y Adv Exp Med Biol. 2019:1148:233-253

# Profile of tonabacase

- Potential first-in-class antibiotic of the endolysin class for the treatment of severe staphylococcal infections
  - Potential for superiority in combination therapy vs. standard-of-care antibiotics
- Activity in *S. aureus* infection models
  - Activity against MRSA and MSSA[1]
- Clinical safety and tolerability demonstrated in phase 1 studies[2, 3]
  - Potential to administer multiple doses of tonabacase
- Plan to start clinical phase 2 program in 2025 upon completion of preclinical profiling
  - Evaluation license and exclusive option to license upon successful completion of preclinical profiling

**Reduction of MRSA counts (cardiac vegetations, kidneys, and spleen) in left-sided endocarditis model**

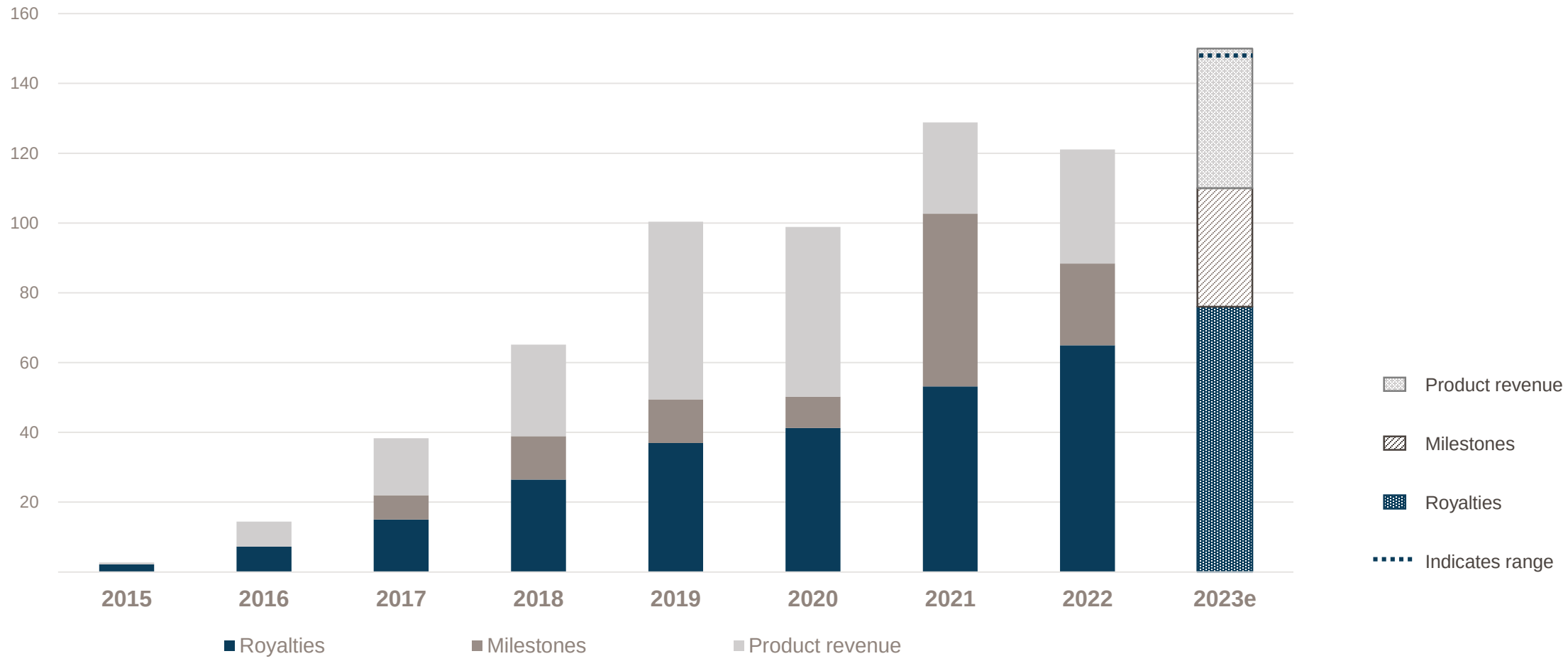



CFU: Colony forming unit; Adapted from Huang DB, Gaukel E, Kerzee N, et al. 2021[4]

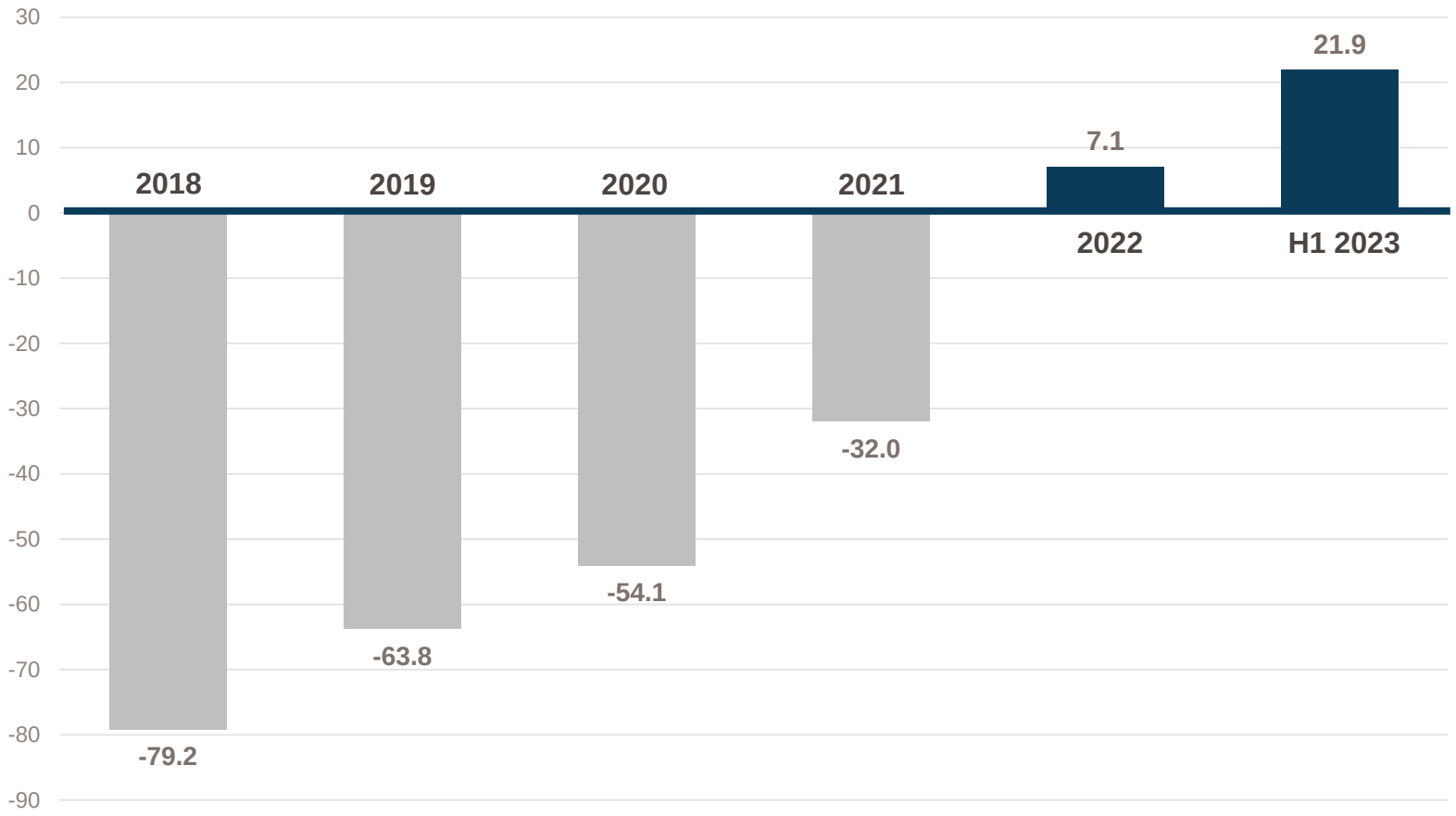
[1] Kim NH, Park WB, Cho JE et al. Antimicrob Agents Chemother 2018 (62), e00731-18
[2] Jun SY, Jang J, Yoon S. et al. Antimicrob Agents Chemother 2017 (61), e02629-16
[3] Wire MB, Jun SY, Jang IJ et al. Antimicrob Agents Chemother 2022 (66), e01842-21
[4] Huang DB, Gaukel E, Kerzee N, et al. Antimicrob Agents Chemother 2021 (65), e00508-21

# Financials & Outlook

# Cresemba & Zevtera related revenue breakdown (in CHF mn)

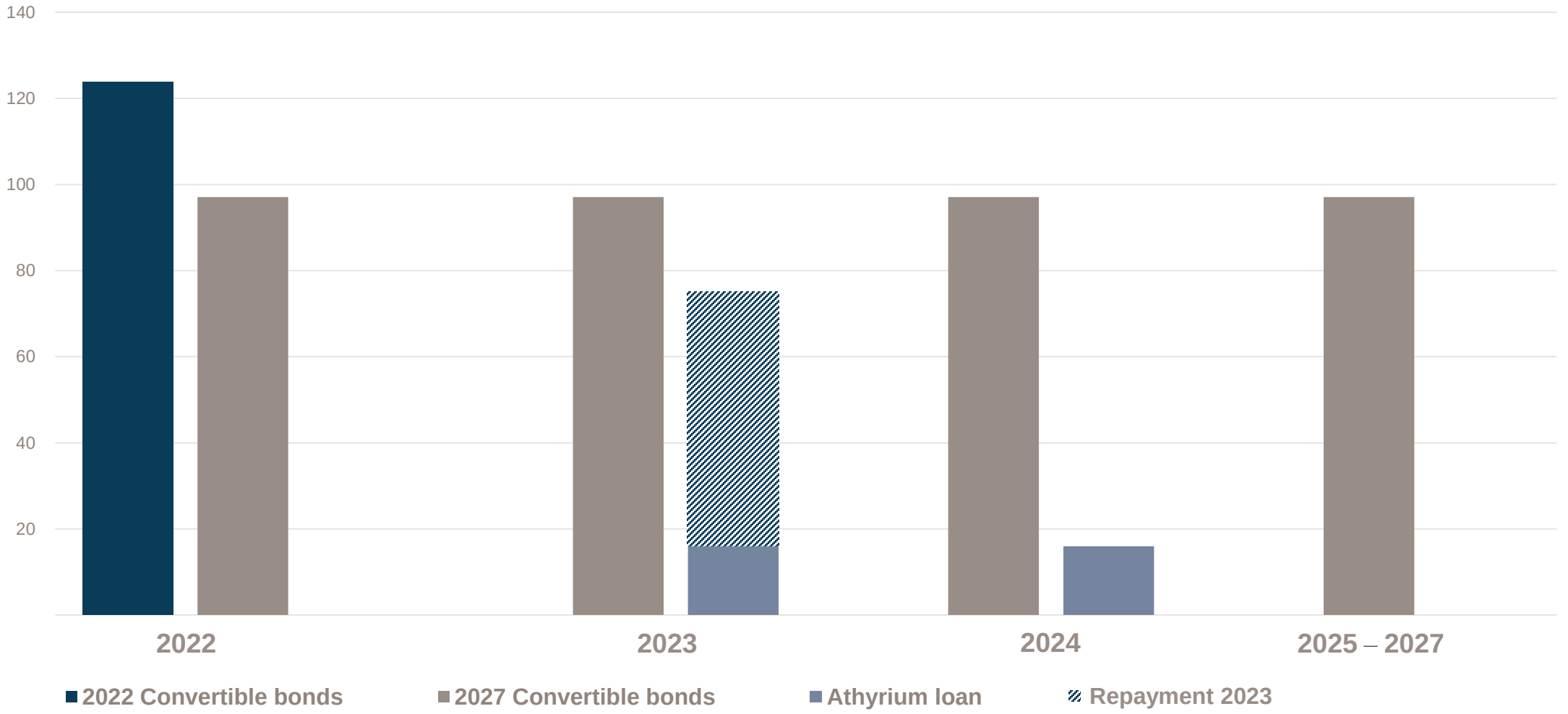


# Cash flows from operating activities (in CHF mn)




Note: Consolidated figures in conformity with US GAAP; rounding applied consistently

# Continued reduction of debt level (in CHF mn)




Note: Figures as of the beginning of the fiscal year; rounding applied consistently

# Updated FY 2023 guidance reflecting impact of in-licensing and acquisitions

| In CHF mn | FY 2023 (new guidance) | FY 2023* (previous guidance) | FY 2022 |
|---|---|---|---|
| **Cresemba & Zevtera related revenue** | **147 – 150** | 147 – 150 | 122.3 |
| ***of which royalty income*** | ***~76*** | *~76* | 65.0 |
| **Total revenue** | **154 – 157** | 157 – 160 | 147.8 |
| **Cost of products sold** | **~27** | 25 – 27 | 24.6 |
| **Operating expenses** | **~115** | ~80 | 104.6 |
| **Operating profit** | **11 – 15** | 50 – 55 | 18.5 |
| **Net profit** | **2 – 6** | 41 – 46 | 12.1 |

*Excluding the impact of in-licensing activities

Note: Consistent rounding was applied.

# Key milestones

| Anti-infective space | Product | H2 2023 | H1 2024 | H2 2024 |
|---|---|---|---|---|
| **Antibacterials** | **Ceftobiprole (Zevtera)** | US NDA submission ✓ | Regulatory decision in the US (PDUFA target action date April 3) | |
| | | US NDA accepted for review ✓ | Executing US partnership (prior to PDUFA target action date) | |
| | **Tonabacase** | Evaluation license & exclusive option to license ✓ | | Decide on definitive licensing option |
| **Antifungals** | **Isavuconazole (Cresemba)** | Pediatric submissions ✓<br>Decision on US pediatric extension ✓ | Decision on EU pediatric extension | |
| | **Fosmanogepix** | Acquisition of rights ✓ | Initiate phase 3 study in candidemia / invasive candidiasis (mid-2024) | Initiate phase 3 study in mold infections (around year-end) |
| | **BAL2062** | Acquisition of rights ✓ | | |

**Increasing Cresemba & Zevtera revenue**

**In-licensing and acquisition of anti-infectives**

**Advancement of preclinical anti-infective assets**

# In-licensing focus

## Partner of choice in the anti-infectives space

- ✓ Strong and proven R&D capabilities to bring drugs from research to market
- ✓ Cost-effective business model
- ✓ Experience in accessing non-dilutive funding incentives
- ✓ Financial strength and strong cash flow generation from commercialized brands

### Antifungals

- Novel mechanisms of action
- Addressing areas of highest unmet medical needs
- Gaining benefits through orphan drug pathways
- Novel formulations

### Commonalities

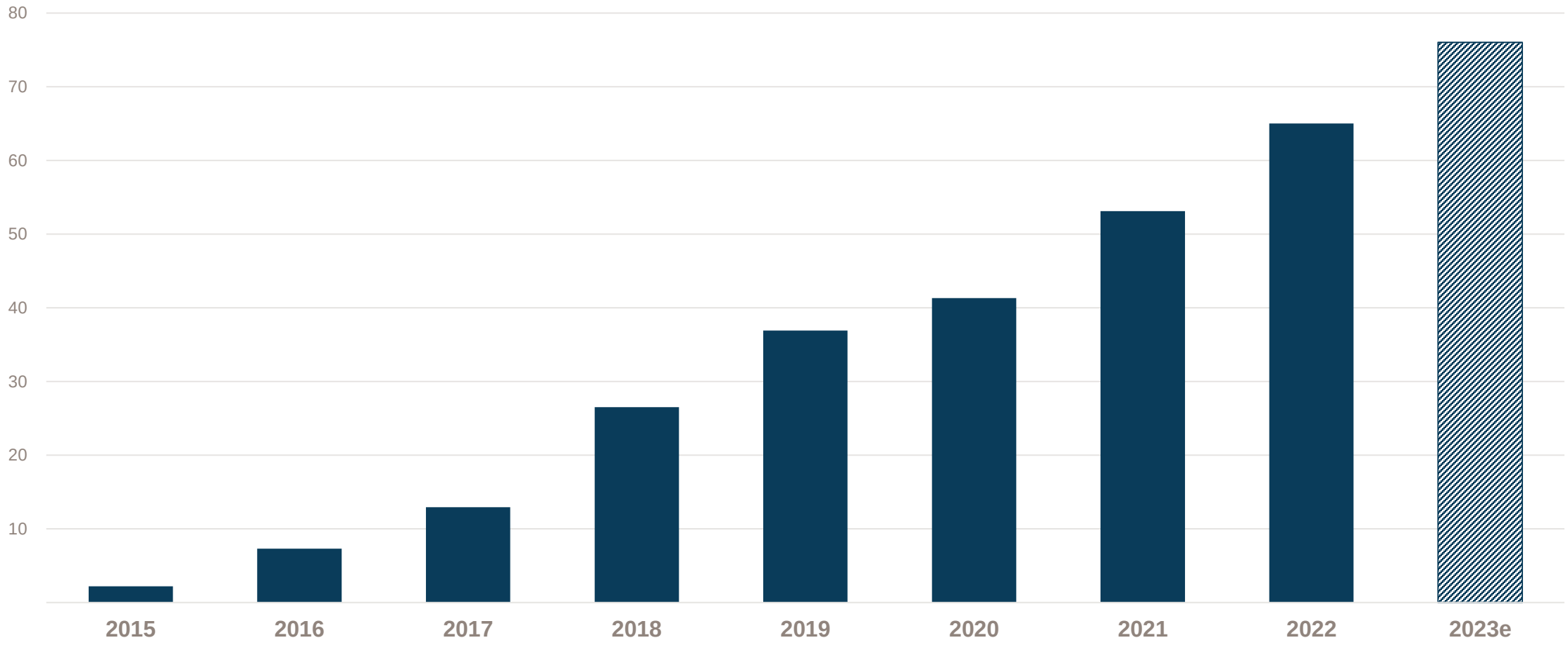
- Addressing serious hospital infections with increasing medical need
- Innovative & differentiated assets with potential for successful commercialization
- In-licensing assets from late stage research through to end of phase 2

### Antibacterials

- Traditional and non-traditional approaches
- Potential for demonstrating superiority
- Balance development risks to optimize market access/label

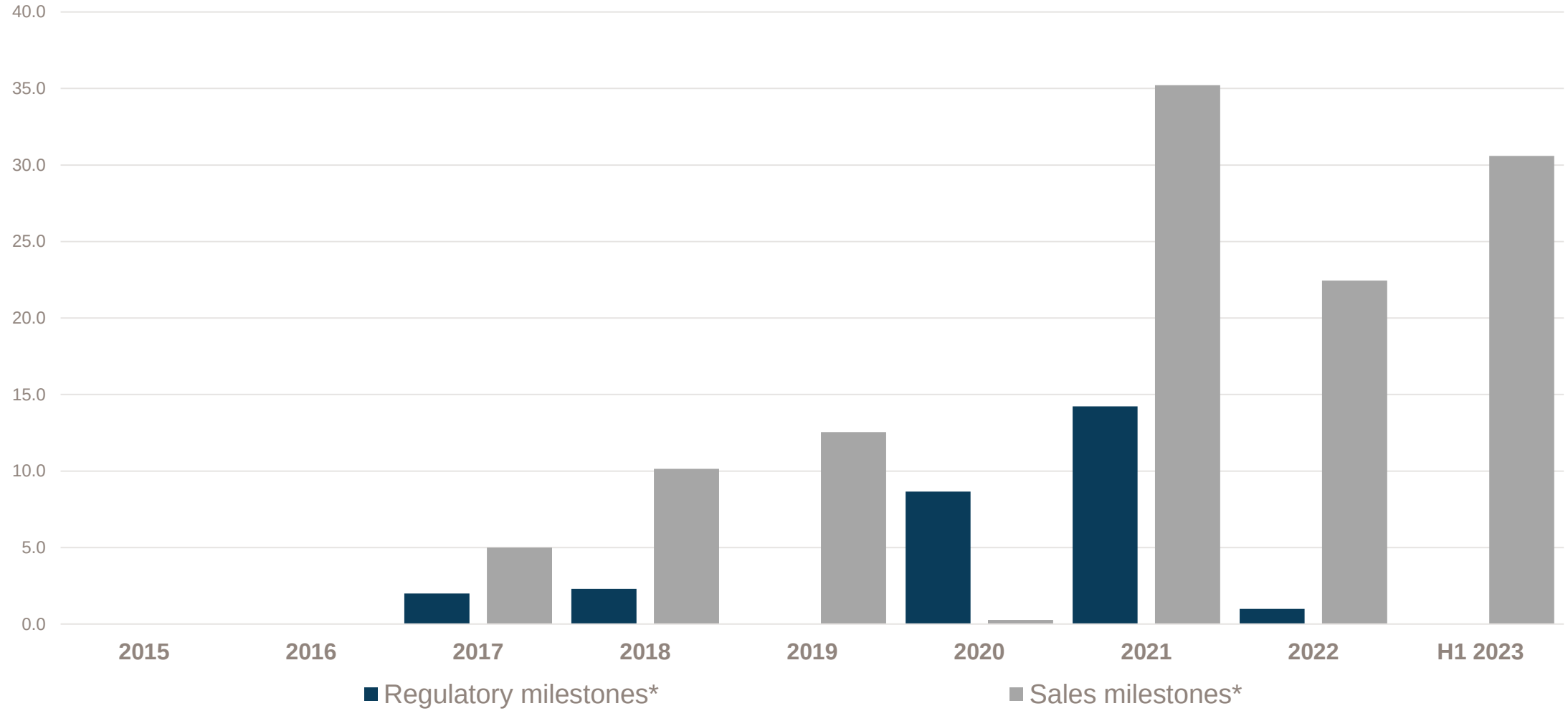
# Appendix

# Cresemba royalty income growth reflects continued commercial success in key territories (in CHF mn)




Note: Consolidated figures in conformity with US GAAP; rounding applied consistently

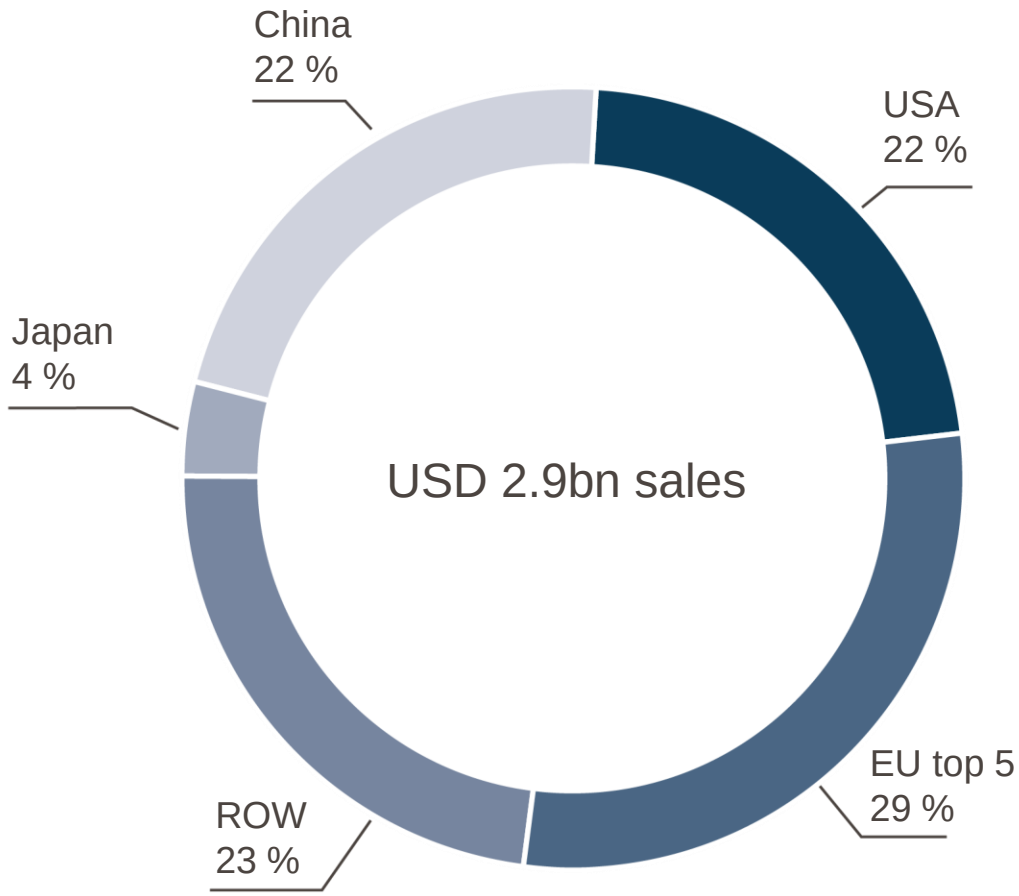
# Regulatory and sales milestones (in CHF mn)




*Combined from license partners and distributors

# Significant growth potential for Cresemba

- USD 2.9 bn sales of best-in-class antifungals* (MAT Q3 2023)
- Recently launched in Japan and China, representing 26% of global potential



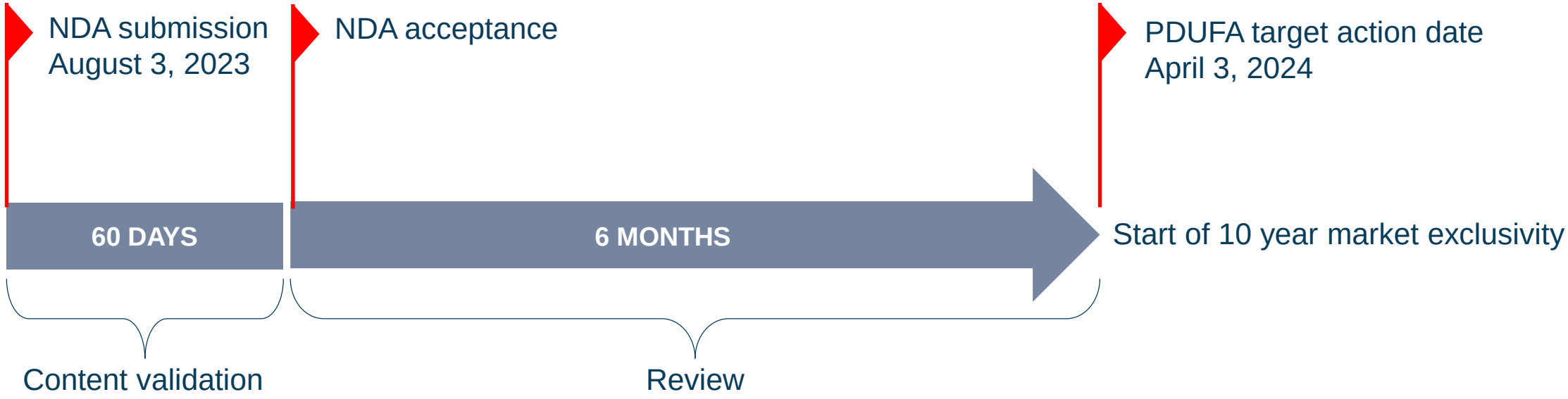

* Best-in-class antifungals: Cresemba (isavuconazole), posaconazole, voriconazole, AmBisome, anidulafungin, caspofungin, micafungin

MAT: Moving annual total; Source: IQVIA Analytics Link, September 2023

# Ceftobiprole — FDA's NDA review process for a Qualified Infectious Disease Product

Ceftobiprole was granted QIDP status for SAB, ABSSSI and CABP

QIDP status provides 6 month priority review and extends market exclusivity to 10 years

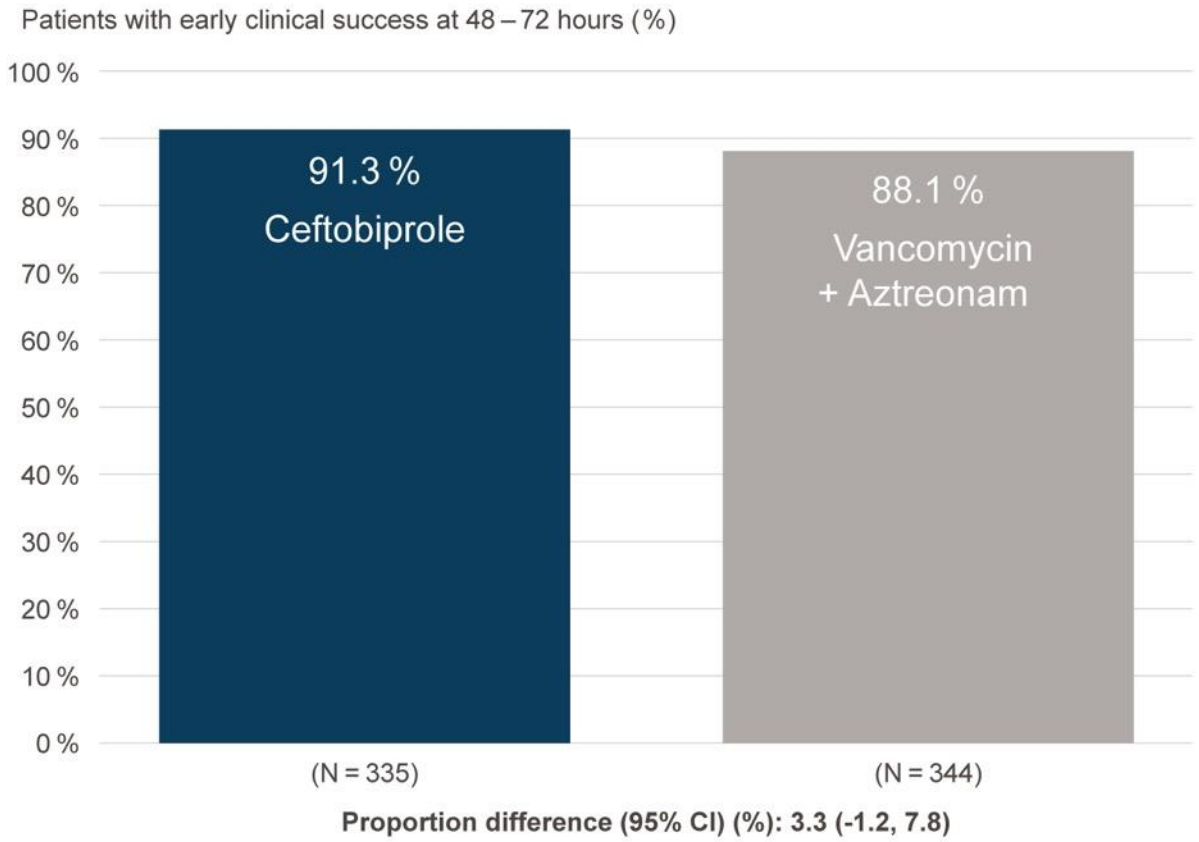


# Ceftobiprole — Positive phase 3 results reported in ABSSSI

Results showing non-inferiority of ceftobiprole to vancomycin plus aztreonam for the primary and secondary endpoints[1]

TARGET ABSSSI Study

## Early clinical response at 48–72h after start of treatment (ITT population)




ITT: intent-to-treat
Pre-defined limit of non-inferiority = lower limit of 95 % CI for difference > -10 %

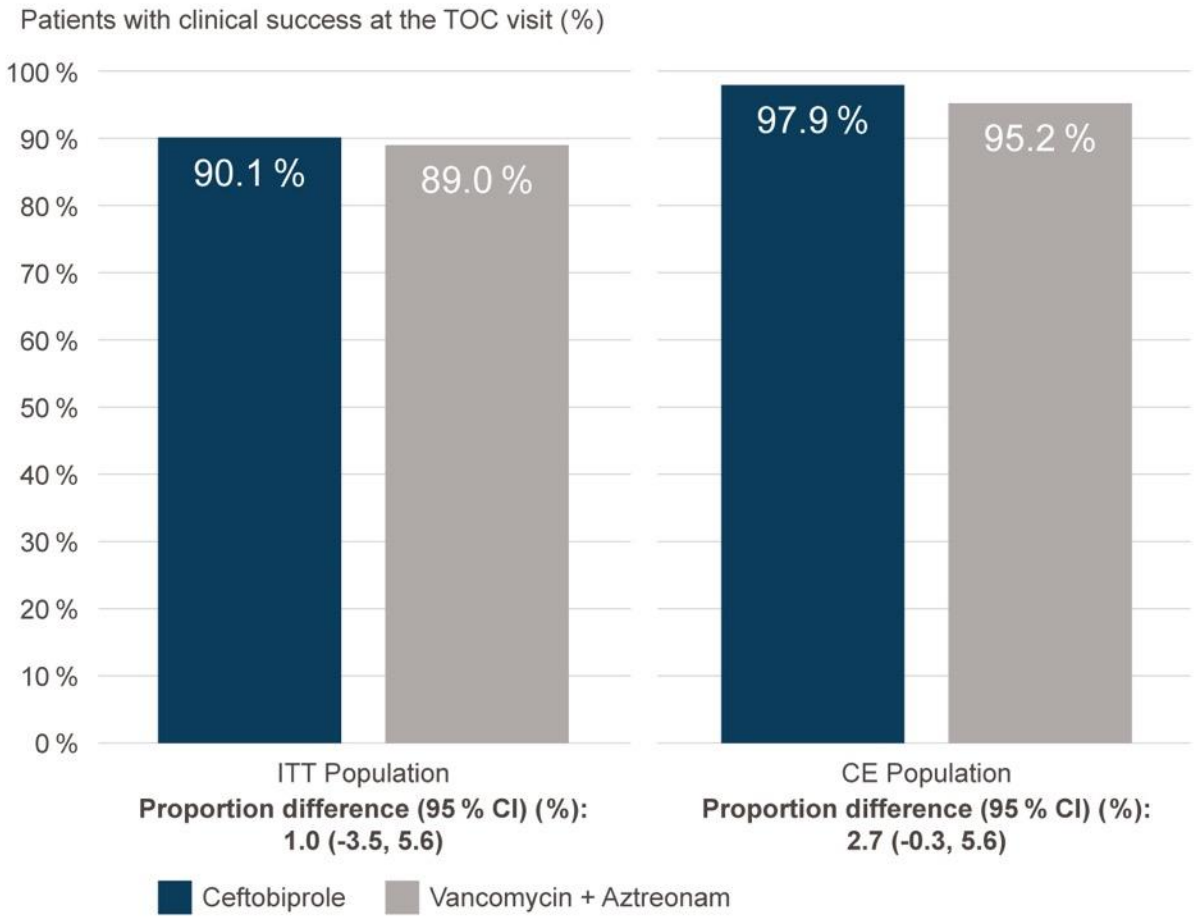
[1] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

# Ceftobiprole — Positive phase 3 results reported in ABSSSI

Key topline study[1] results showing non-inferiority of ceftobiprole to vancomycin plus aztreonam for the primary and secondary endpoints

TARGET ABSSSI Study

## Investigator-assessed clinical success at test-of-cure (TOC) 15-22 days after randomization (ITT, CE populations)

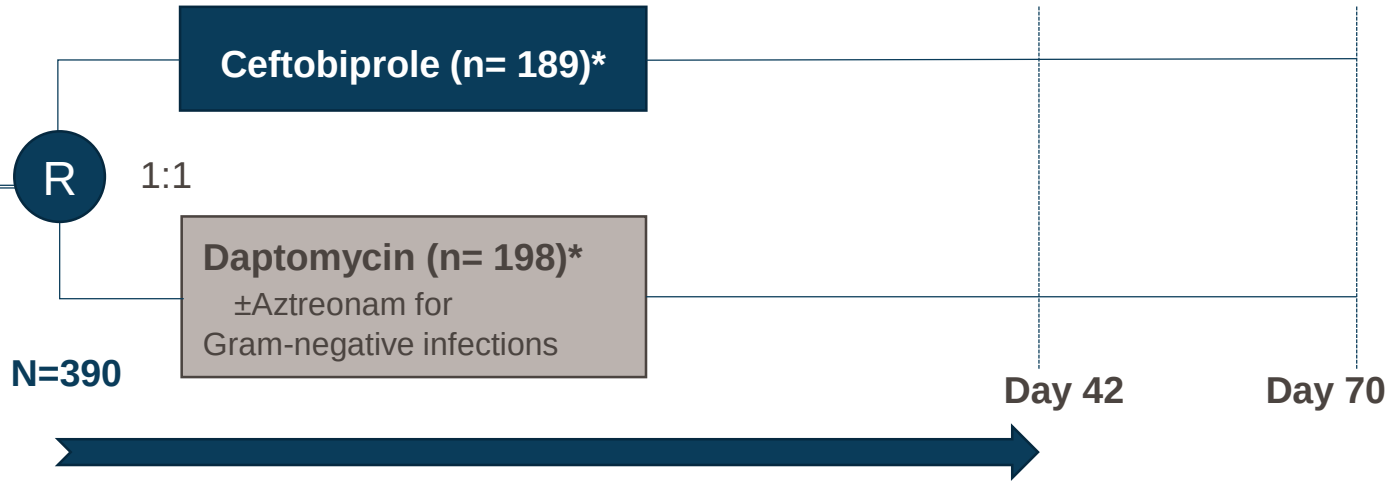



[1] NCT03137173
ABSSSI: Acute bacterial skin and skin structure infections

CE: clinically evaluable; ITT: intent-to-treat

# ERADICATE — SAB[1] Study design

- Patients age ≥ 18 years
- SAB based on ≥1 positive blood culture within 72 h of randomization
- Confirmed or suspected complicated SAB or definitive right-sided infective endocarditis
- Requirement for ≤ 42 days of antibacterial treatment




**Screening assessments (up to 72 hours prior to randomization)**

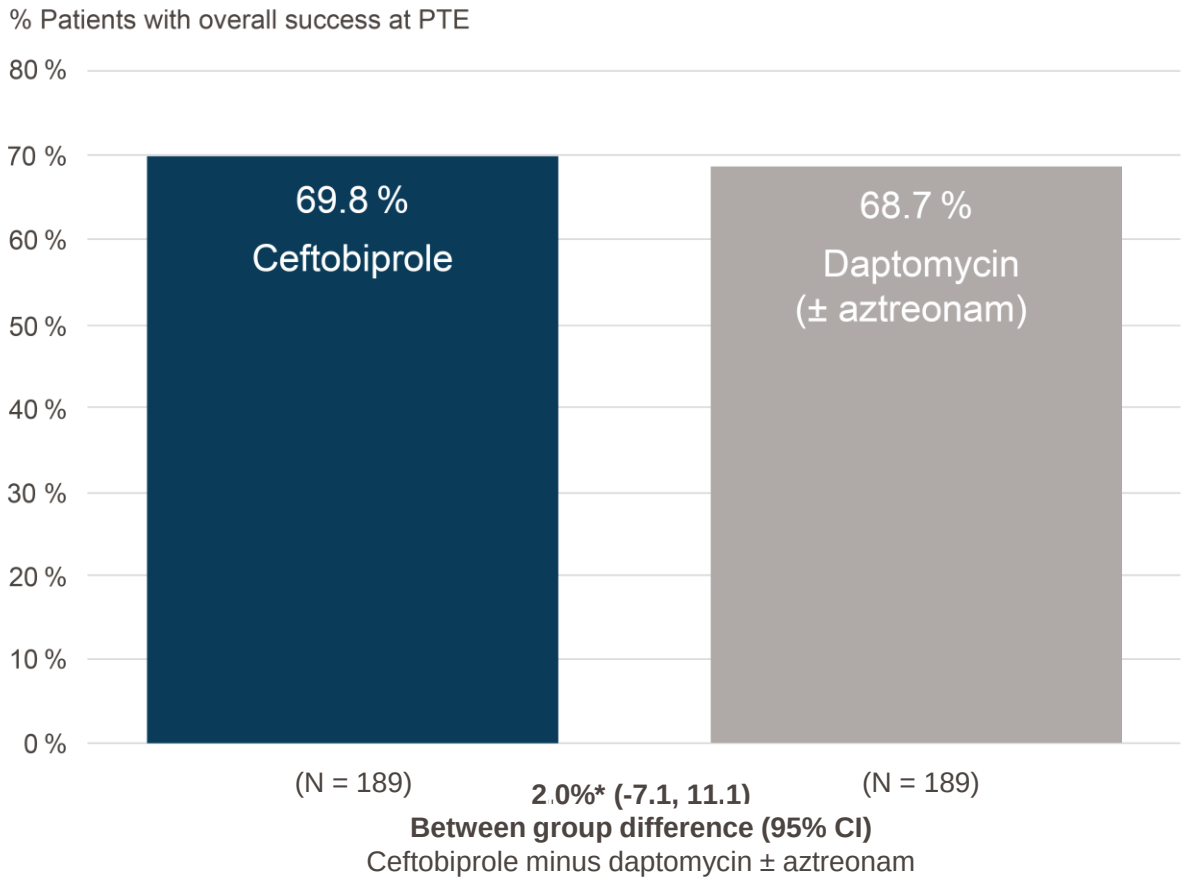
**Active treatment (up to 42 days)**

**Primary endpoint assessment**

Adapted from Hamed K et al. Future Microbiol. 2020;15:35-48

[1] Holland TL et al. N Engl J Med 2023;389:1390-1401.
*Ceftobiprole was administered 500 mg q6h on Day 1-8 and 500 mg q8h from Day 9 onwards. Daptomycin was administered at 6mg/kg up to 10 mg/kg q24h. Three patients in the ITT population were excluded from the modified intent-to-treat population (mITT): One patient was randomized but not dosed, and two patients did not have a positive *S. aureus* blood culture at baseline

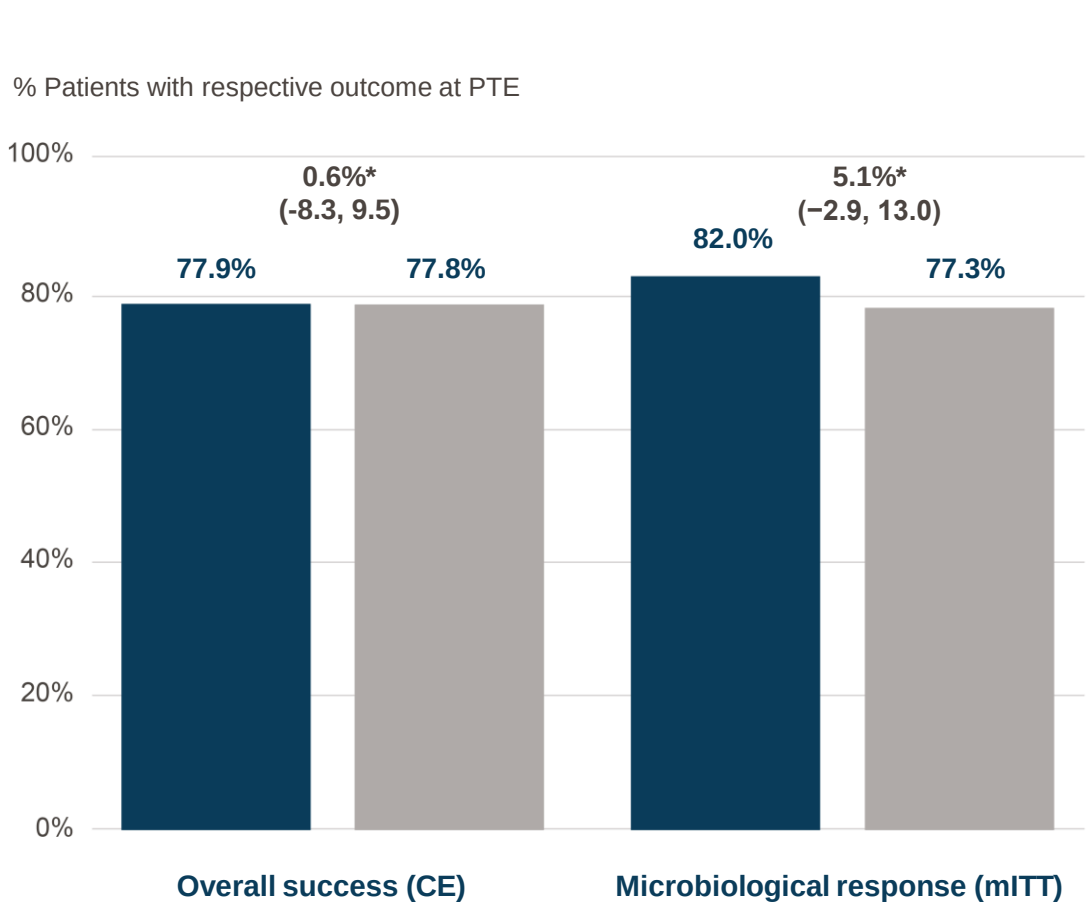
# Primary endpoint in SAB is achieved
## (DRC assessed overall success at PTE in mITT population)

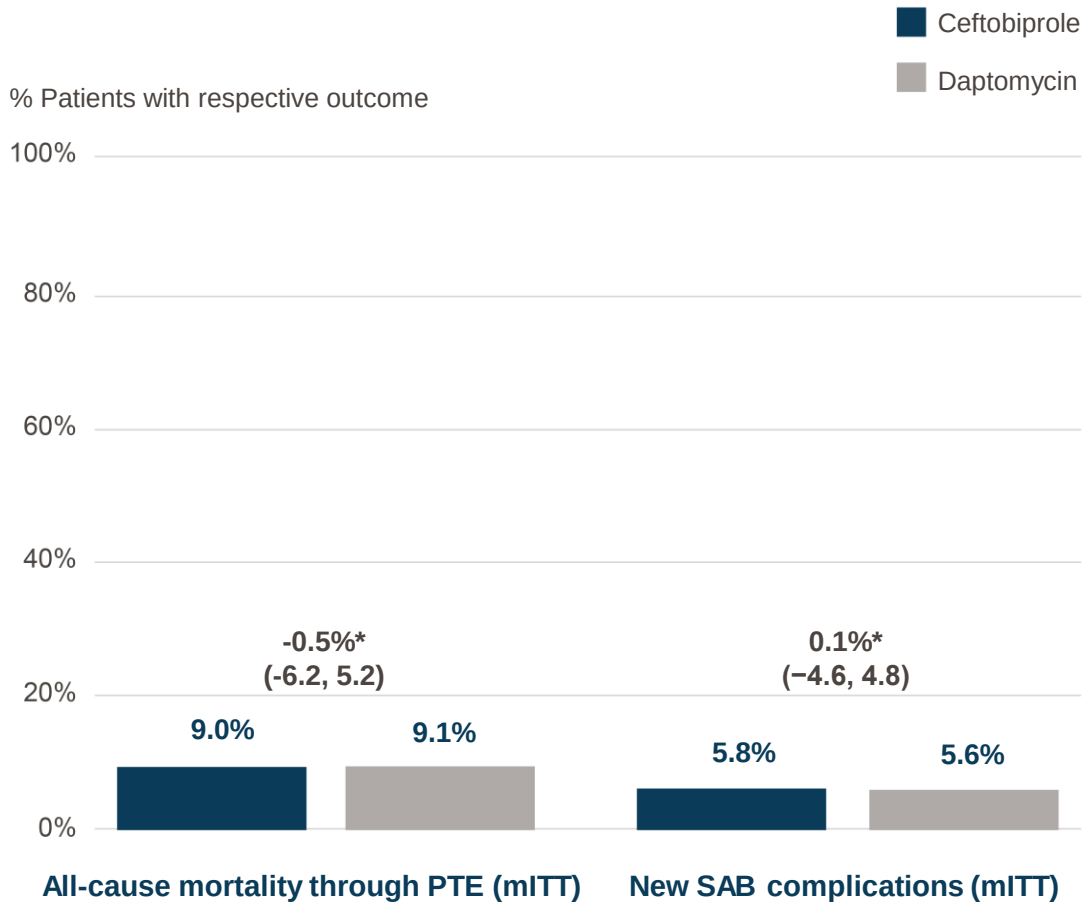



- Non-inferiority demonstrated based on the pre-defined non-inferiority margin of 15%
- Consistent results in key subgroups and various categories of underlying conditions:
  - MSSA or MRSA bloodstream infections at baseline
  - Skin and skin structure infections
  - Abdominal abscesses
  - Chronic dialysis
  - Septic arthritis
  - Osteomyelitis
  - Definite right-sided infective endocarditis
  - Patients with persistent SAB

DRC: Data review committee; PTE: Post-treatment evaluation visit at 70 days post-randomization
*Cochran-Mantel-Haenszel (CMH) weights method adjusted for actual stratum (dialysis status and prior antibacterial treatment use)

# Secondary efficacy outcomes in SAB are similar




* Between-group difference (95%CI) of ceftobiprole minus daptomycin (± aztreonam), adjusted for actual stratum (dialysis status and prior antibacterial treatment use) using Cochran-Mantel-Haenszel weights method. CE: Clinically evaluable population.

# ERADICATE — Further SAB results

- Median time to *Staphylococcus aureus* bloodstream clearance
  - MSSA: 3 days with ceftobiprole and 4 days with daptomycin
  - MRSA: 5 days for both ceftobiprole and daptomycin
- Emergence of resistance under treatment was observed in three patients on daptomycin.
  No emergence of resistance under treatment was observed with ceftobiprole
- Observed ceftobiprole safety and tolerability profile is consistent with previous phase 3 studies and the post-marketing experience
- Ceftobiprole was well tolerated and overall rate of adverse events similar between the ceftobiprole and daptomycin groups; gastrointestinal side effects were more frequent with ceftobiprole (mainly driven by mild to moderate nausea)

# Glossary

- ABSSSI: **A**cute **b**acterial **s**kin and **s**kin **s**tructure **i**nfections
- AML **A**cute **M**yeloid **L**eukemia
- BARDA: **B**iomedical **A**dvanced **R**esearch and **D**evelopment **A**uthority
- CABP: **C**ommunity-**a**cquired **b**acterial **p**neumonia
- CE: **C**linically **e**valuable
- CARB-X: **C**ombating **A**ntibiotic-**R**esistant **B**acteria Biopharmaceutical **Accelerator**
- CNS **C**entral **N**ervous **S**ystem
- CYP-450 **Cy**tochrome-**P-450** enzymes
- DRC: **D**ata **r**eview **c**ommittee
- EMA: **E**uropean **M**edicines **A**gency
- FDA: US **F**ood and **D**rug **A**dministration
- HABP: **H**ospital-**a**cquired **b**acterial **p**neumonia
- ITT: **I**ntent-**T**o-**T**reat
- i.v.: **I**ntra**v**enous
- mITT: **M**odified **i**ntent-**t**o-**t**reat
- MSSA: **M**ethicillin-**s**usceptible ***S**taphylococcus **a**ureus*
- MRSA: **M**ethicillin-**r**esistant ***S**taphylococcus **a**ureus*
- NDA: **N**ew **D**rug **A**pplication
- OR: **O**dds **r**atio
- PDUFA **P**rescription **D**rug **U**ser **F**ee **A**ct
- PTE: **P**ost-**t**reatment **e**valuation
- QIDP: **Q**ualified **I**nfectious **D**isease **P**roduct
- SAB: ***S**taphylococcus **a**ureus* **b**acteremia
- SPA: **S**pecial **P**rotocol **A**ssessment
- US GAAP: **U**nited **S**tates **G**enerally **A**ccepted **A**ccounting **P**rinciples
- VAP: **V**entilator-**a**ssociated **p**neumonia

# Disclaimer and forward-looking statements

This communication, including the accompanying oral presentation, contains certain forward-looking statements, including, without limitation, statements containing the words “believes”, “anticipates”, “expects”, “supposes”, “considers”, and words of similar import, or which can be identified as discussions of strategy, plans or intentions. Such forward-looking statements are based on the current expectations and belief of company management, and are subject to numerous risks and uncertainties, which may cause the actual results, financial condition, performance, or achievements of Basilea, or the industry, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: the uncertainty of pre-clinical and clinical trials of potential products, limited supplies, future capital needs and the uncertainty of additional funding, compliance with ongoing regulatory obligations and the need for regulatory approval of the company’s operations and potential products, dependence on licenses, patents, and proprietary technology as well as key suppliers and other third parties, including in preclinical and clinical trials, acceptance of Basilea’s products by the market in the event that they obtain regulatory approval, competition from other biotechnology, chemical, and pharmaceutical companies, attraction and retention of skilled employees and dependence on key personnel, and dependence on partners for commercialization of products, limited manufacturing resources, management’s discretion as to the use of proceeds, risks of product liability and limitations on insurance, uncertainties relating to public health care policies, adverse changes in governmental rules and fiscal policies, changes in foreign currency and other factors referenced in this communication. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements. Basilea disclaims any obligation to update any such forward-looking statements to reflect future events or developments, except as required by applicable law.

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