# Focused on Growth and Innovation

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

**Investor presentation**

May 23, 2023

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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

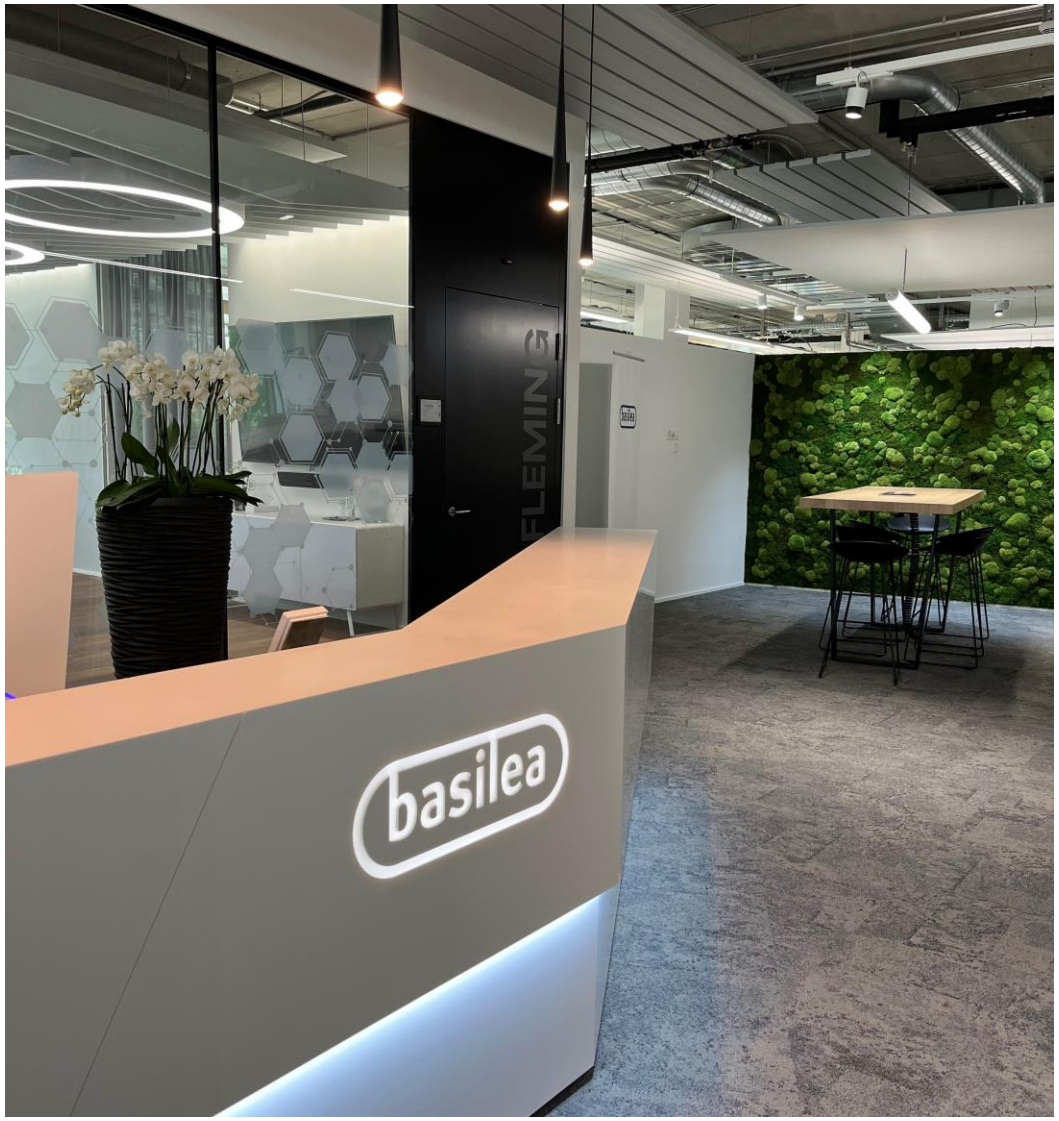
**Laurenz Kellenberger Ph.D.** CSO

Joined: 2000

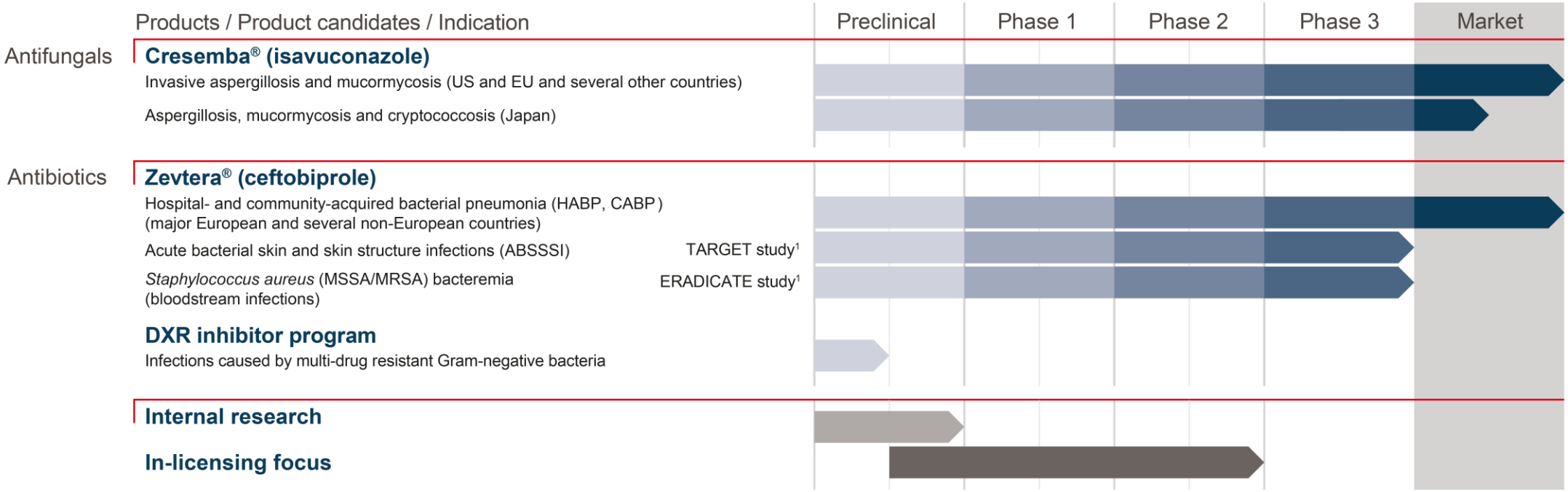
Previous roles: UNIVERSITY OF CAMBRIDGE; Roche

# 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 programs which are in an earlier stage of development
- Profitable company listed on SIX Swiss Stock Exchange, SIX: BSLN
- Located in the Basel area life sciences hub, Switzerland

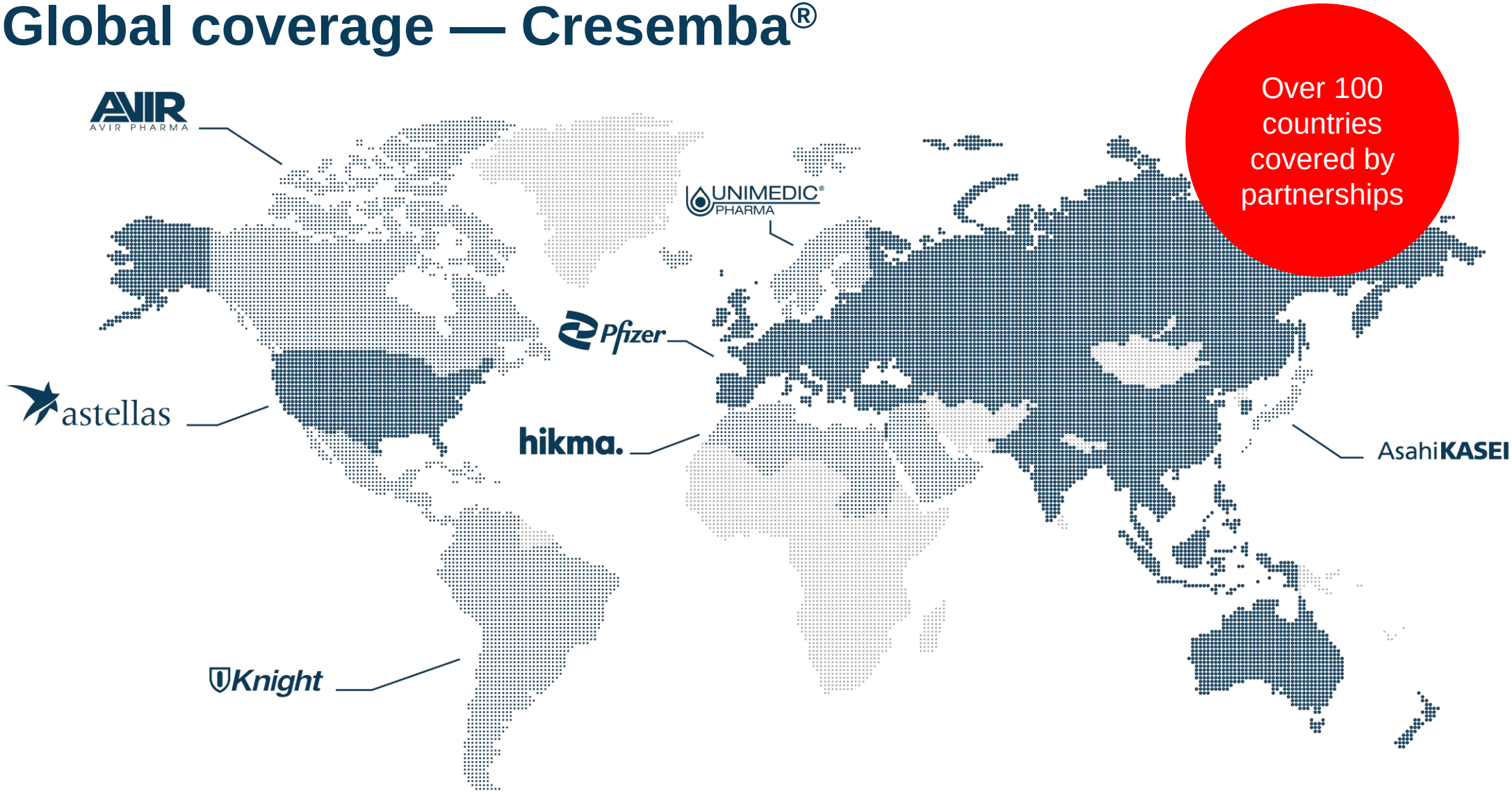


# Potential for sustainable growth and value creation based on commercialized brands and innovative pipeline




1 Studies to support US NDA. Phase 3 program is funded in part with federal funds from the US Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA).

# Global coverage — Cresemba®



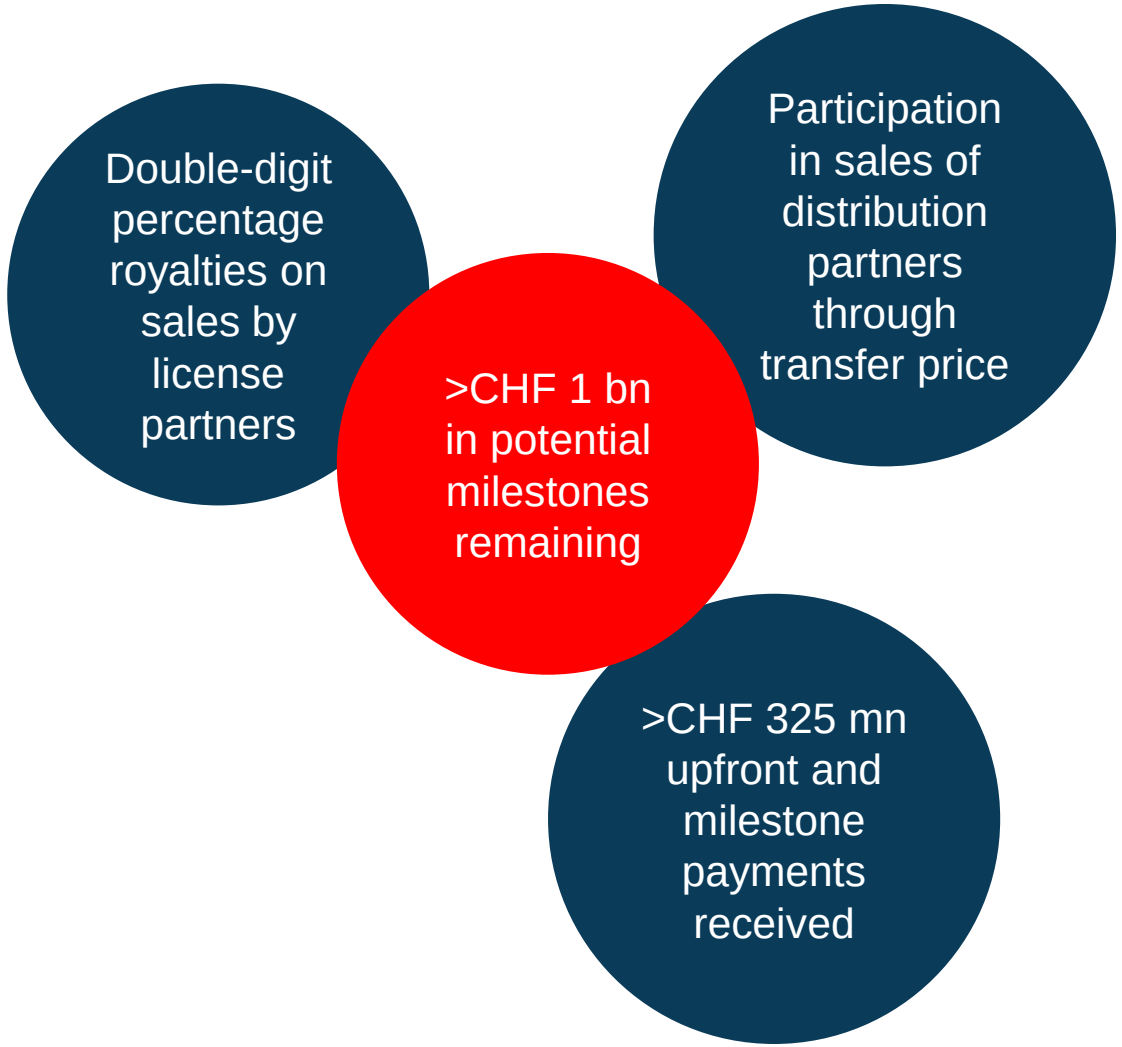
# The company we keep — Established strong partnerships

## License partners

| | |
|---|---|
| Pfizer<br>Europe (excl. Nordics), China Asia-Pacific, Russia, Turkey and Israel (Cresemba®) | astellas<br>U.S. (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®) |



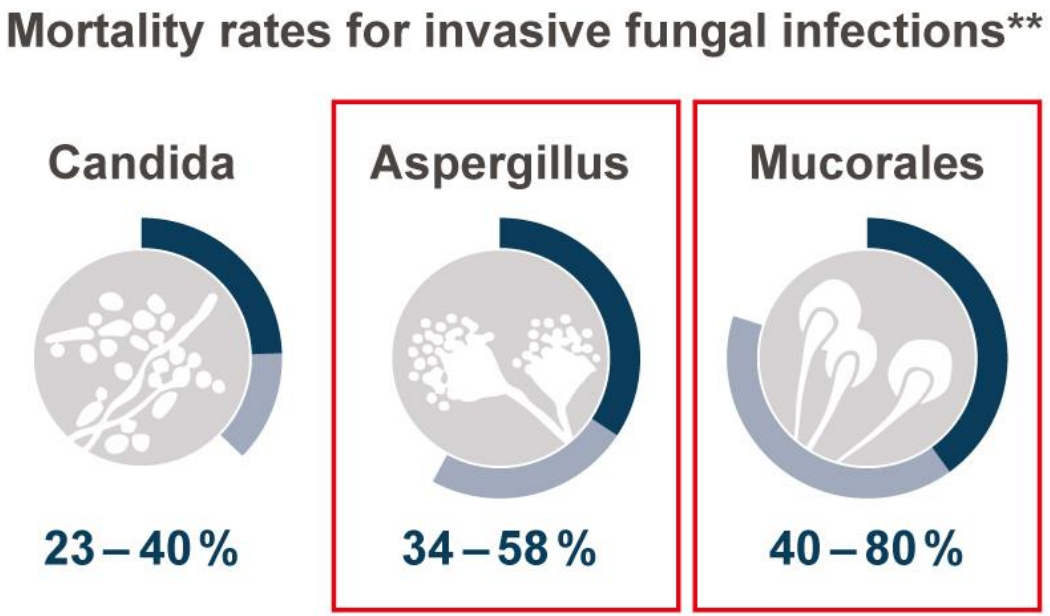
Antifungal

# Cresemba® (isavuconazole)

Invasive mold infections

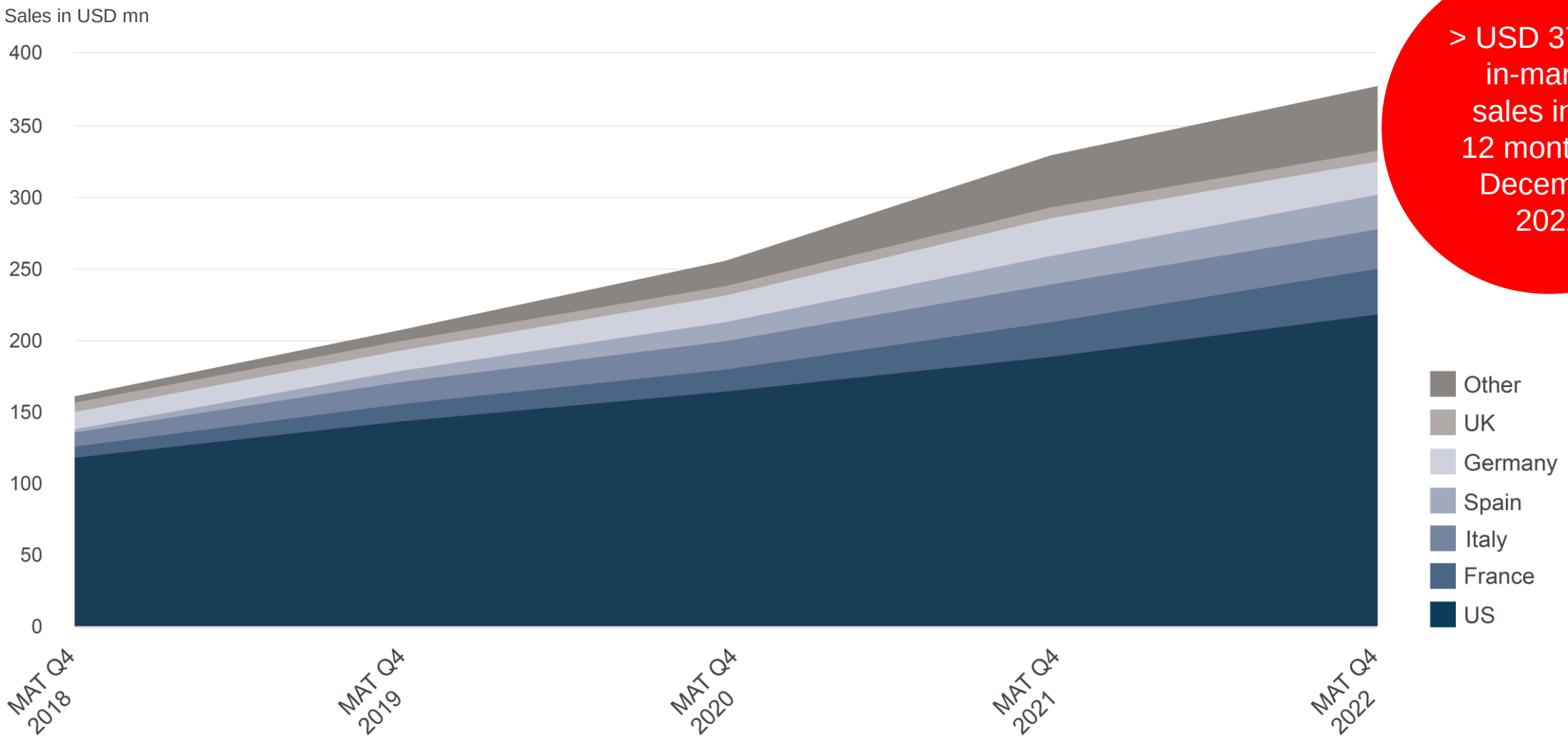
# The market — Invasive fungal infections

- 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

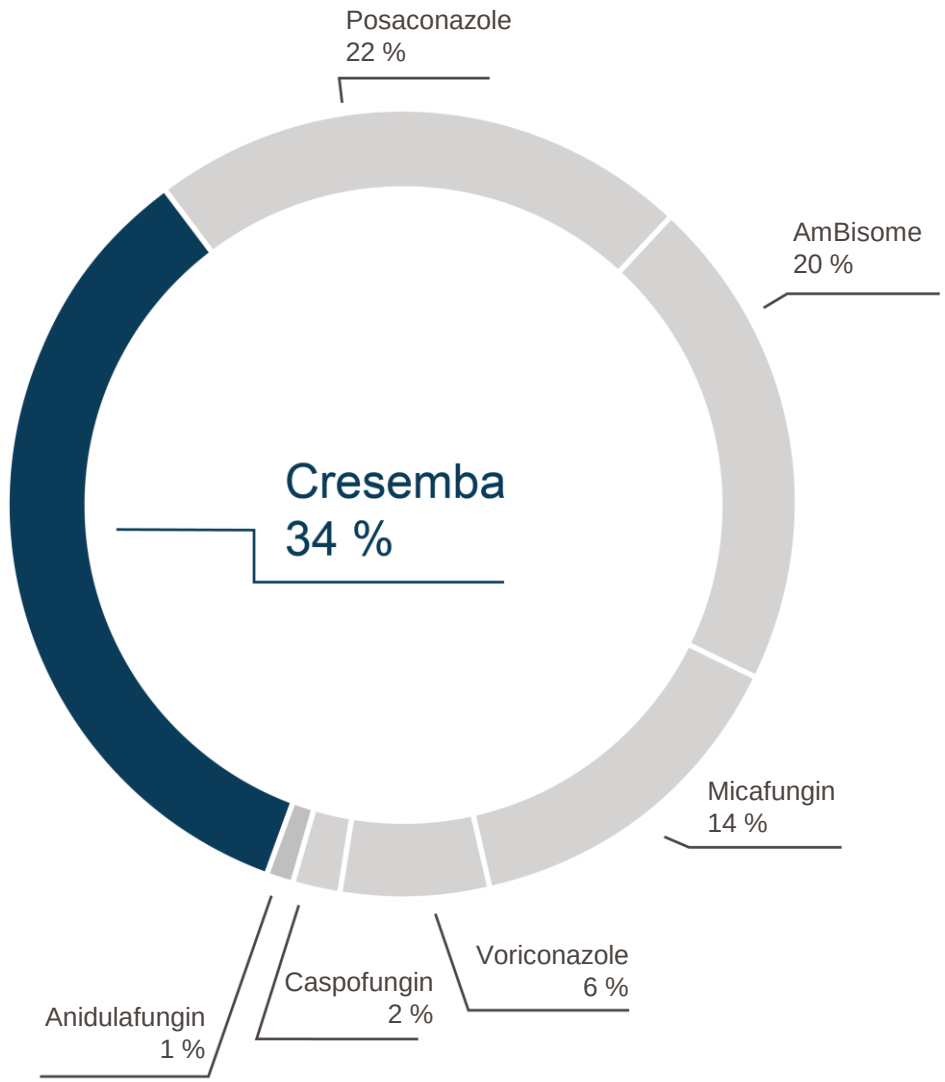



> USD 373 mn in-market sales in the 12 months to December 2022

MAT: Moving annual total; Source: IQVIA Analytics Link, December 2022

# 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 34% by December 2022**




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

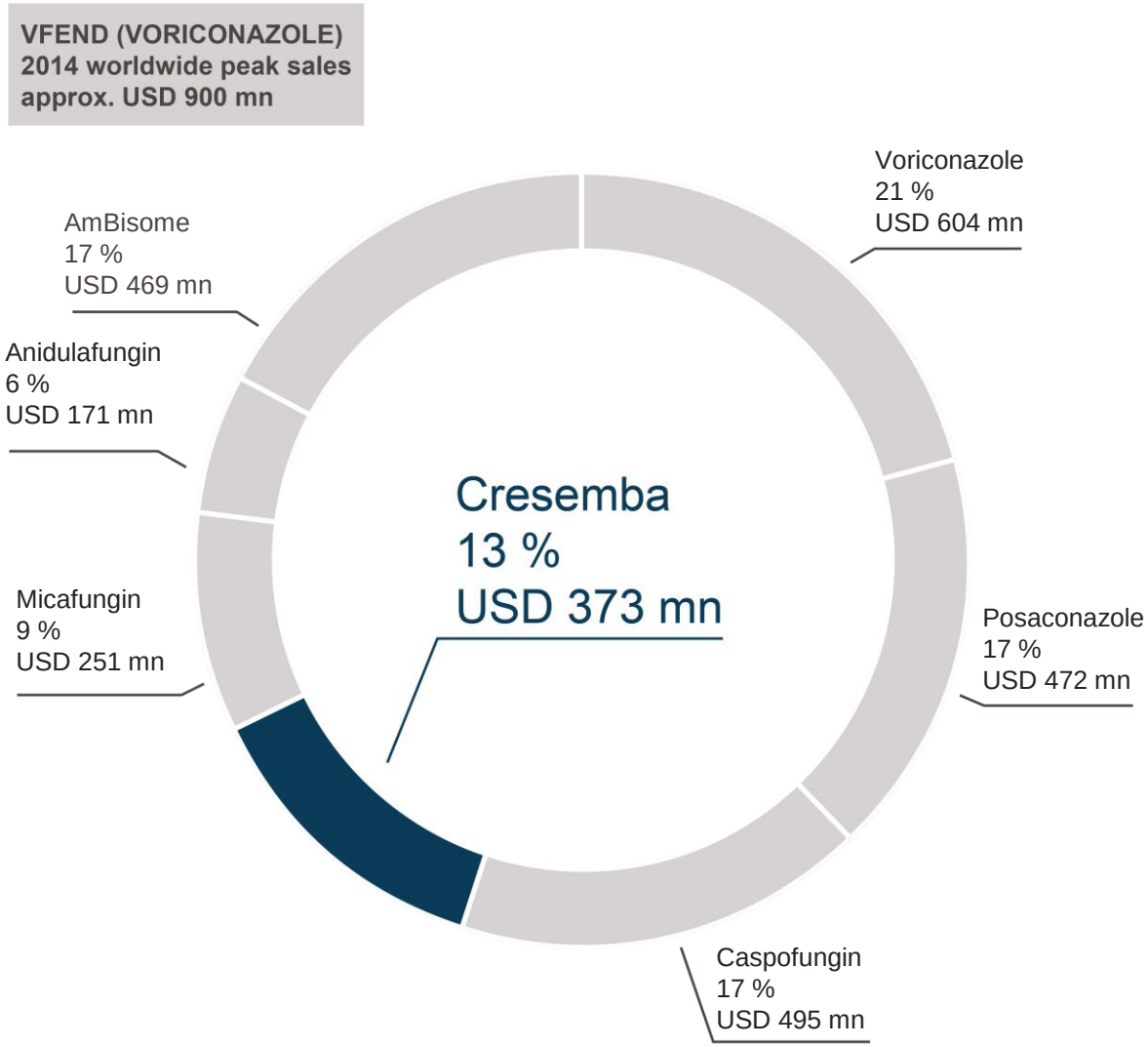
**Market share based on MAT Q4 2022, in-market sales reported as moving annual total (MAT) in US dollar; rounding consistently applied. Source: IQVIA Analytics Link, December 2022

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

**USD 2.8 bn sales (MAT Q4 2022)**

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

- Launched in 63 countries by end-2022
- Exclusivity through 2027 in the US and potential pediatric exclusivity extension to 2027 (from 2025) in the EU




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

MAT: Moving annual total; Source: IQVIA Analytics Link, December 2022, 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.

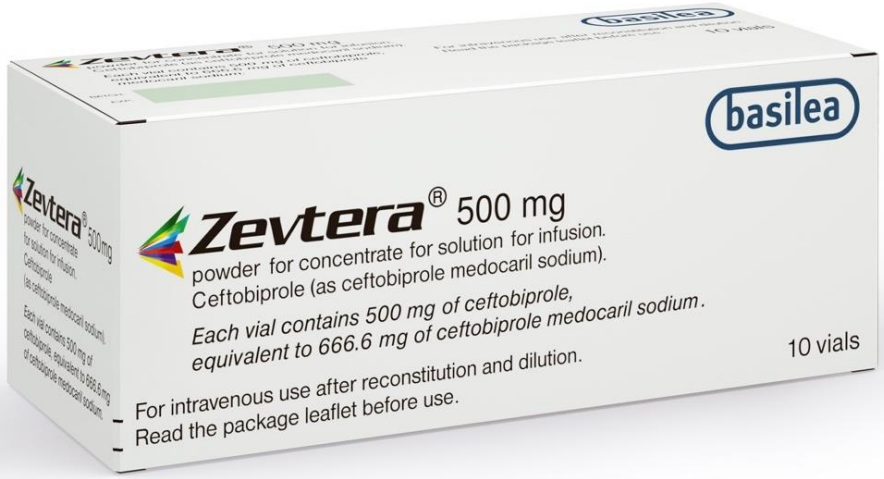
Antibacterial

# 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 NDA submission in preparation



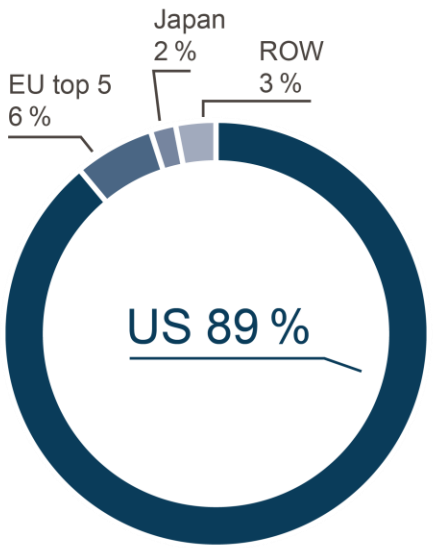

Approved in major European countries & several non-European countries for both hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated pneumonia (VAP), and community-acquired bacterial pneumonia (CABP). Not approved in the US

MENA: Middle East and North Africa

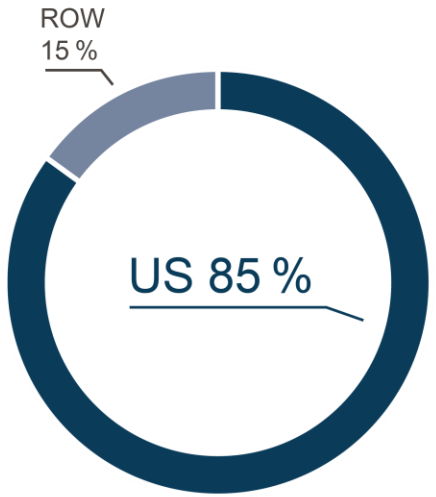

[1] Syed YY. Drugs. 2014;74:1523-1542 and Basilea data on file.
[2] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.
[3] Holland TL et al., Open Forum Infect. Dis. 2022, 9: (S931–S932).
[4] Rubino CM et al. Pediatr Infect Dis J. 2021;40:997-1003.

# The hospital anti-MRSA antibiotic market — A USD 2.6 bn market* with the US being the most important region

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




**Ceftaroline sales by region (MAT Q4 2022)**




* 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, December 2022

# Ceftobiprole — Strategy for accessing the US market

- Planned US NDA submission in Q3 2023:
  - Two cross-supportive phase 3 studies under FDA Special Protocol Assessment (SPA)
    1. Acute bacterial skin and skin structure Infections (ABSSSI)[1]
    2. *Staphylococcus aureus* bacteremia (SAB)[2]

TARGET ABSSSI Study

ERADICATE SAB Study

  - Previously completed phase 3 study in community-acquired bacterial pneumonia (CABP) as a third indication[3]

- Phase 3 program largely funded by BARDA (~70% total program costs; up to USD ~136 mn)
- Qualified Infectious Disease Product (QIDP) designation extends US market exclusivity to 10 years from approval
- Commercialization planned through partnership
  - Partnership to be secured prior to the regulatory decision

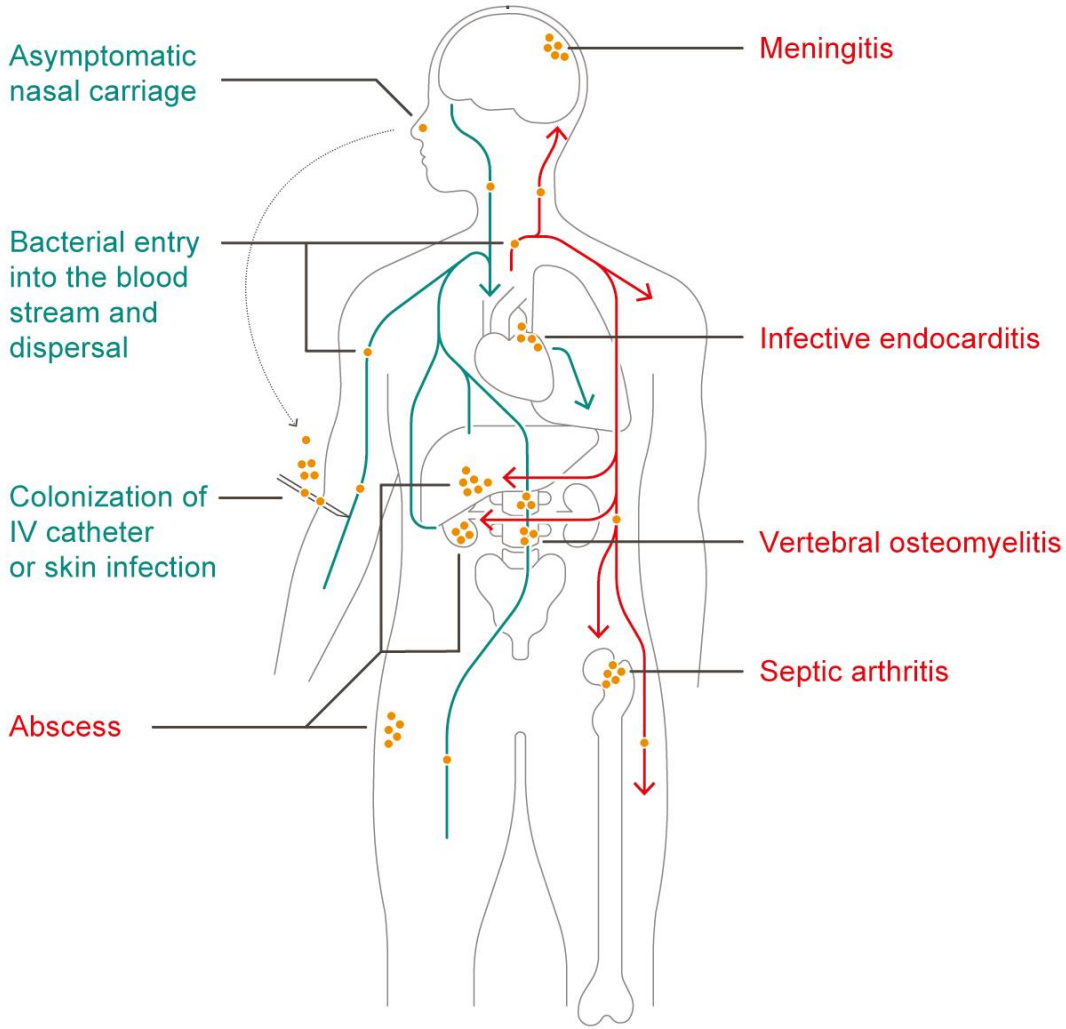
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
BARDA

[1] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.
[2] Holland TL et al., Open Forum Infect. Dis. 2022, 9: (S931–S932).
[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

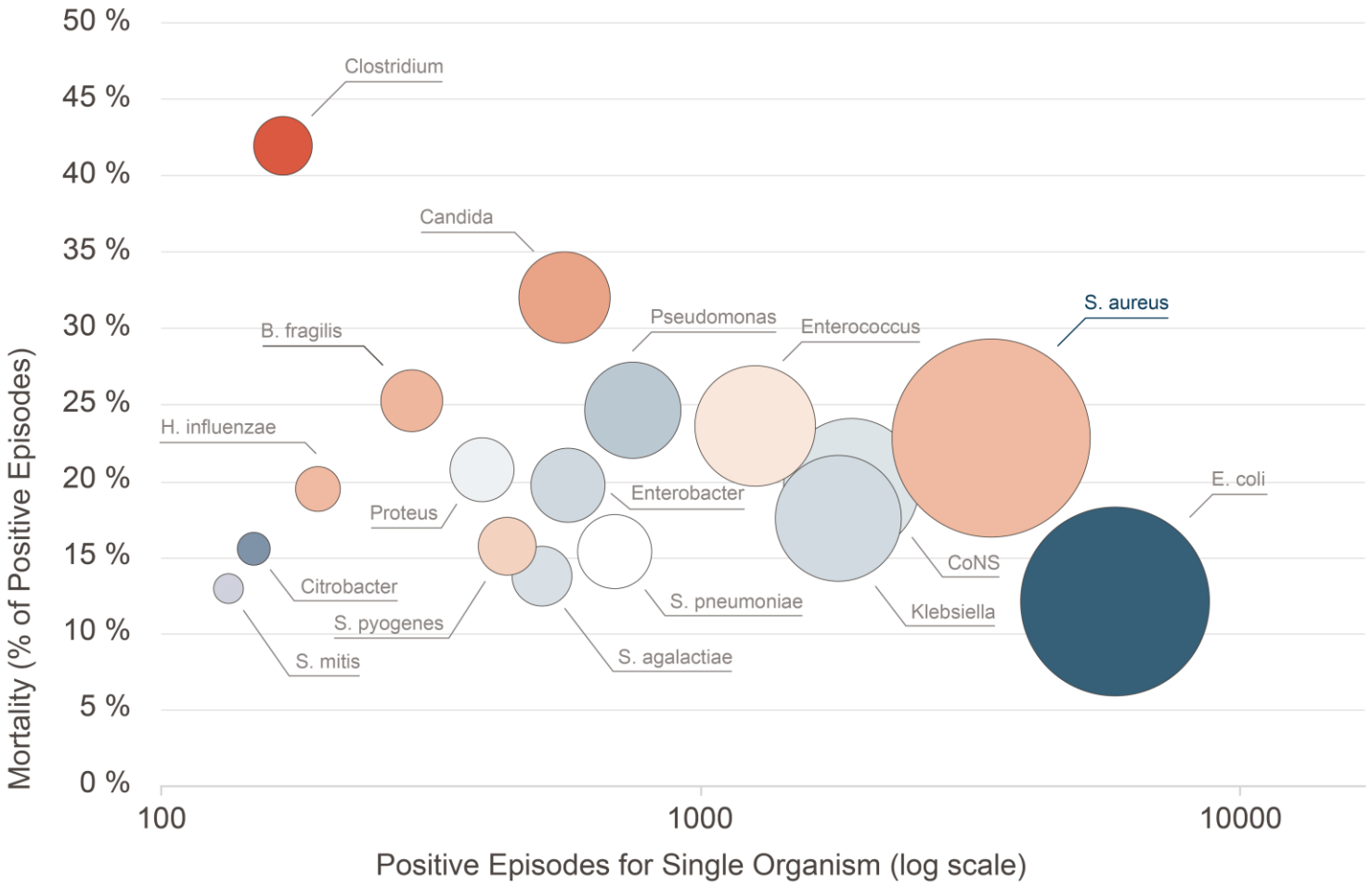
**Causes and consequences of SAB**




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

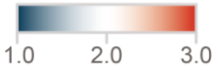
[1] MMWR, 2019;68:214–219.
[2] Hamed K et al. Future Microbiol. 2020;15:35-48.
MRSA: methicillin-resistant *Staphylococcus aureus*
MSSA: methicillin-susceptible *Staphylococcus aureus*

# 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

- 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.

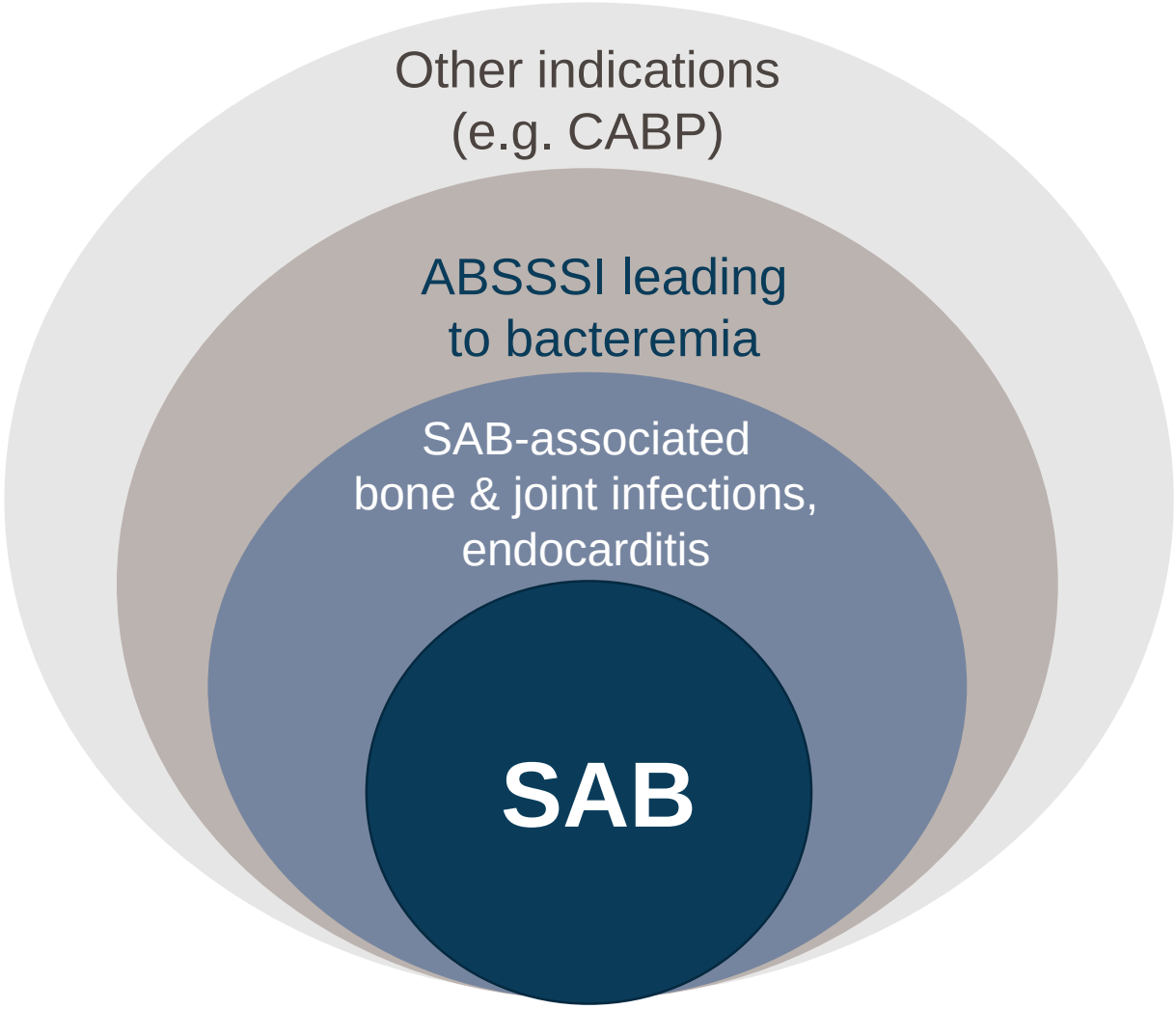
# Ceftobiprole — Place in therapy

- 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 renal safety profile
  - The low propensity for resistance development

# Focused launch in area of highest unmet medical with expansion opportunities

**Patient potential in the United States**

- *Staphylococcus aureus* bacteremia (SAB): 130,000 cases
- Acute bacterial skin and skin structure Infections (ABSSSI): 600,000 cases
- Community-acquired bacterial pneumonia (CABP): 800,000 cases



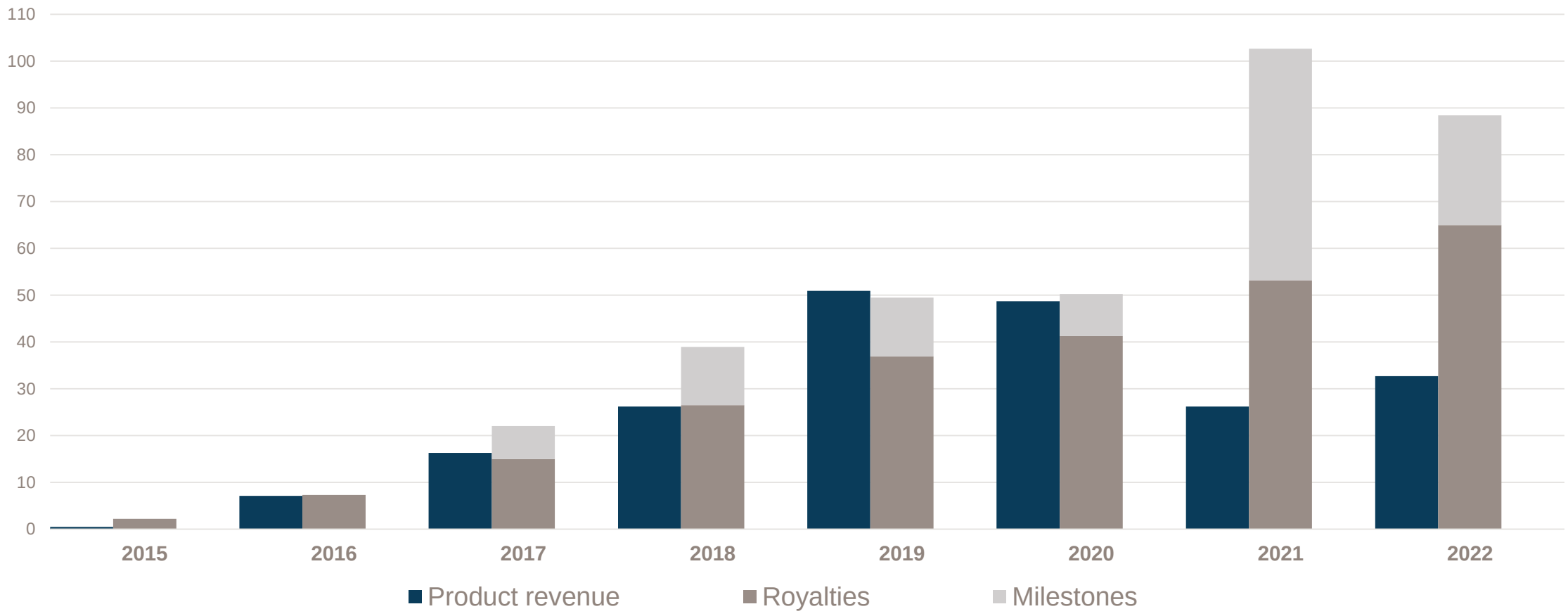
# Financials & Outlook

# Exceeded guidance – Strong financial results 2022

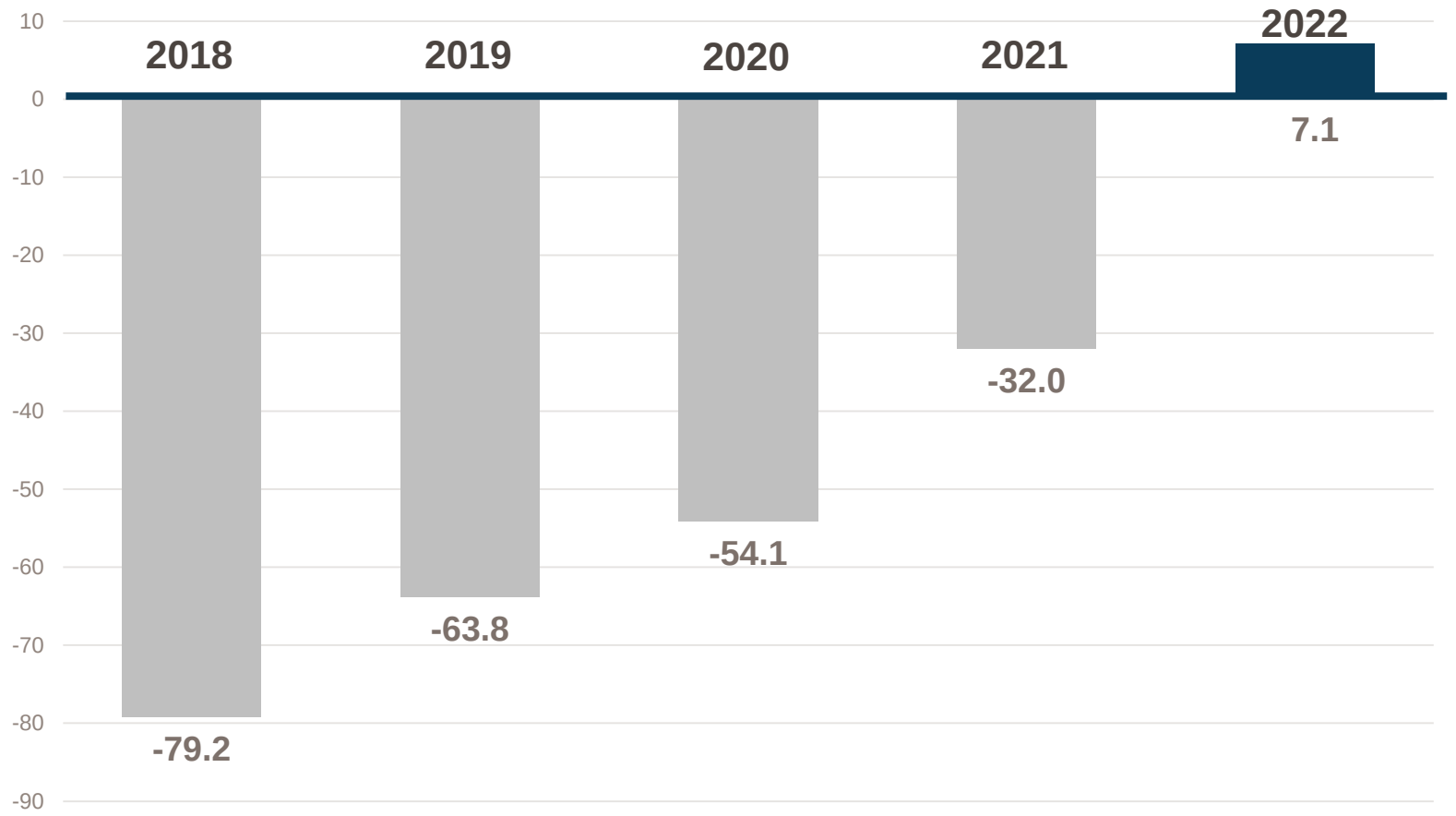
| In CHF mn | FY 2022 (actual) | FY 2022 (guidance) |
|---|---|---|
| Cresemba & Zevtera related revenue | 122.3 | 98 – 104 |
| Royalty income | 65.0 | ~59 |
| Total revenue | 147.8 | 116 – 122 |
| Cost of products sold<br>Operating expenses | 24.6<br>104.6 | 21 – 24<br>~110 |
| Operating profit/(loss) | 18.5 | (10 – 15) |

Note: Consistent rounding was applied.

# Cresemba and Zevtera revenue breakdown (in CHF mn)

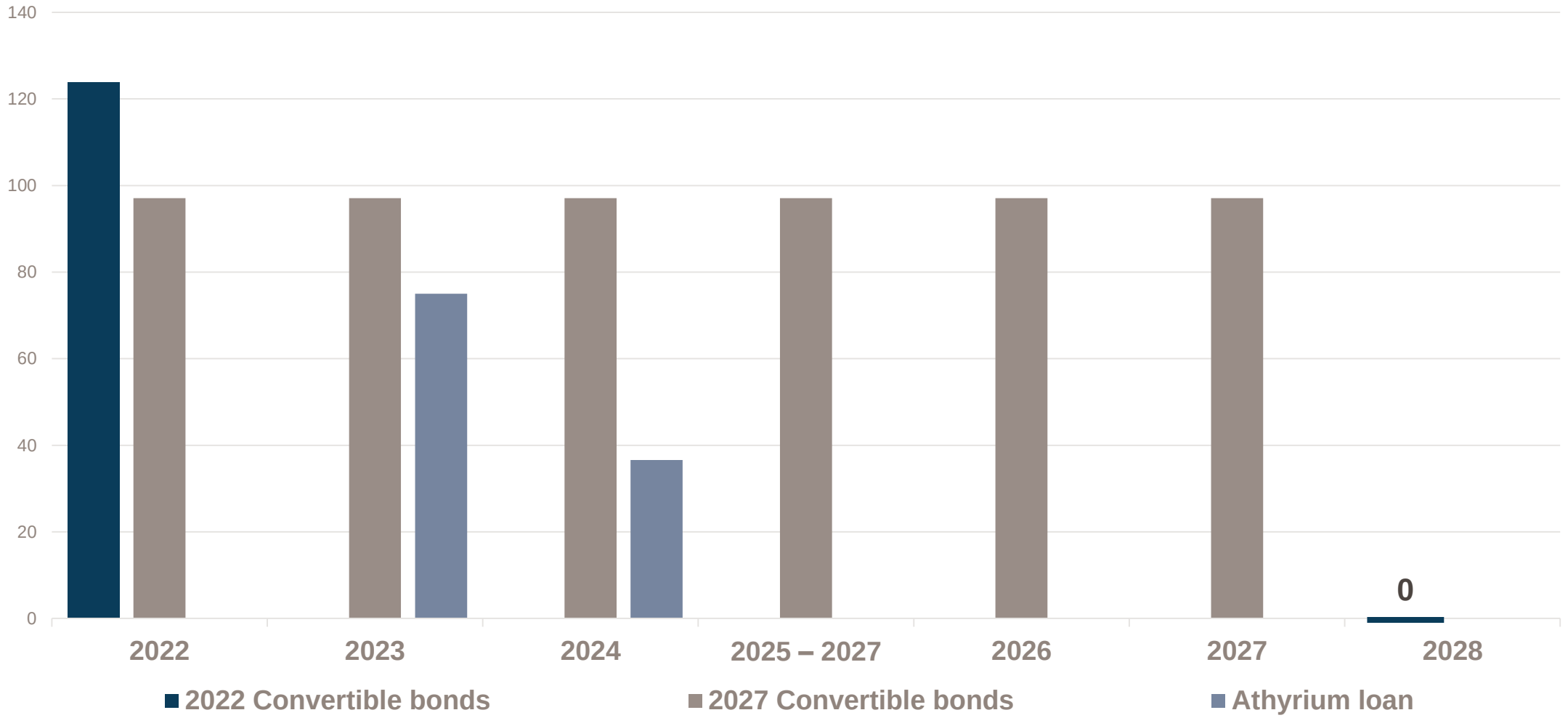


# Cash flows from operating activities (in CHF mn)




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

# 2023 guidance – Continued growth in Cresemba & Zevtera related revenue and significant increase in profitability*

| In CHF mn | FY 2023e (guidance) | FY 2022 |
|---|---|---|
| Cresemba & Zevtera related revenue | 145 – 148 | 122.3 |
| Royalty income | ~74 | 65.0 |
| Total revenue | 155 – 158 | 147.8 |
| Cost of products sold<br>Operating expenses | 25 – 28<br>~80 | 24.6<br>104.6 |
| Operating profit | 45 – 50 | 18.5 |
| Net profit | 36 – 41 | 12.1 |

*Excluding the impact of in-licensing activities

# Key milestones

| Product | H1 2023 | H2 2023 | H1 2024 |
|---|---|---|---|
| **Ceftobiprole (Zevtera)** | | US NDA submission (Q3) | Regulatory decision in the US (Q2) |
| | | | Executing US partnership (before regulatory decision) |
| **Isavuconazole (Cresemba)** | Launched in Japan ✓ | | |
| | | Pediatric submission | |

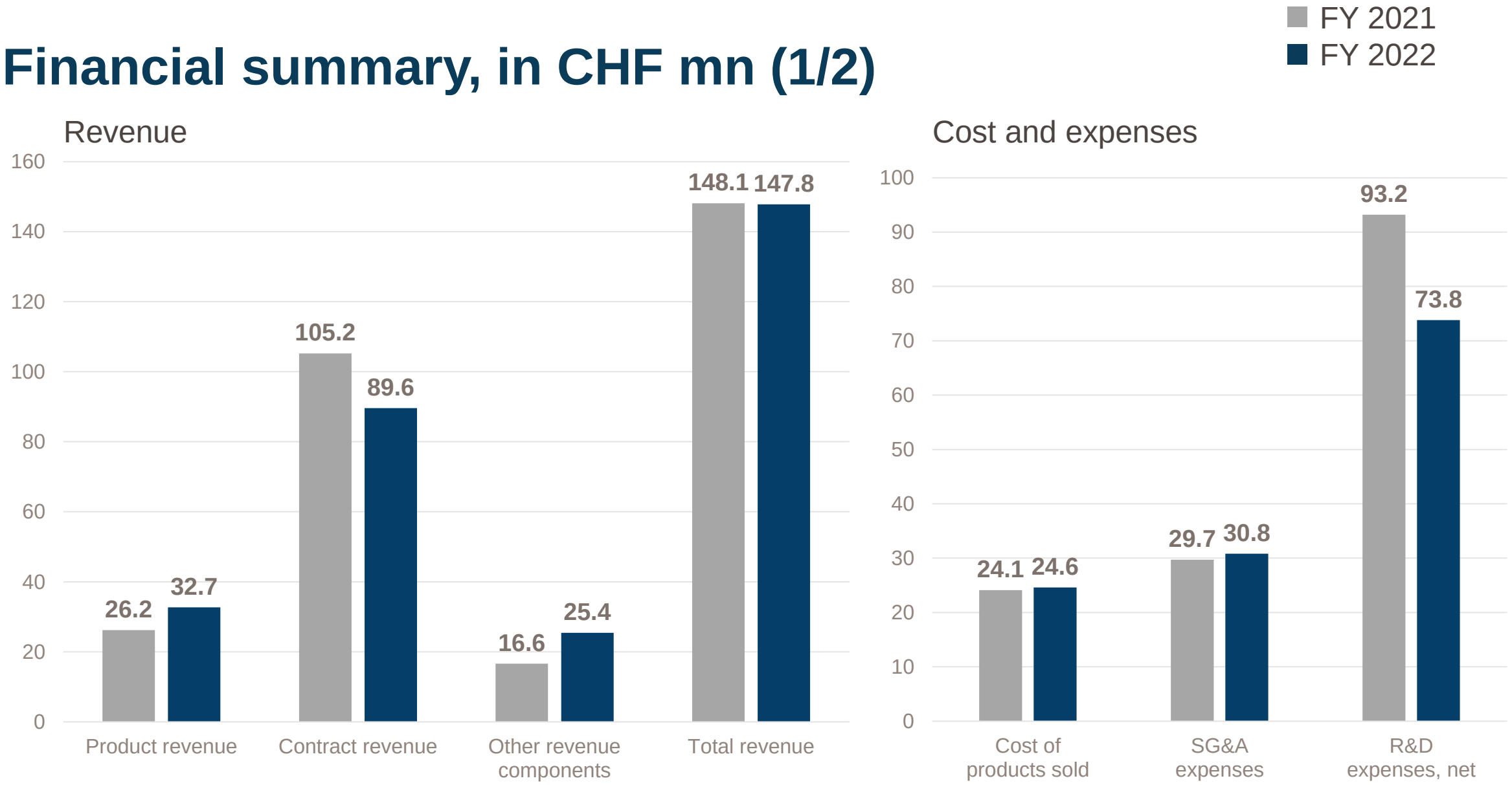
Increasing Cresemba & Zevtera revenue

In-licensing of anti-infectives (2023 and beyond)

Advancement of preclinical anti-infective assets

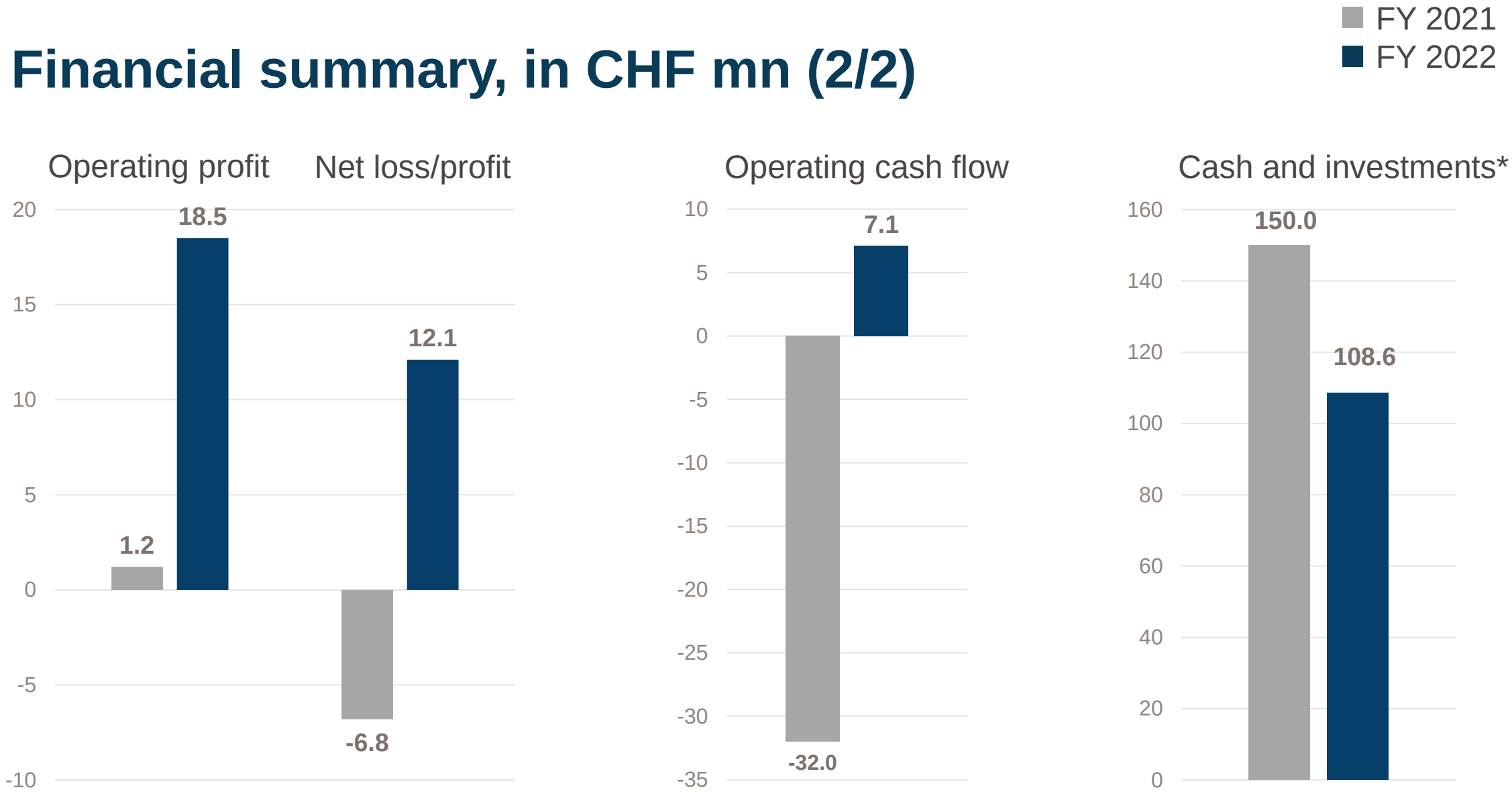
# Appendix

# Financial summary, in CHF mn (1/2)



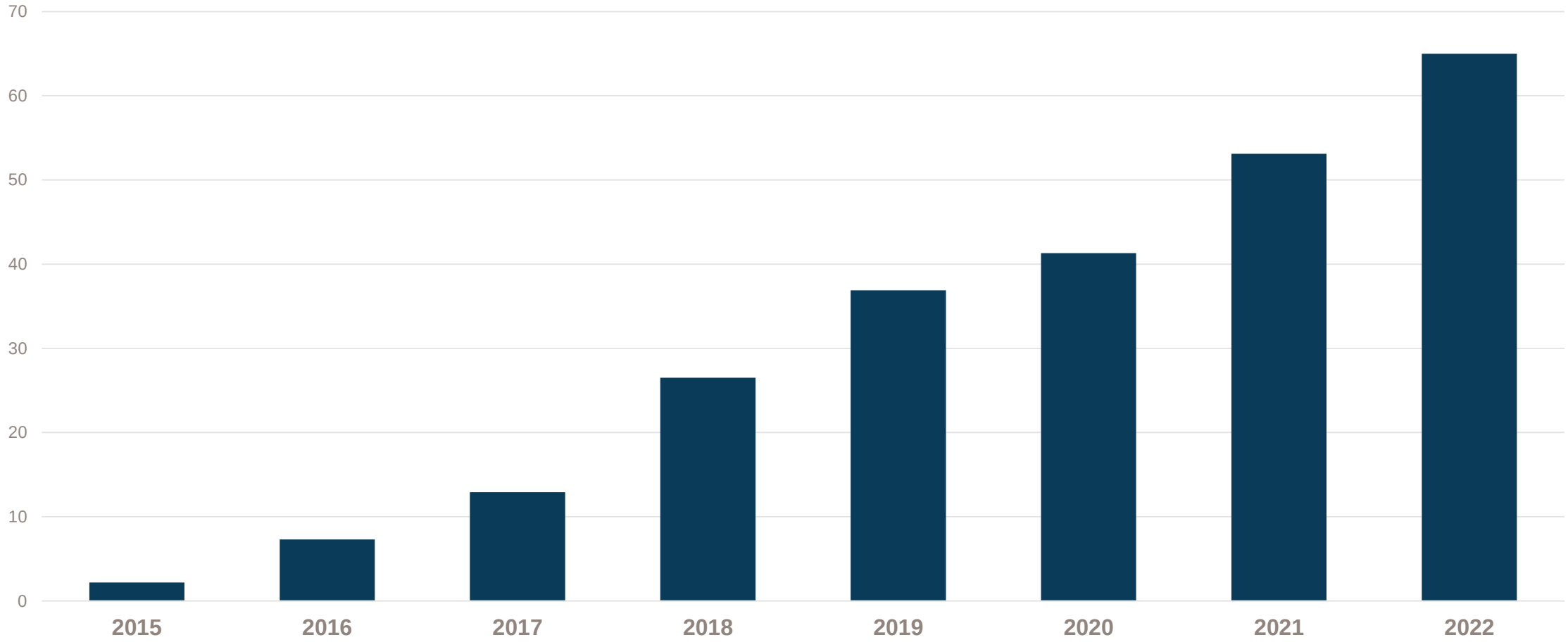

Note: Consolidated figures in conformity with US GAAP; rounding applied consistently

# Financial summary, in CHF mn (2/2)



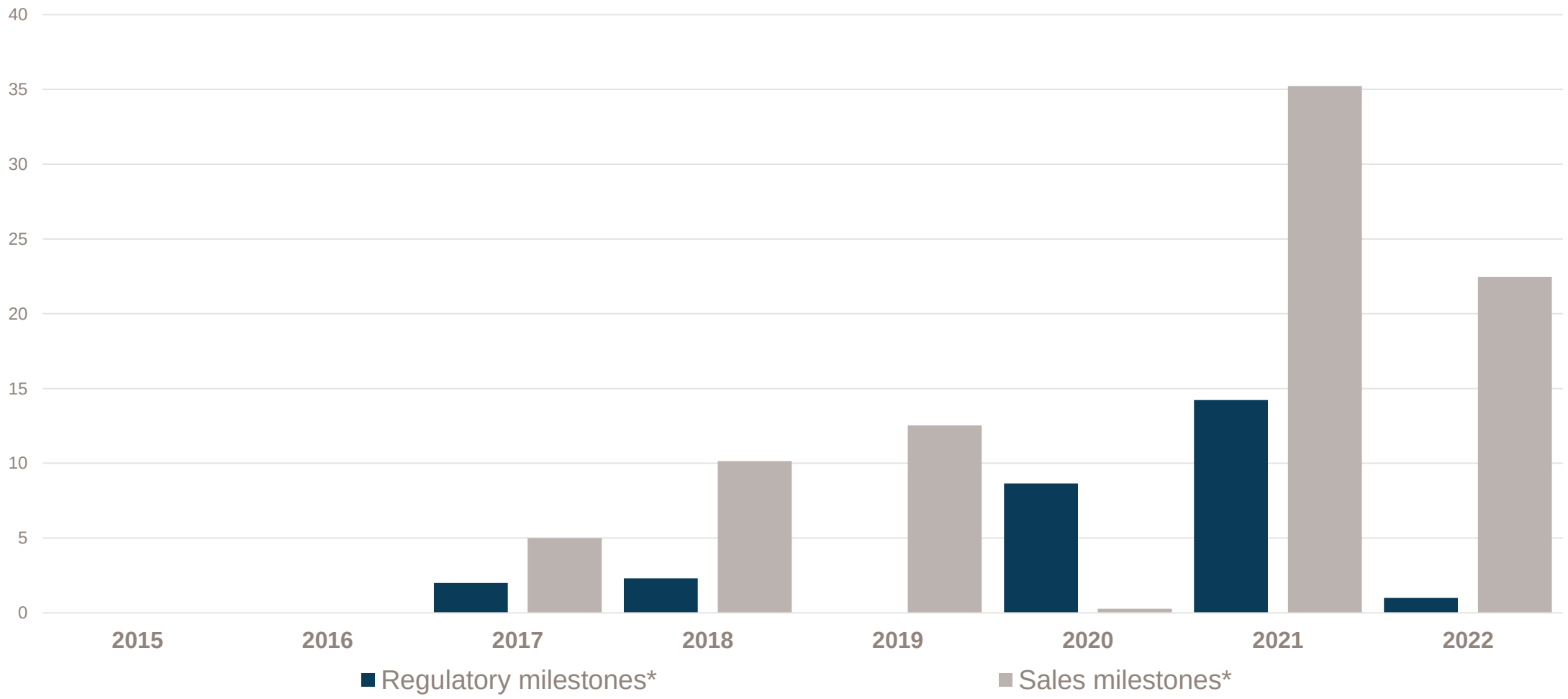

Note: Consolidated figures in conformity with US GAAP; rounding applied consistently, *Cash, cash equivalents, restricted cash and investments

# 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

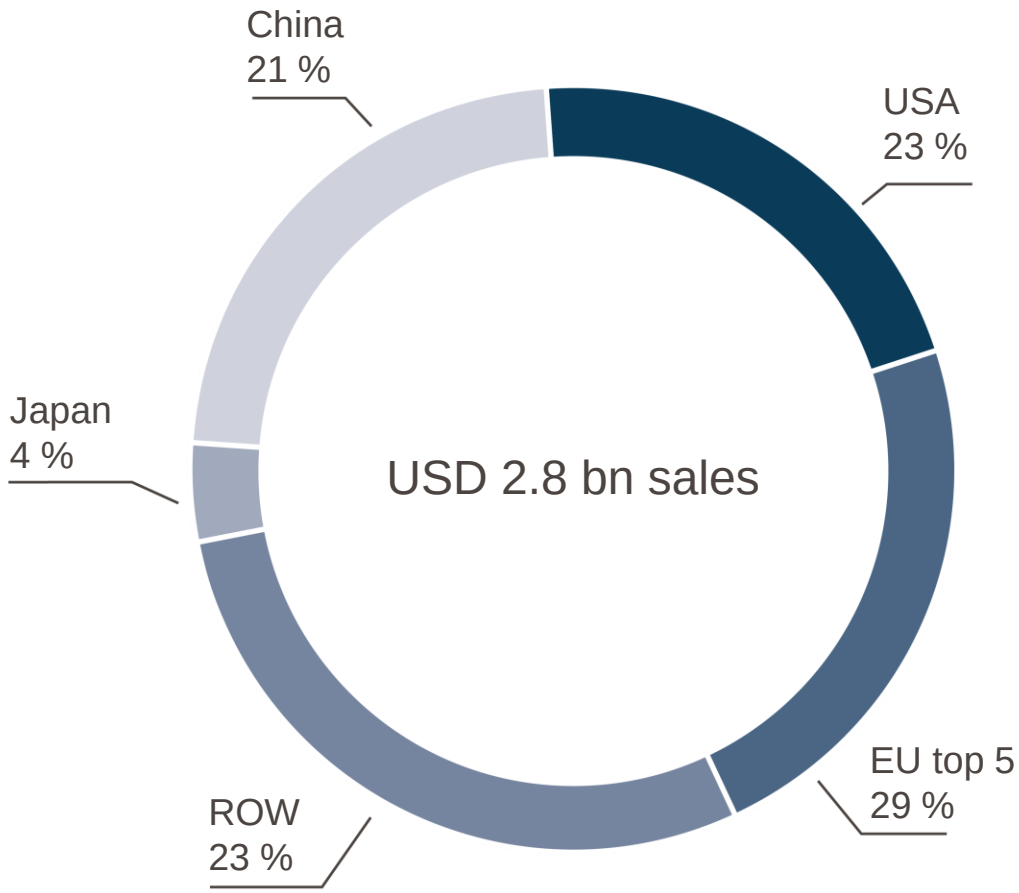
# Regulatory and sales milestones (in CHF mn)




*Combined from license partners and distributors

# Significant sales of best-in-class antifungals in all major regions — Covered by our partnerships

USD 2.8 bn sales of best-in-class antifungals*
(MAT Q4 2022)




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

MAT: Moving annual total; Source: IQVIA Analytics Link, December 2022

# Cresemba pediatric development

- A pediatric development plan comprising 2 clinical studies was agreed with the FDA and the EMA
- Successful completion of the plan potentially results in 2 years additional market exclusivity in Europe and 6 months additional market exclusivity in the USA
- Clinical studies were undertaken in collaboration with Basilea's US partner Astellas and completed enrollment in August 2022
- FDA/EMA submission to propose pediatric labelling and request extension of exclusivity is planned in H2 2023
- Pediatric label approval is expected in H2 2024 in order to gain the exclusivity extension in both territories

| Study | Age group | Study design | Study identifier |
|---|---|---|---|
| **Study 1**<br>9766-CL-0046 | 1 – 17 years<br>i.v. and capsules* | Phase 1, open-label, multicenter, non-comparative pharmacokinetics and safety study of intravenous and oral isacuvonazole sulfate<br><br>**> Study completed in 2019** (49 patients enrolled) | Clinicaltrials.gov<br>NCT03241550† |
| **Study 2**<br>9766-CL-0107 | 1 – 17 years<br>i.v. and capsules* | Phase 2, open-label, non-comparative, multicenter study to evaluate the safety and tolerability, efficacy and pharmacokinetics of isavuconazonium sulfate for the treatment of invasive aspergillosis or invasive mucormycosis<br><br>**> Study completed in 2022** (31 patients enrolled) | Clinicaltrials.gov<br>NCT03816176 |

*Capsules only studied in children 6 years or older

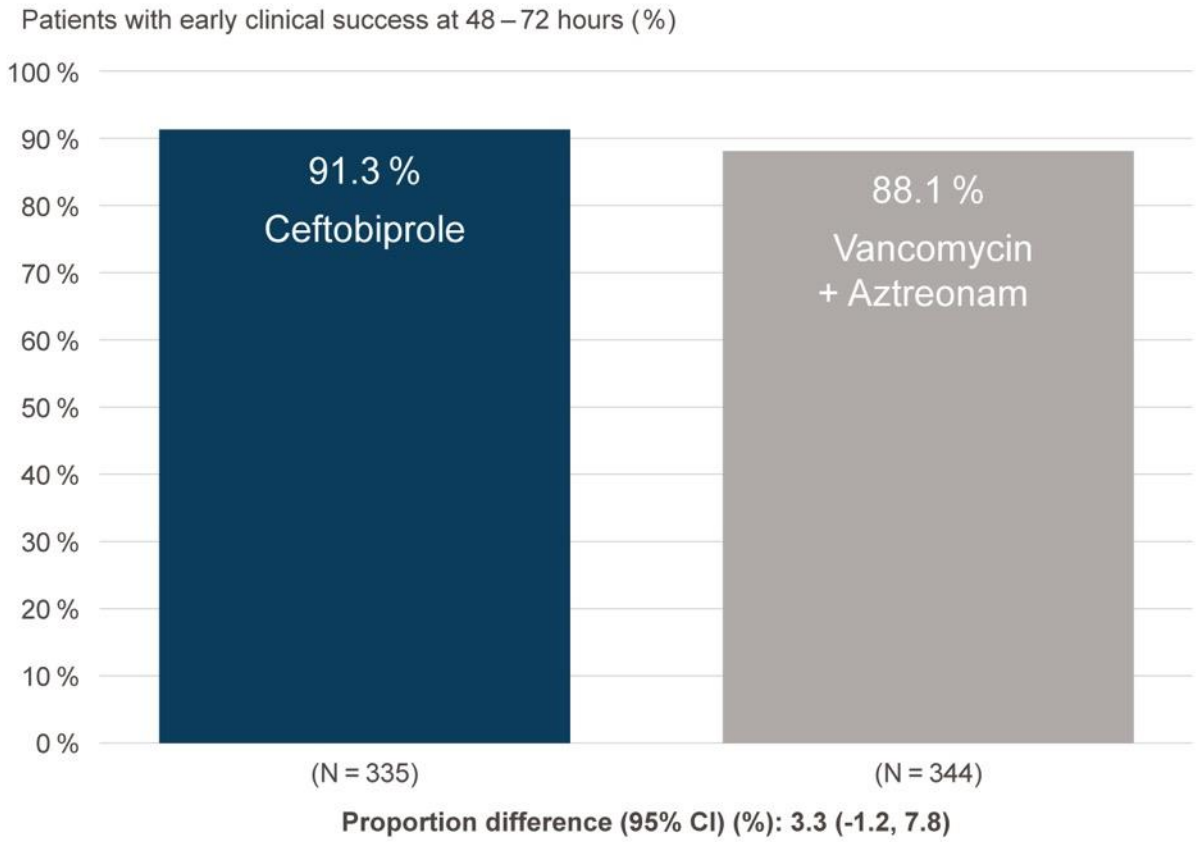
†Arrieta AC, et al. Safety, Tolerability, and Population Pharmacokinetics of Intravenous and Oral Isavuconazonium Sulfate in Pediatric Patients. Antimicrob Agents Chemother. 2021;65:e0029021.

# 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 %

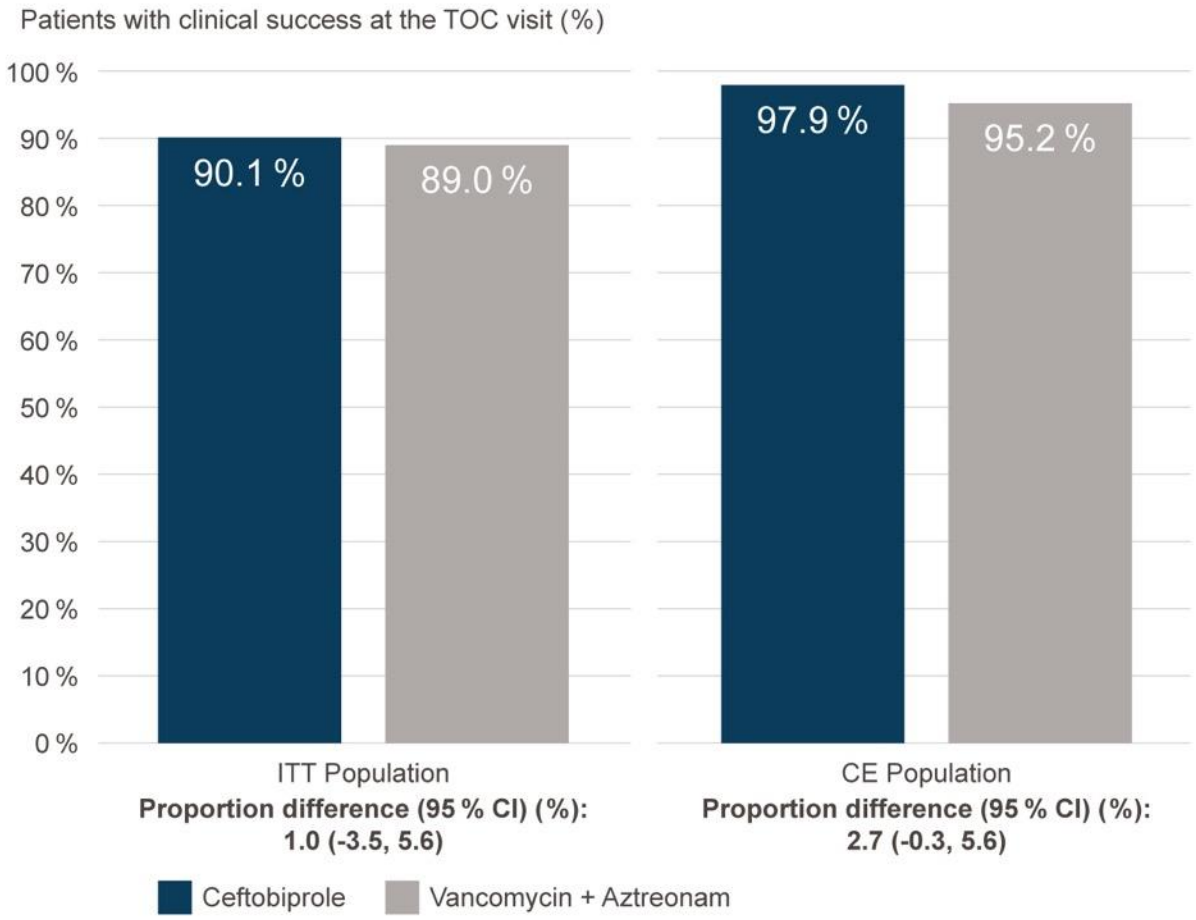
[1] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

# 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)



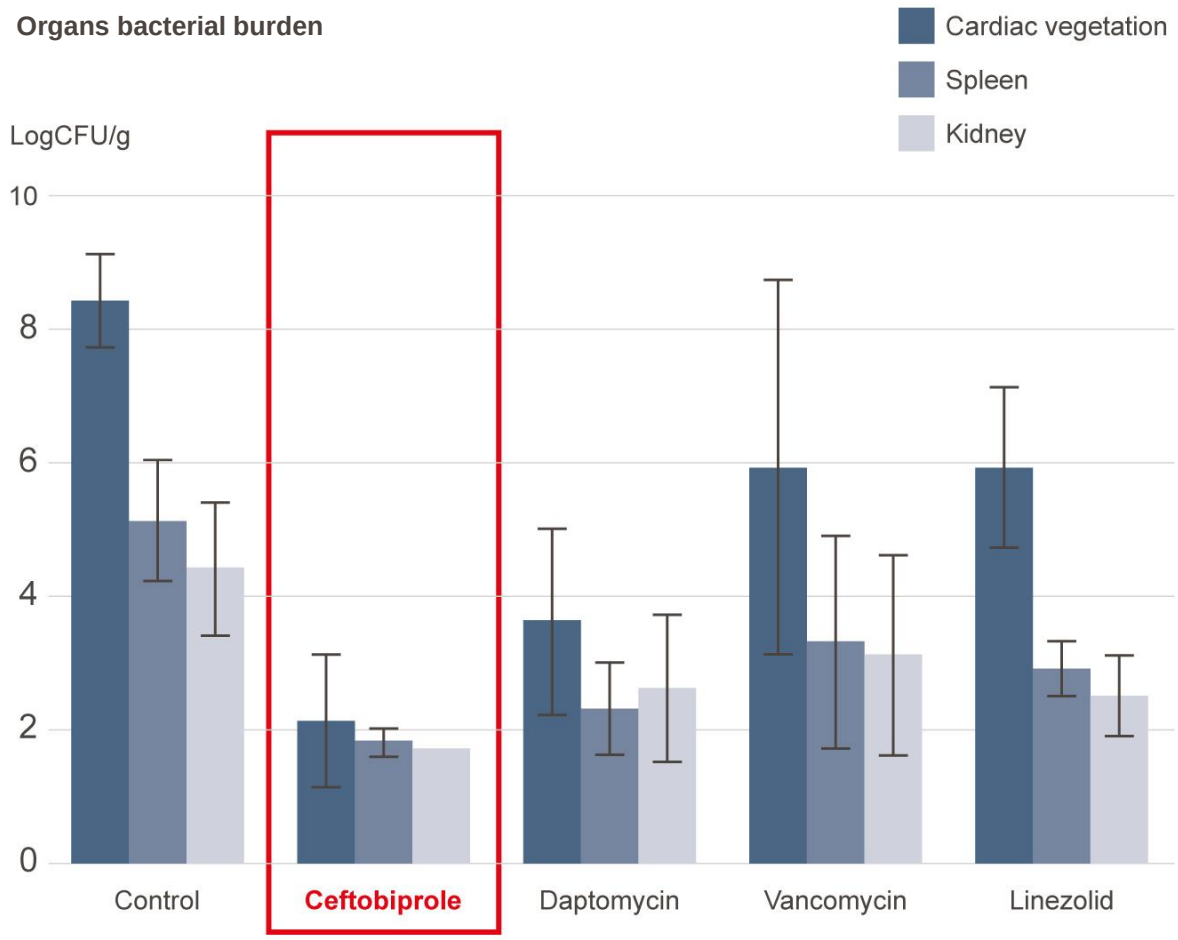

[1] NCT03137173
ABSSSI: Acute bacterial skin and skin structure infections

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

# Ceftobiprole key attributes for SAB treatment

- Advanced generation cephalosporin with broad spectrum bactericidal activity against Gram-positive organisms, including MRSA and MSSA, and Gram-negative organisms[1]
- Efficacy demonstrated in phase 3 clinical studies in acute bacterial skin and skin structure infections, and pneumonia[1,2]
- Superior activity profile in multiple in vivo models of severe infection compared to vancomycin and daptomycin[3]
- Low propensity for resistance development[1]
- Established safety profile consistent with the cephalosporin class, demonstrated in both adult and pediatric patients[1,2,4]

## Comparative efficacy in a rabbit model of endocarditis

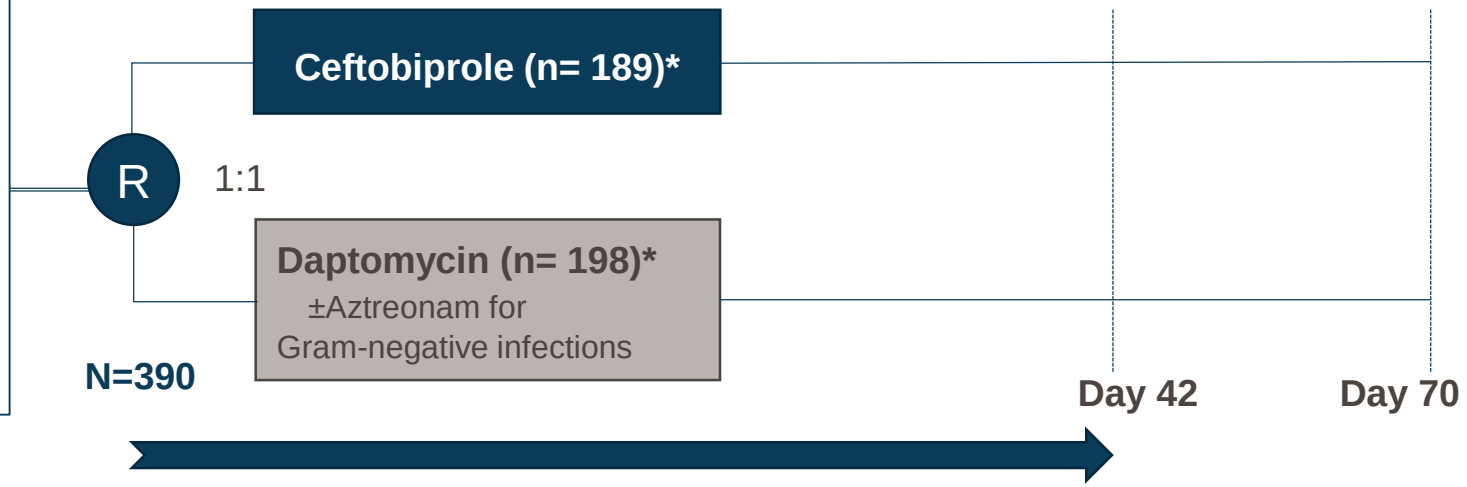



Organism titers in cardiac vegetations, spleens and kidneys of untreated and antibiotic treated rabbits infected with MRSA[3]

[1]Syed YY. Drugs. 2014;74:1523-1542.
[2]Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.
[3]Tattevin P et al. Antimicrob Agents Chemother. 2010;54:610-613.
[4]Rubino CM et al. Pediatr Infect Dis J. 2021;40:997-1003.

# ERADICATE — SAB 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)**

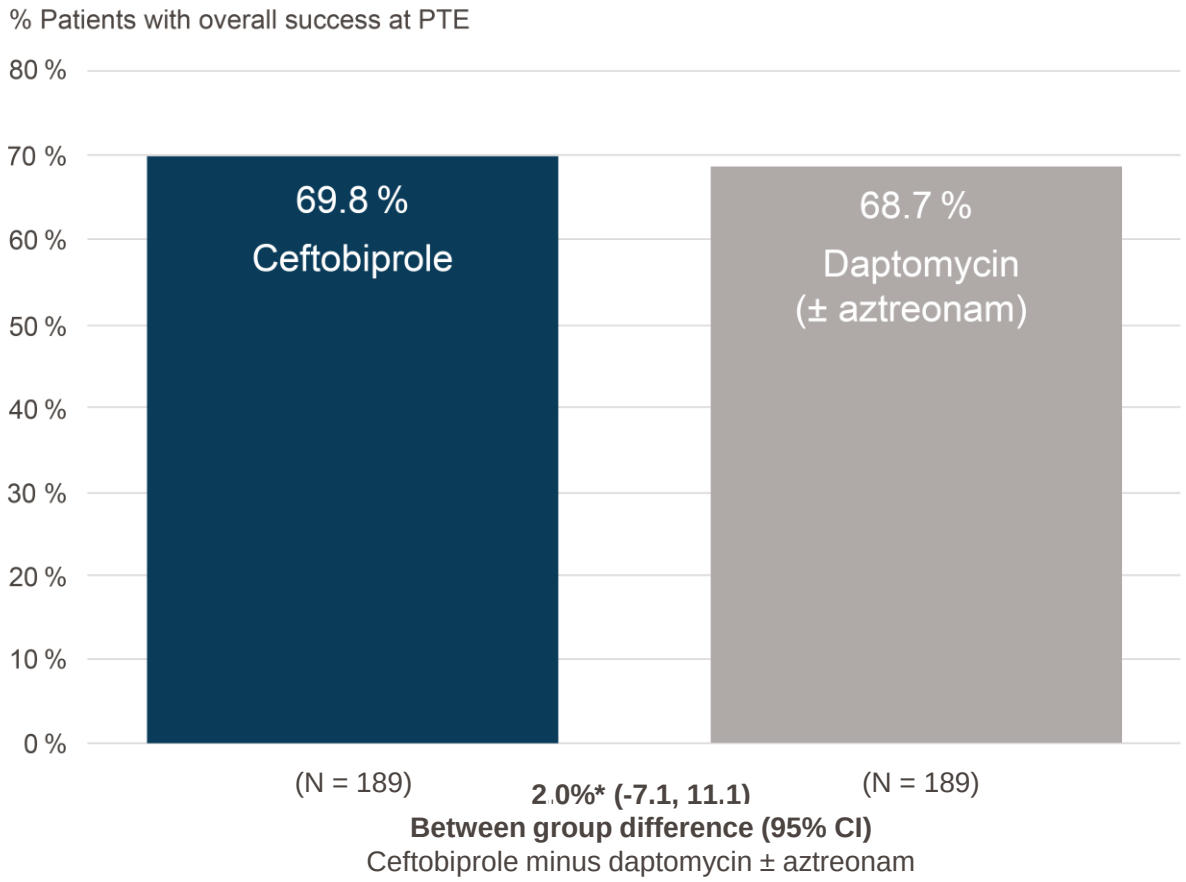
**Active treatment (up to 42 days)**

**Primary endpoint assessment**

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

*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

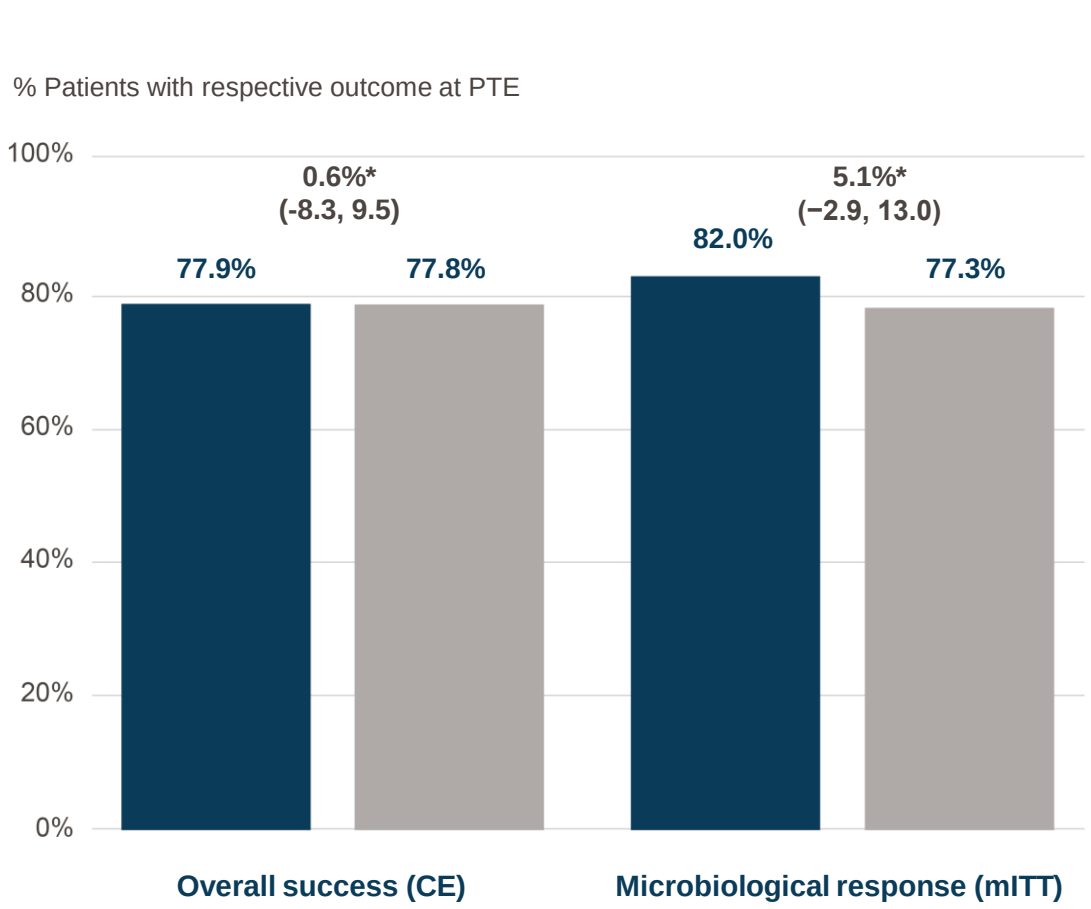
# Primary endpoint in SAB is achieved
## (DRC assessed overall success at PTE in mITT population)

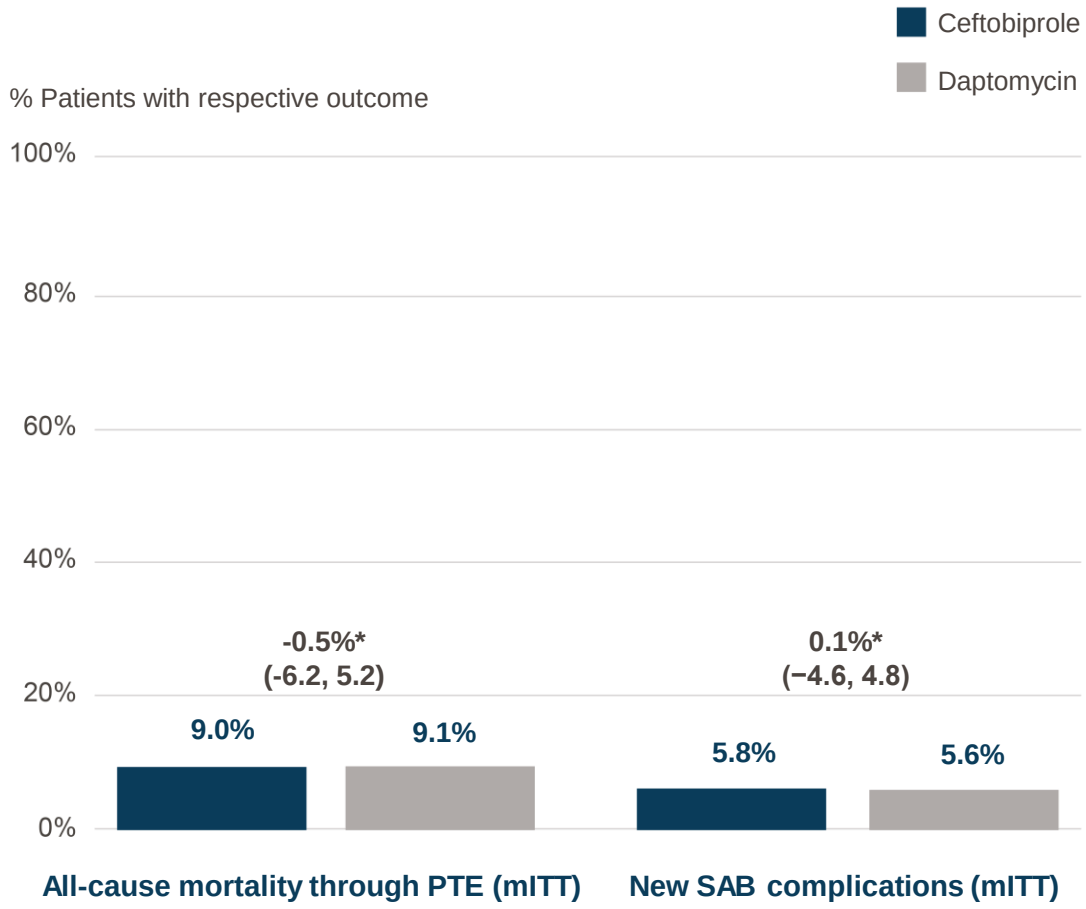



- Non-inferiority demonstrated based on the pre-defined non-inferiority margin of 15%
- Consistent results in key subgroups and various categories of underlying conditions:
  - MSSA or MRSA bloodstream infections at baseline
  - Skin and skin structure infections
  - Abdominal abscesses
  - Chronic dialysis
  - 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
- 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**
- DRC: **D**ata **r**eview **c**ommittee
- 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
- 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

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