



**Focused on  
Growth and Innovation**

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

Investor presentation

November 24, 2022



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## Executive summary



# Experienced leadership team



**David  
Veitch** CEO

Joined

2014

Previous  
roles:



Bristol-Myers Squibb



SmithKline Beecham



**Adesh  
Kaul** CFO

2009



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

2010



**Gerrit  
Hauck**  
Ph.D. CTO

2018



**Laurenz  
Kellenberger**  
Ph.D. CSO

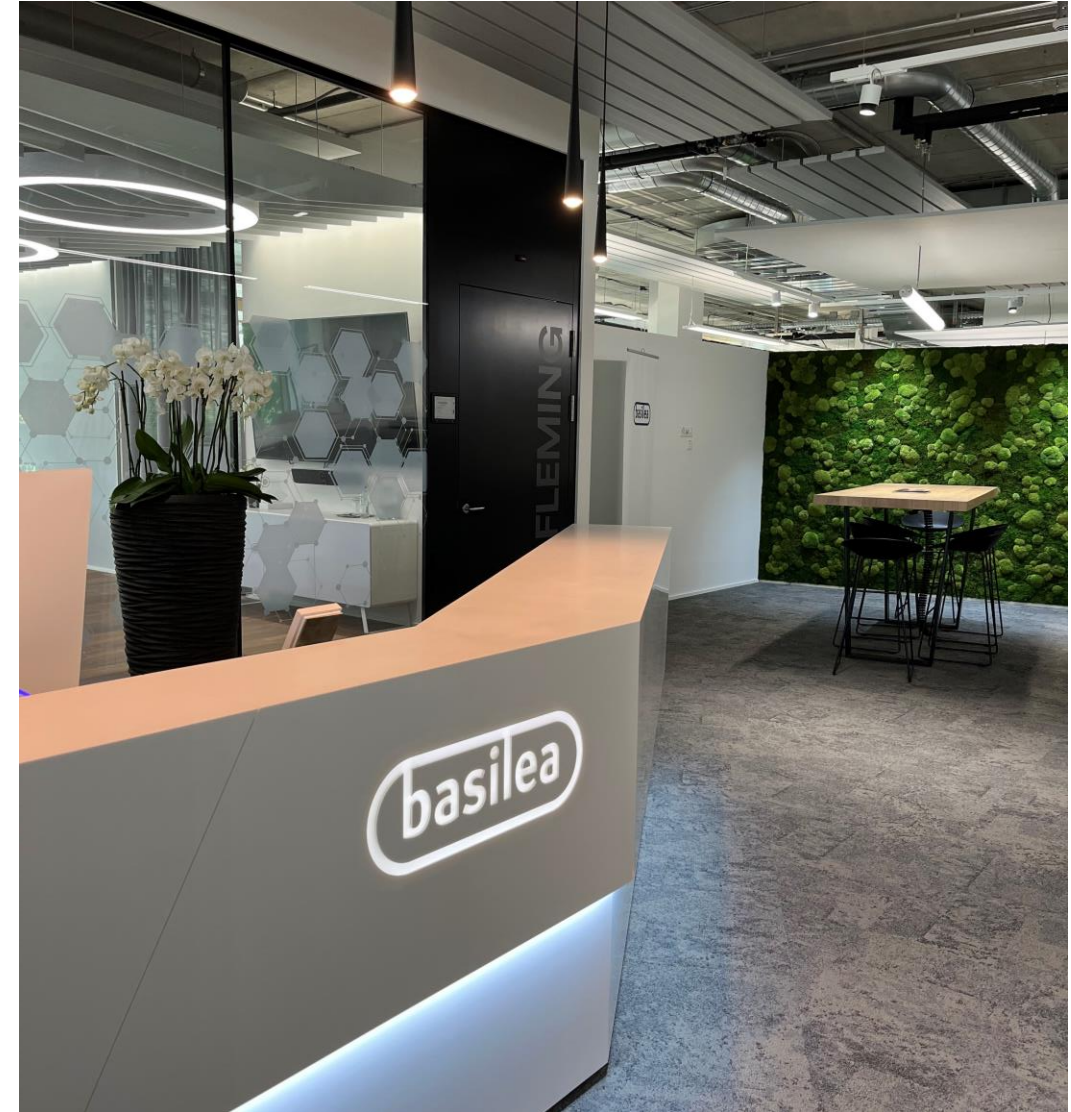
2000





# At a glance

- Focus on the treatment of serious 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
- On track to achieve sustainable profitability in 2023
- Listed on SIX Swiss Stock Exchange, SIX: BSLN
- Located in the Basel area life sciences hub, Switzerland

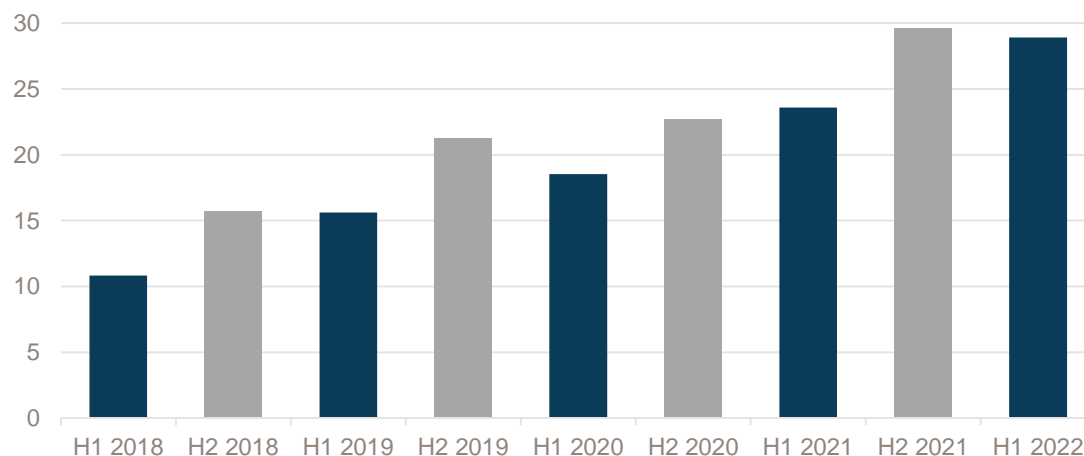


# Uniquely positioned to create sustainable value in an area of increasing unmet medical need

## Cresemba

- > USD 352 mn global in-market sales in 12-months to June 2022
- Recently launched in China and regulatory decision expected in Japan in H2 2022
- 22.5% royalty income growth in H1 2022

Royalty income growth (in CHF mn)



Note: Consolidated figures in conformity with U.S. GAAP; rounding applied consistently

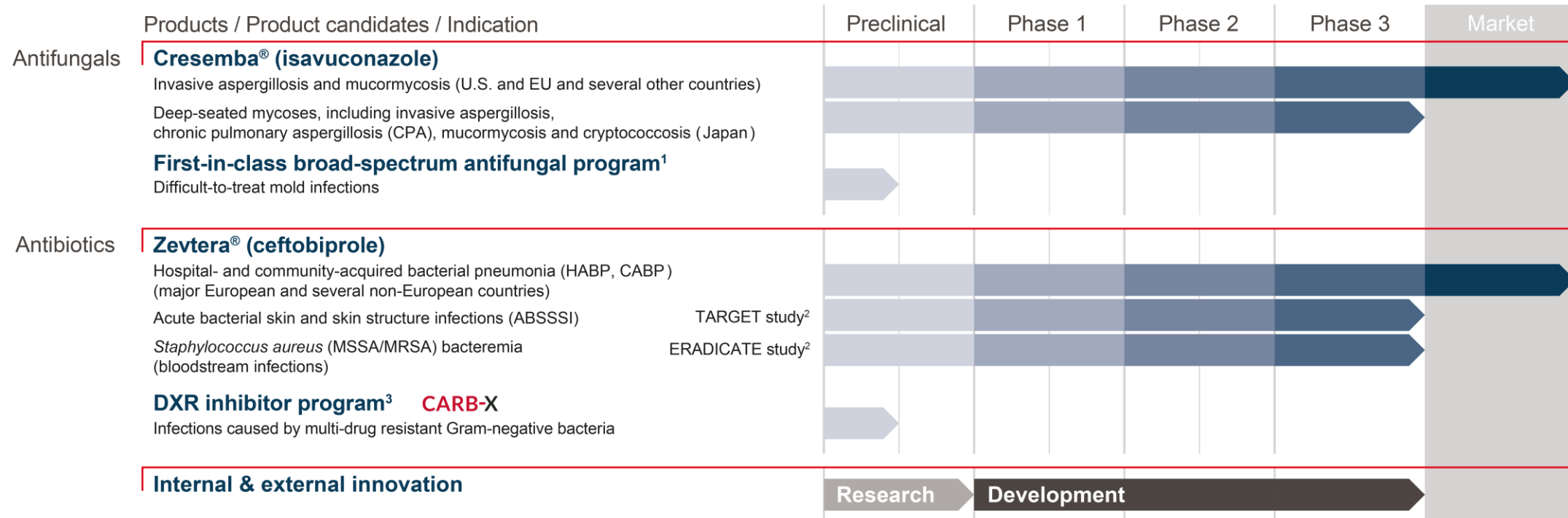
## Zevtera

- Successful ERADICATE and TARGET phase 3 studies
- Preparing to access the U.S. market: NDA submission expected around year-end
- U.S. represents ~ 80–90% of global commercial potential for branded MRSA hospital antibiotics

## Portfolio

- A number of preclinical programs, including a CARB-X funded antibiotic against multi-drug resistant Gram-negative bacteria and a potential first-in-class broad-spectrum antifungal
- Focus on external sourcing of additional clinical and preclinical anti-infective compounds

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



<sup>1</sup> Licensed from FCCDC

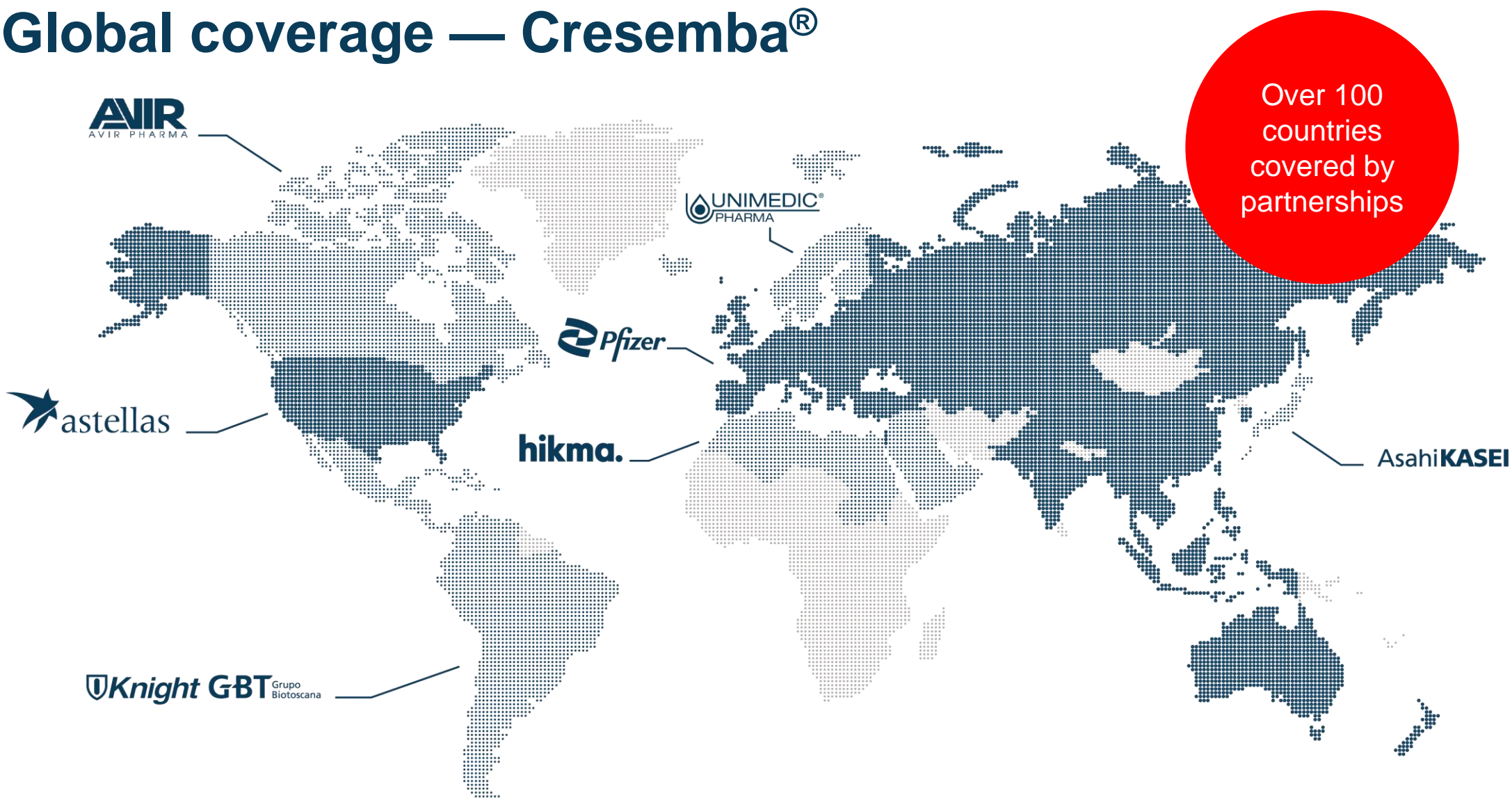
<sup>2</sup> Studies to support U.S. NDA. Phase 3 program is funded in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA).

<sup>3</sup> CARB-X's funding for this project is sponsored by Cooperative Agreement Number IDSEP160030 from ASPR/BARDA and by awards from Wellcome Trust and Germany's Federal Ministry of Education and Research.

The content is solely the responsibility of the authors and does not necessarily represent the official views of CARB-X or any of its funders.



# Global coverage — Cresemba®





# The company we keep — established strong partnerships

## License partners



Europe (excl. Nordics), China  
Asia-Pacific, Russia, Turkey  
and Israel (Cresemba®)



U.S. (Cresemba®)



Japan (Cresemba®)



China (Zevtera®)

## Distribution partners



Europe (excl. Nordics),  
Israel (Zevtera®)



MENA region  
(Cresemba® and Zevtera®)



LatAm  
(Cresemba® and Zevtera®)



Nordics  
(Cresemba® and Zevtera®)



Canada  
(Cresemba® and Zevtera®)



Russia and the Eurasian  
Economic Union  
(Zevtera®)

Double-digit  
percentage  
royalties on  
sales by  
license  
partners

>USD 1 bn  
in potential  
milestones  
remaining

Participation  
in sales of  
distribution  
partners  
through  
transfer price

>CHF 300 mn  
upfront and  
milestone  
payments  
received

Antifungal

# **Cresemba® (isavuconazole)**

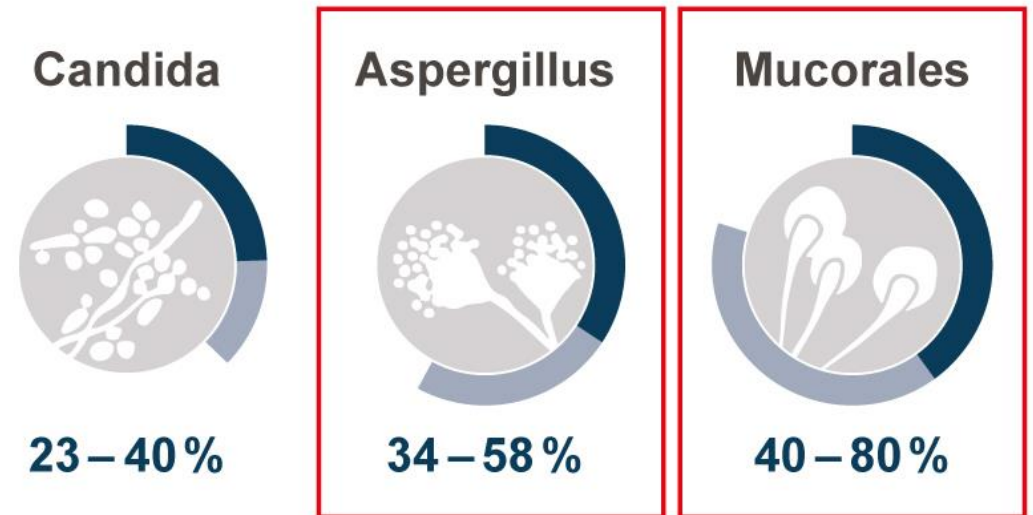
Invasive mold infections



# The market — Invasive fungal infections

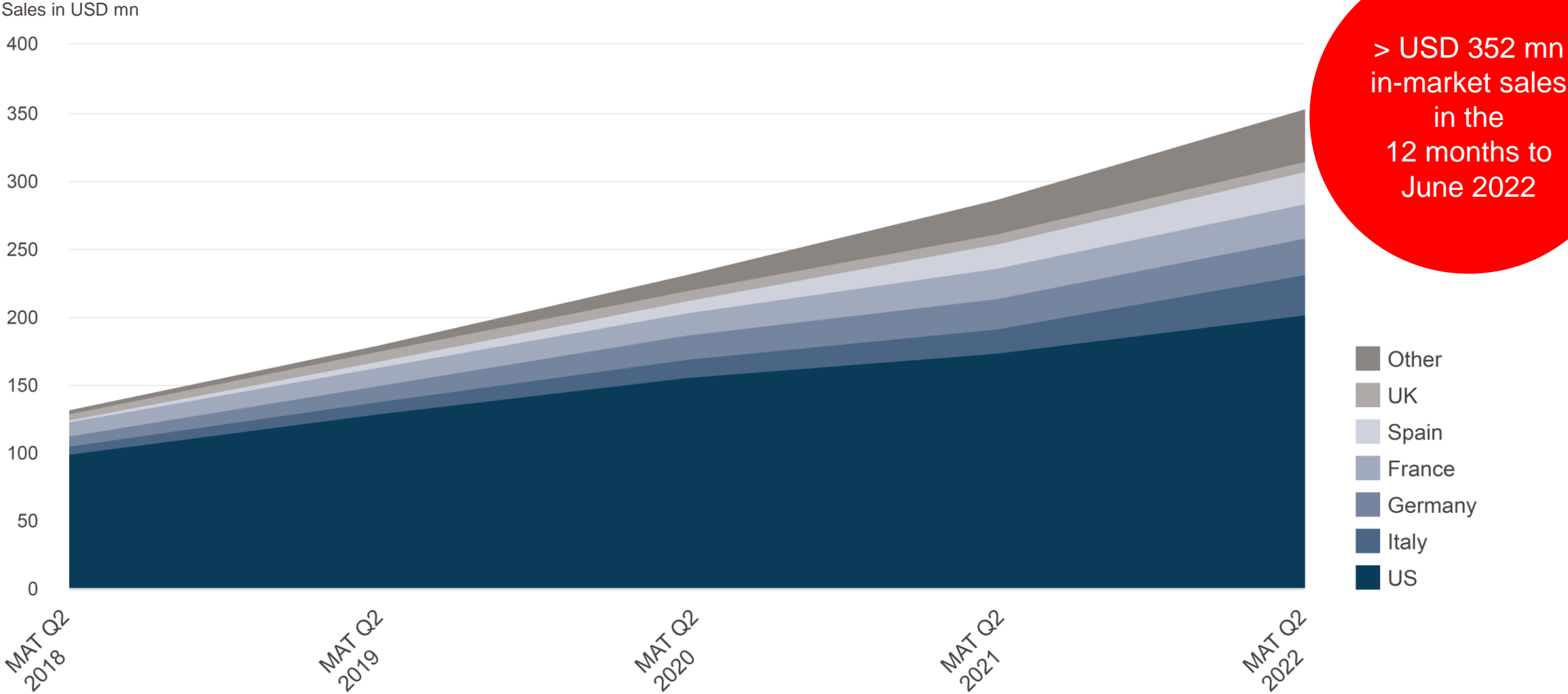
- Severe, potentially life-threatening infections mainly affecting immunocompromised patients
- An important cause of morbidity and mortality in cancer patients undergoing intensive chemotherapy regimens
- Rising number of immunocompromised patients (cancer and transplantations) driving therapeutic demand
- 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

## Mortality rates for invasive fungal infections\*\*



\*\*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



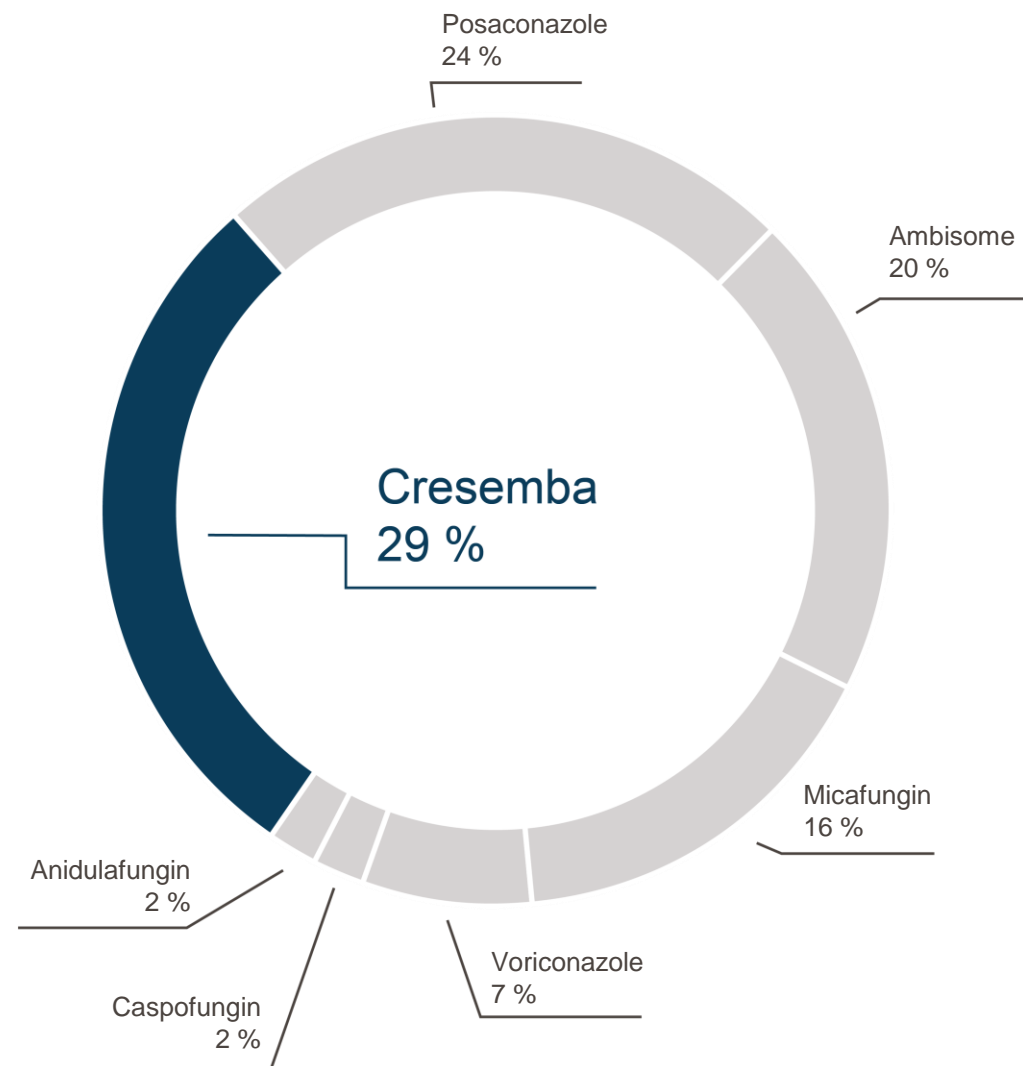
MAT: Moving annual total; Source: IQVIA Analytics Link, June 2022



# Cresemba has become the market leader in the U.S. in terms of value

- Consistently increased market share among best-in-class antifungals\* since launch to 29% by June 2022\*\*

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



\*\*Market share based on MAT Q2 2022, in-market sales reported as moving annual target (MAT) in U.S. dollar; rounding consistently applied. Source: IQVIA Analytics Link, June 2022

# Sales of best-in-class antifungals\* by product

USD 3.1 bn sales (MAT Q2 2022)

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

- Anticipated to be launched in ~70 countries by end-2022
- Exclusivity through 2027 in the U.S. 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, June 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<sup>®</sup>**  
**(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<sup>1, 2, 3</sup>
  - Low propensity for resistance development<sup>1</sup>
  - Safety profile consistent with the cephalosporin class safety profile, demonstrated in both adult and pediatric patients<sup>1, 2, 3, 4</sup>
- Marketed in selected countries in Europe, Latin America, the MENA-region and Canada
- U.S. NDA submission expected around year-end 2022

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 (CAPB). Not approved in the U.S.

MENA: Middle East and North Africa



**Focused on Growth and Innovation**



<sup>1</sup> Syed YY. Drugs. 2014;74:1523-1542 and Basilea data on file.

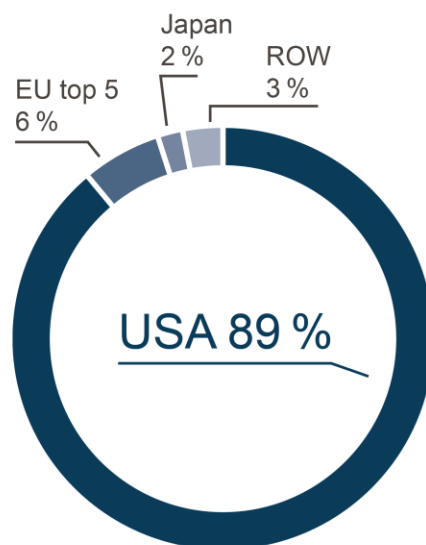
<sup>2</sup> Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

<sup>3</sup> Holland TL et al. IDWeek 2022, LB2302

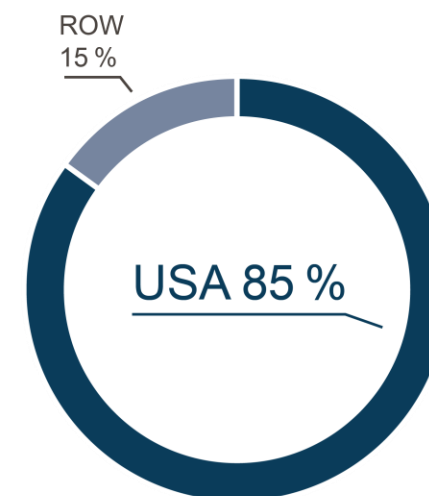
<sup>4</sup> Rubino CM et al. Pediatr Infect Dis J. 2021;40:997-1003.

# The hospital anti-MRSA antibiotic market — A USD 2.7 bn market\* with the U.S. being the most important region

Daptomycin sales by region  
(2015, before LOE)



Ceftaroline sales by region  
(MAT Q2 2022)



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

MRSA: Methicillin-resistant *Staphylococcus aureus*; LOE: Loss of exclusivity; ROW: Rest of world; MAT: Moving annual total; Source: IQVIA Analytics Link, June 2022

# Ceftobiprole — Strategy for accessing the U.S. market

- Planned U.S. NDA submission to be supported by:
    - Two successfully completed cross-supportive phase 3 studies under FDA Special Protocol Assessment (SPA)
      1. Acute bacterial skin and skin structure Infections (ABSSSI)<sup>1</sup>
      2. *Staphylococcus aureus* bacteremia (SAB)<sup>2</sup>
  - Phase 3 program largely funded by BARDA (~70% total program costs; up to USD ~136 mn)
  - Qualified Infectious Disease Product (QIDP) designation extends U.S. market exclusivity to 10 years from approval
  - Commercialization planned through partnership
- Additionally explore the possibility of gaining approval for CABP as a third indication
- Phase 3 study in CABP previously completed<sup>3</sup>



<sup>1</sup> Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517. (NCT03137173)

<sup>2</sup> Holland TL et al. IDWeek 2022, LB2302

<sup>3</sup> 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 U.S. (in 2017)<sup>1</sup>
- 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<sup>2</sup>
- Limited antibiotic treatment options with only two approved treatments for SAB in the U.S. that cover both MSSA and MRSA, i.e. vancomycin and daptomycin

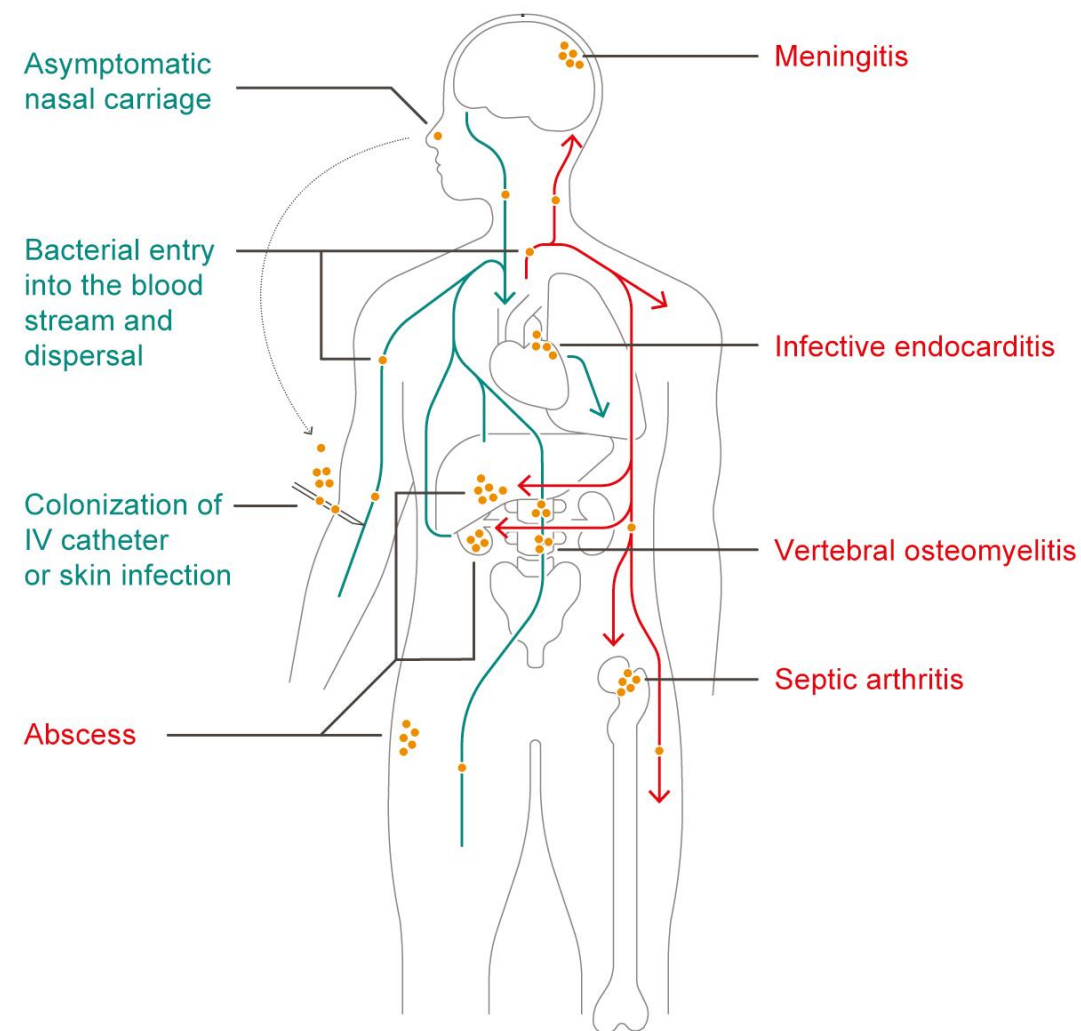
<sup>1</sup> MMWR, 2019;68:214–219.

<sup>2</sup> Hamed K et al. Future Microbiol. 2020;15:35-48.

MRSA: methicillin-resistant *Staphylococcus aureus*

MSSA: methicillin-susceptible *Staphylococcus aureus*

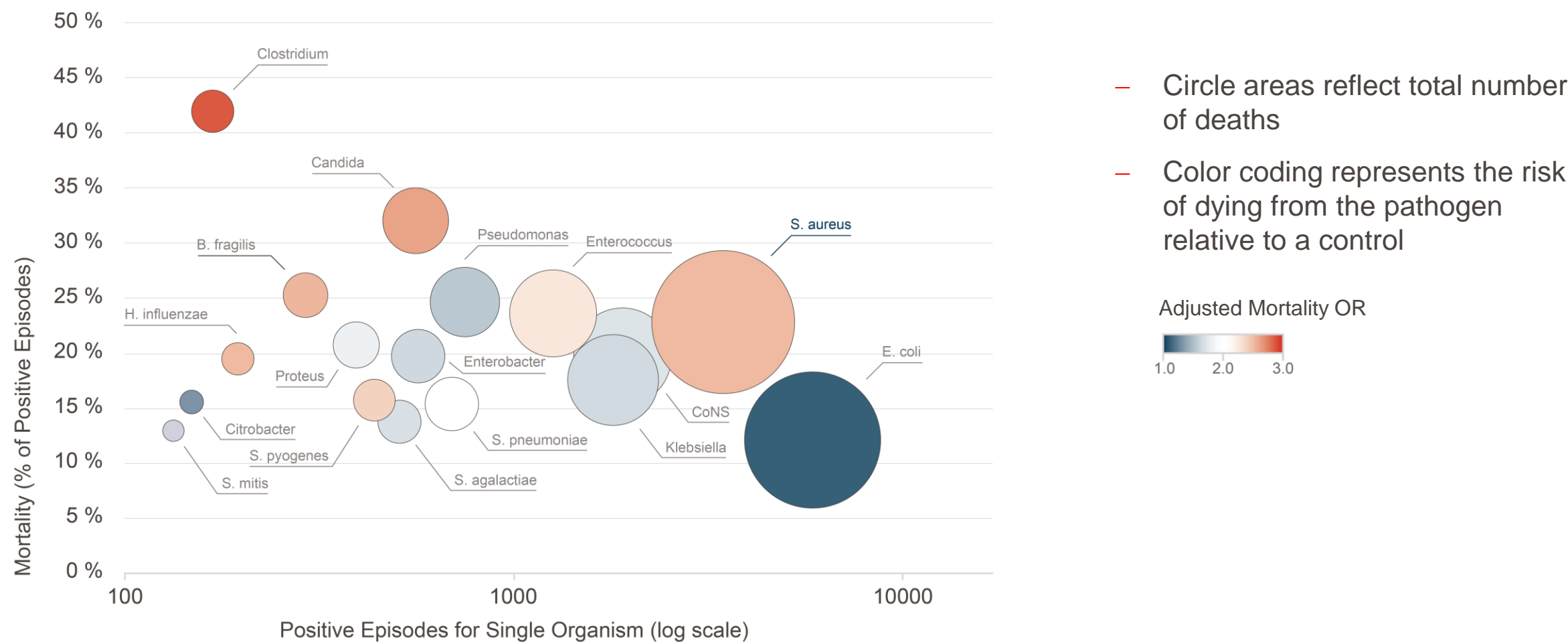
## Causes and consequences of SAB



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



# SAB — Highest disease burden among bloodstream infections

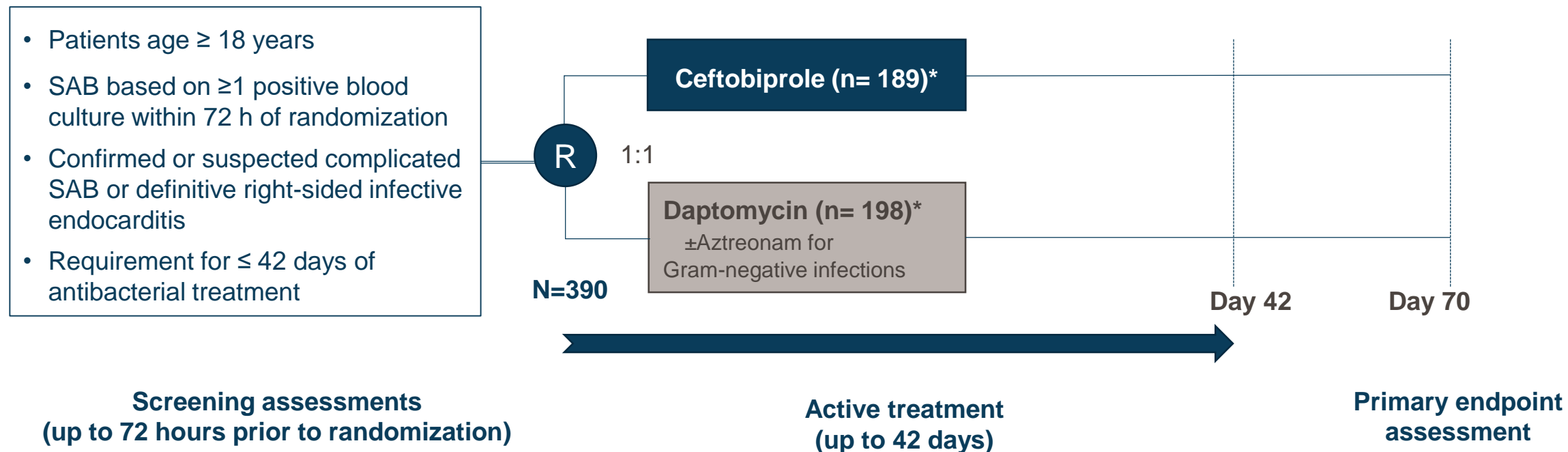


Adapted from: Verway M et al. J Clin Microbiol. 2022;60:e0242921.

# 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.

# ERADICATE — Study design



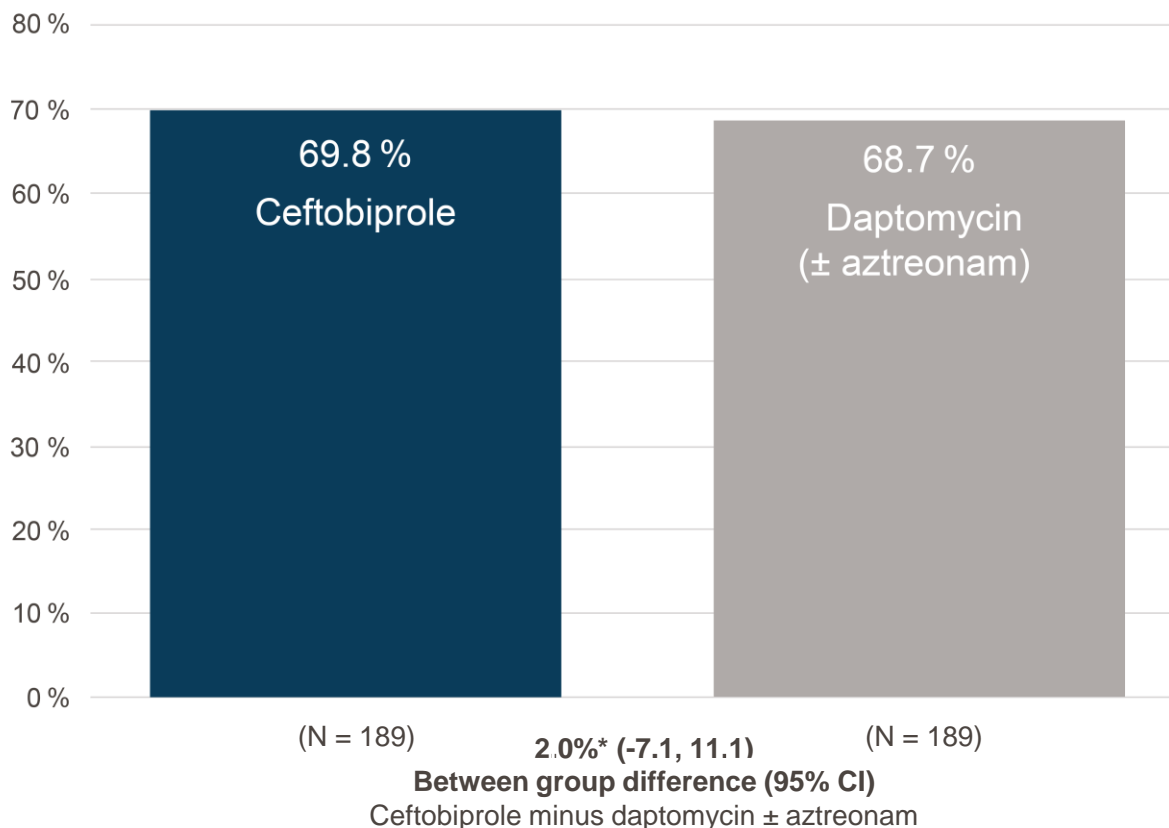
Adapted from Hamed K et al. Future Microbiol. 2020;15:35-48

\*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 is achieved

(DRC assessed overall success at PTE in mITT population)

% Patients with overall success at PTE



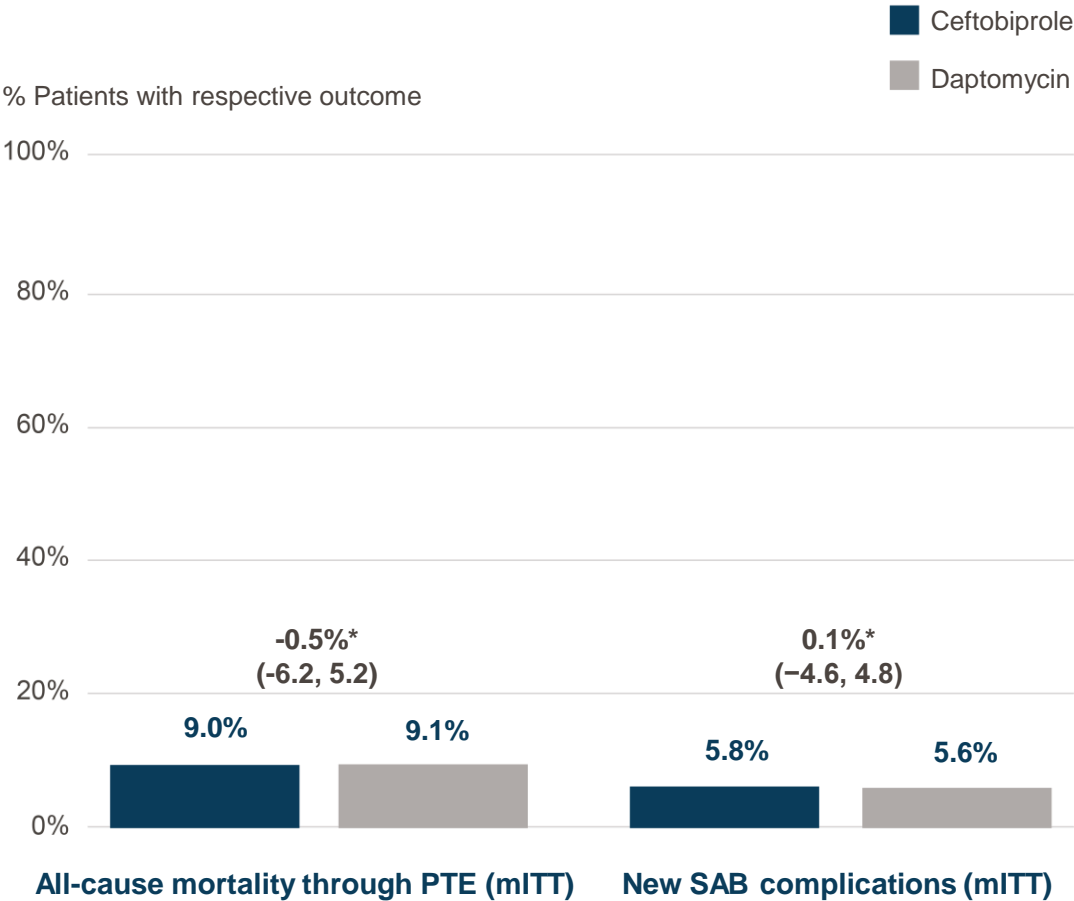
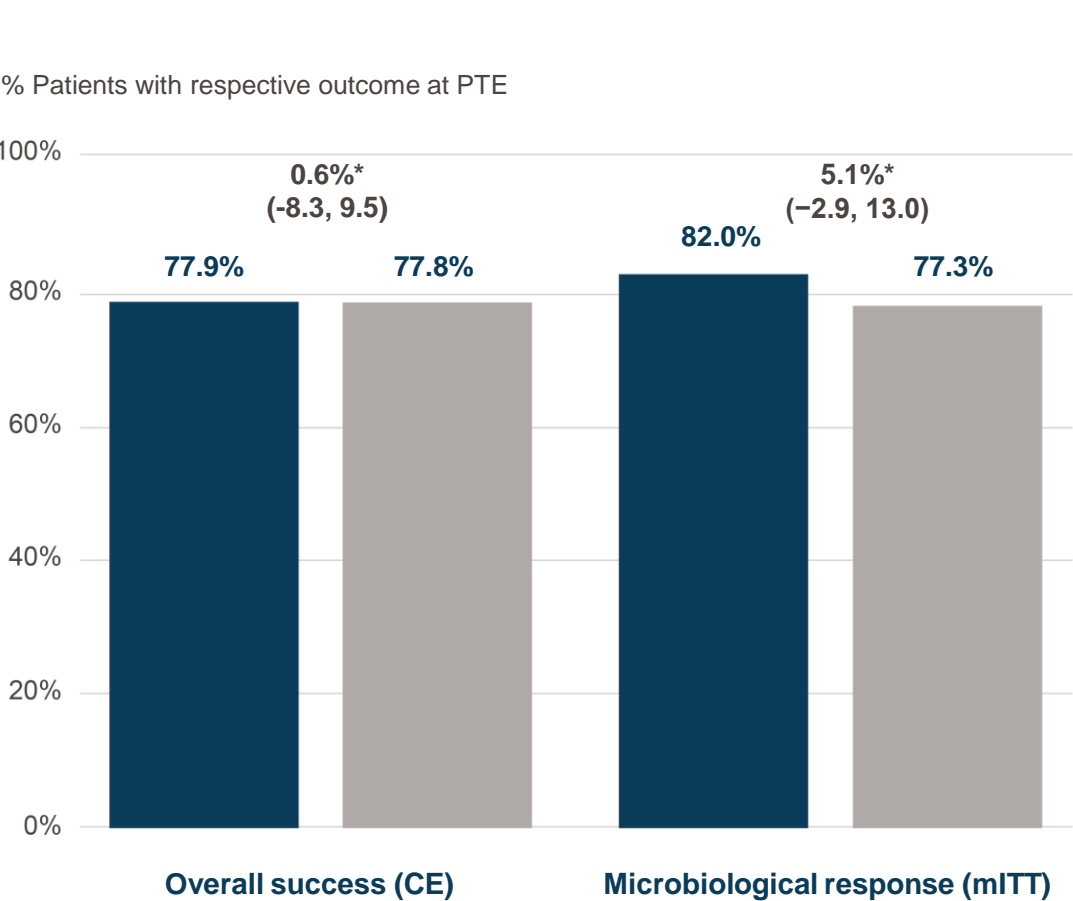
- Non-inferiority demonstrated based on the pre-defined non-inferiority margin of 15%
- Consistent results in key subgroups and various categories of underlying conditions:
  - MSSA or MRSA bloodstream infections at baseline
  - Skin and skin structure infections
  - Abdominal abscesses
  - Chronic dialysis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

# Zevtera — Place in therapy

- Ceftobiprole is an 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*
- For these patients ceftobiprole provides a 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



## Financials & Outlook



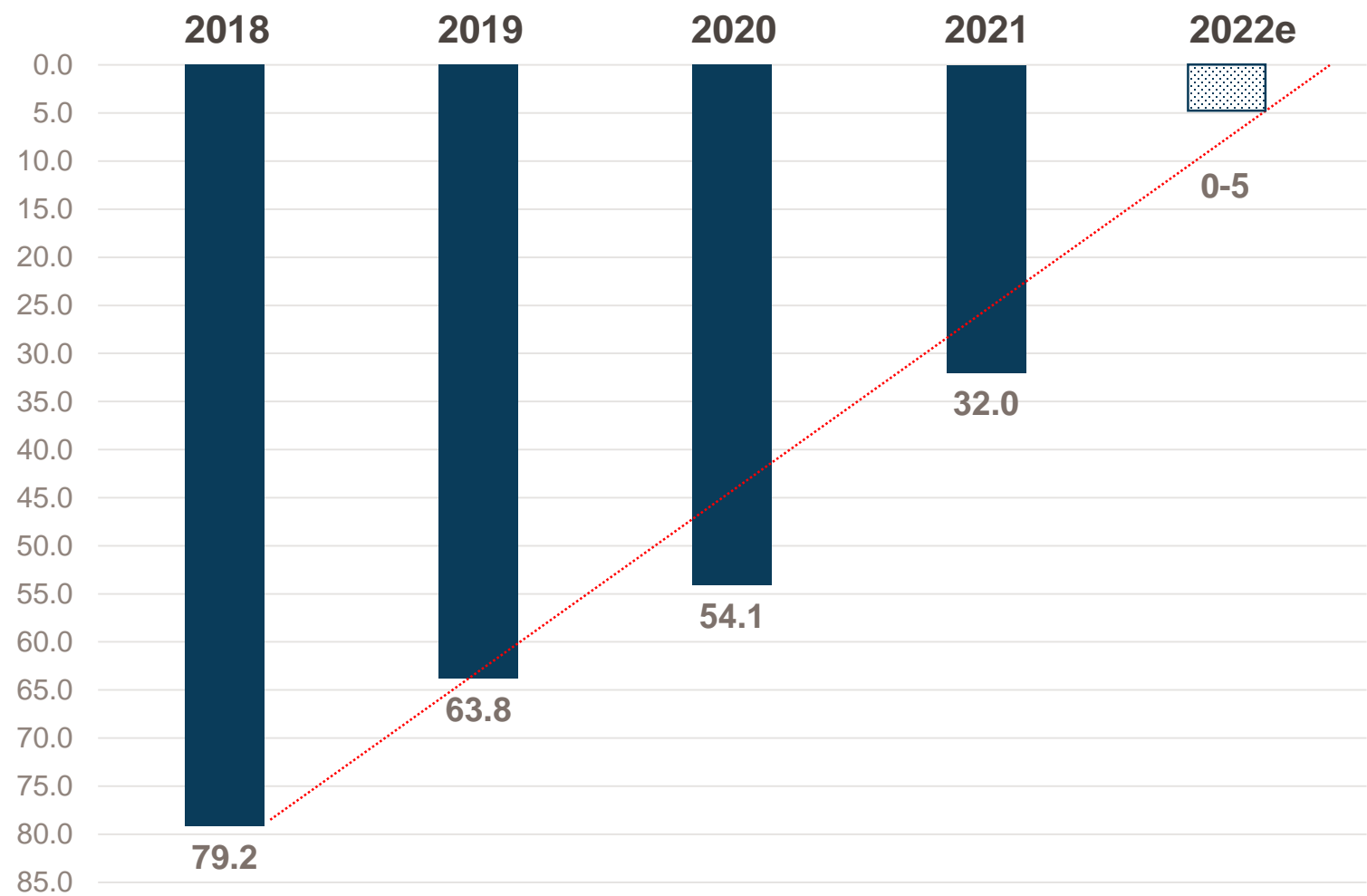


# Guidance — Sustainable profitability from FY 2023 expected

In CHF mn	FY 2023e	FY 2022e*	FY 2021
Cresemba & Zevtera related revenue	-	98 – 104	131.4
Royalty income	-	~ 59	53.2
Total revenue	-	116 – 122	148.1
Cost of products sold	-	21 – 24	24.1
Operating expenses	-30% vs. 2022	~ 110	122.9
Operating (loss)/profit	> 0	(10 – 15)	1.2
Net cash used in operating activities	Cash flow positive	0 – 5	32.0

Decrease in Cresemba & Zevtera related revenue 2022 vs. 2021 due to lower expected milestone payments

# Net cash used in operating activities



# Key milestones

Product	H1 2022	H2 2022
Ceftobiprole (Zevtera)	Completed patient enrolment in phase 3 SAB study (ERADICATE) ✓	
	Positive results of phase 3 SAB study (ERADICATE) ✓	U.S. NDA submission (around year-end)
Isavuconazole (Cresemba)	Marketing approvals in China ✓	Marketing approval in Japan
		Launched in ~70 countries

Complete transactions of oncology assets

Increasing Cresemba & Zevtera revenue

Advancement of preclinical anti-infective assets

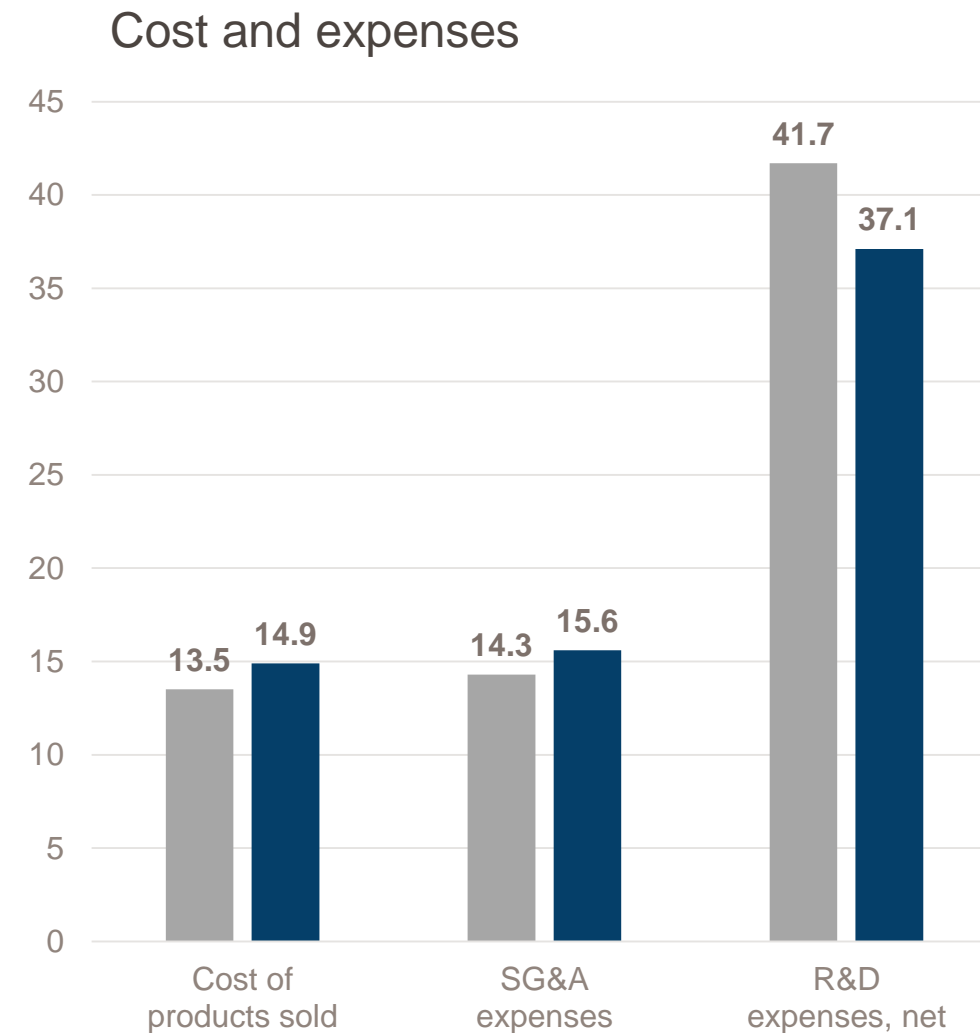
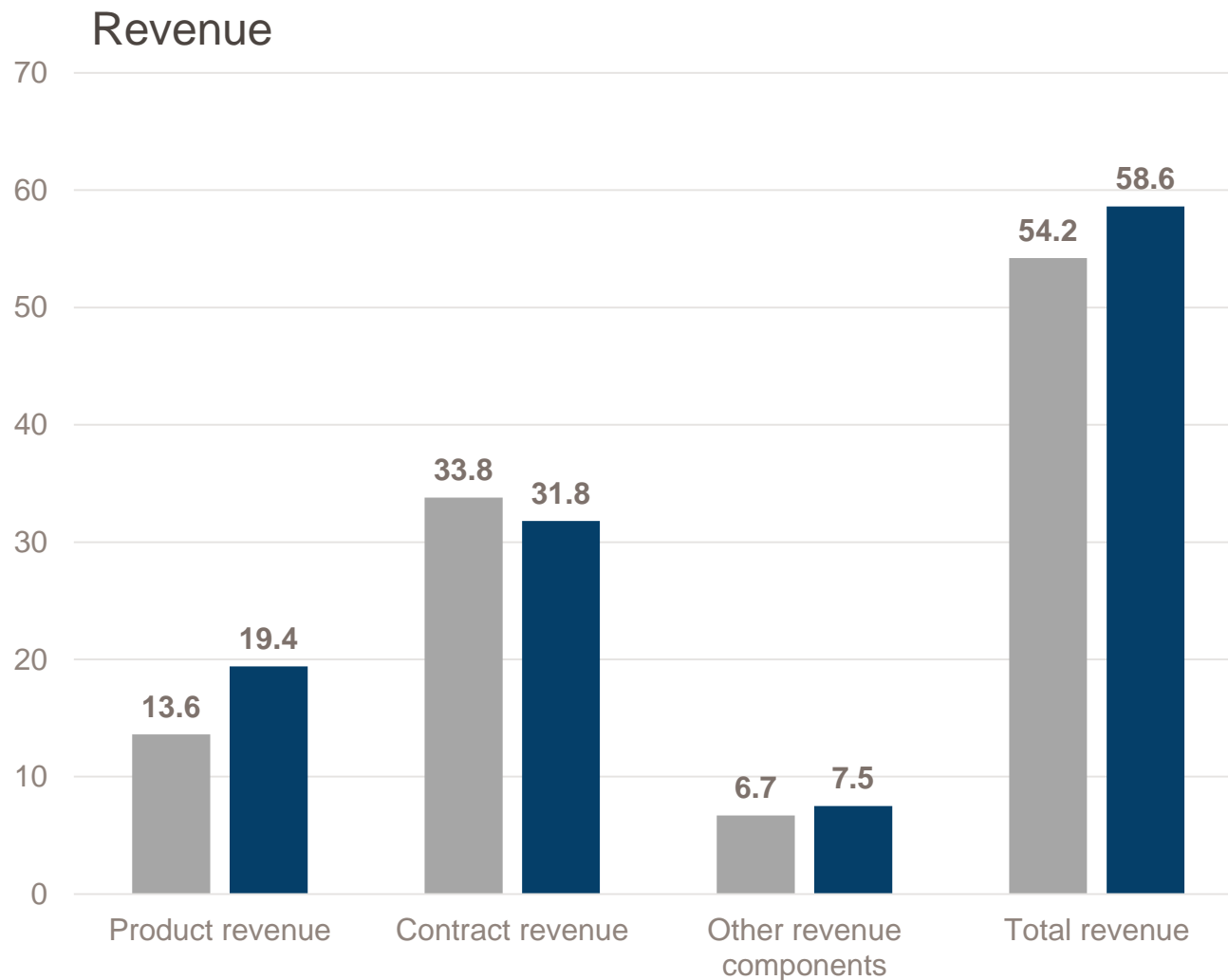
In-licensing of anti-infectives

# Appendix



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

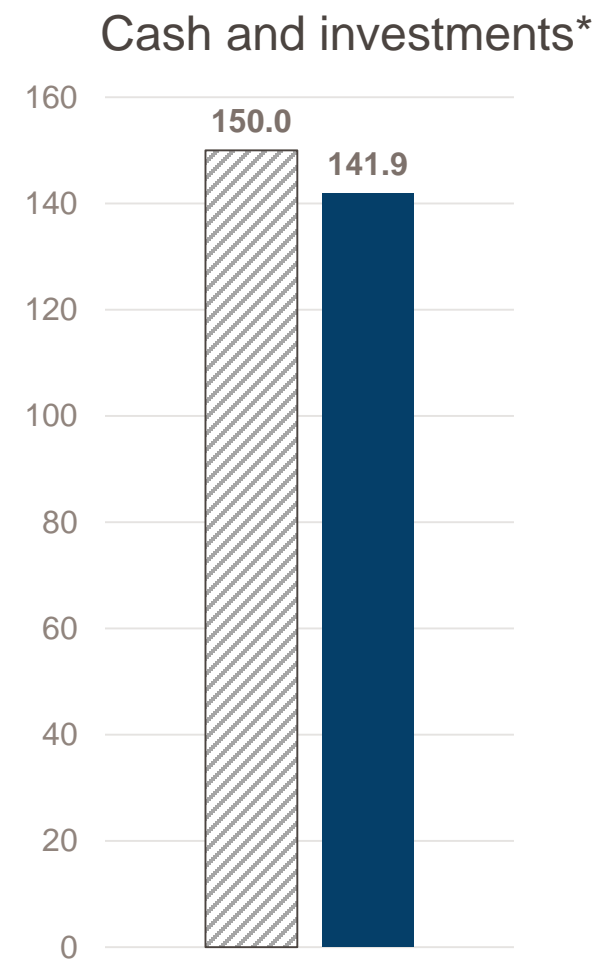
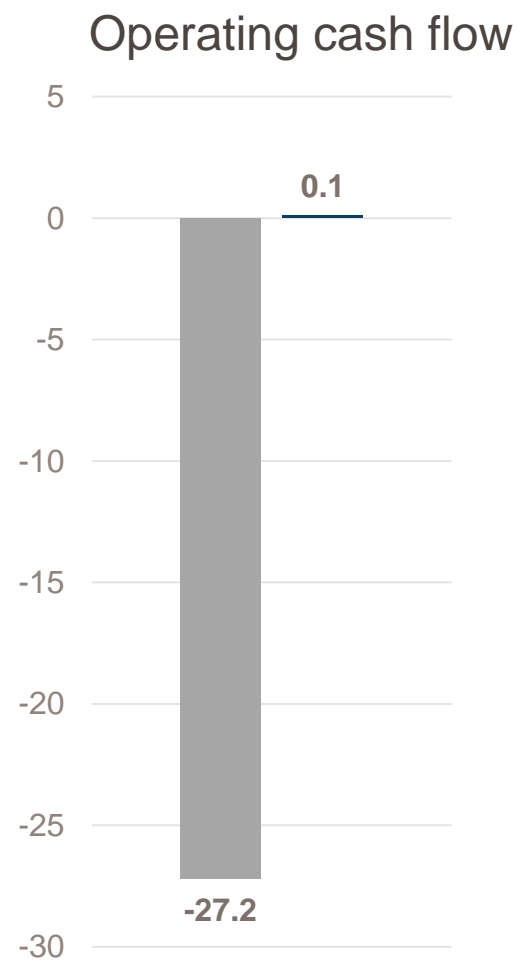
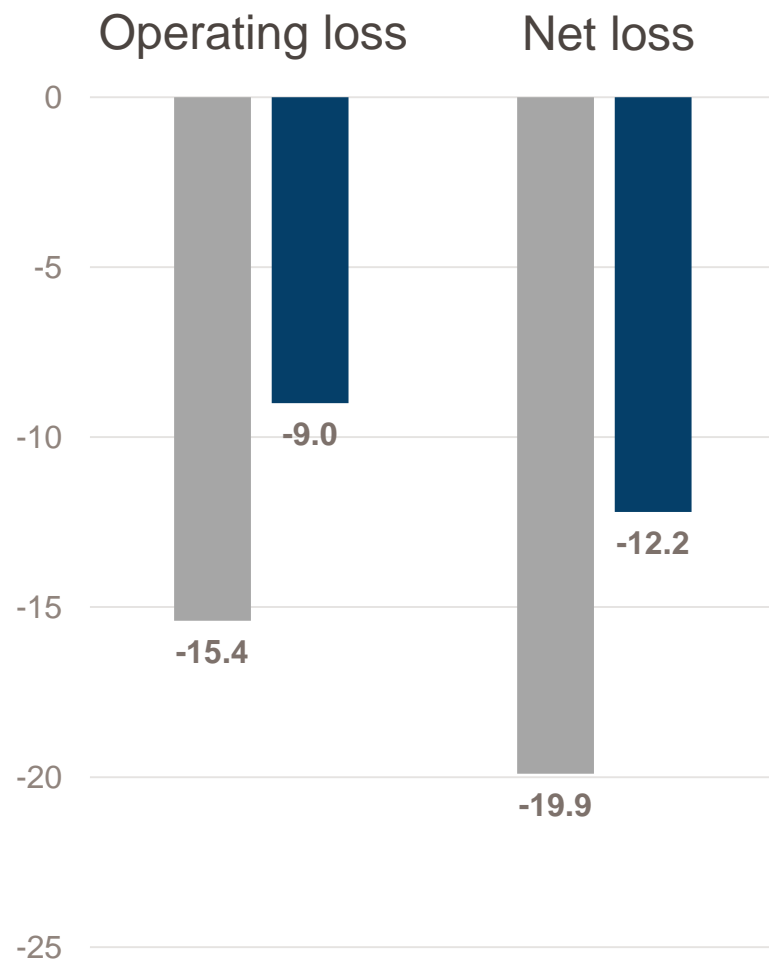
■ HY 2021  
■ HY 2022



Note: Consolidated figures in conformity with U.S. GAAP; rounding applied consistently

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

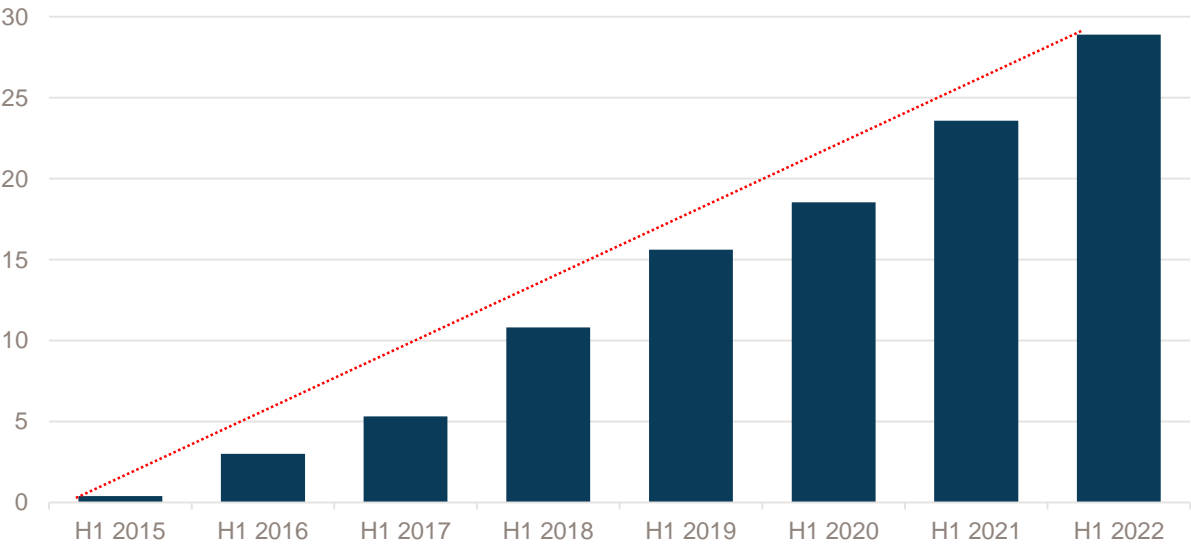
■ HY 2021  
■ HY 2022  
▨ FY 2021



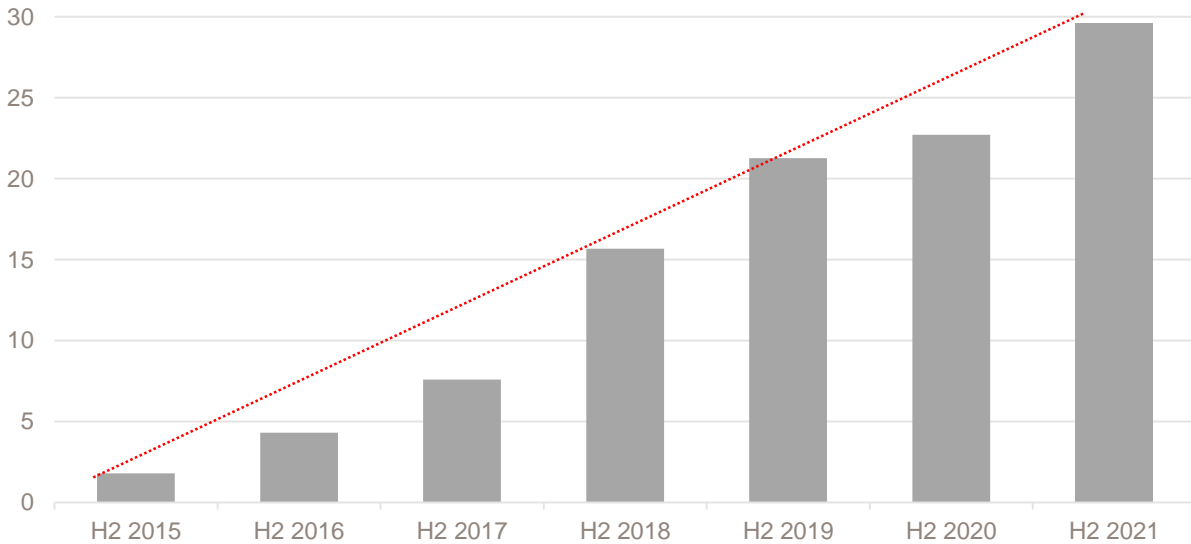
Note: Consolidated figures in conformity with U.S. GAAP; rounding applied consistently, \*Cash, cash equivalents, restricted cash and investments

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

First half-year



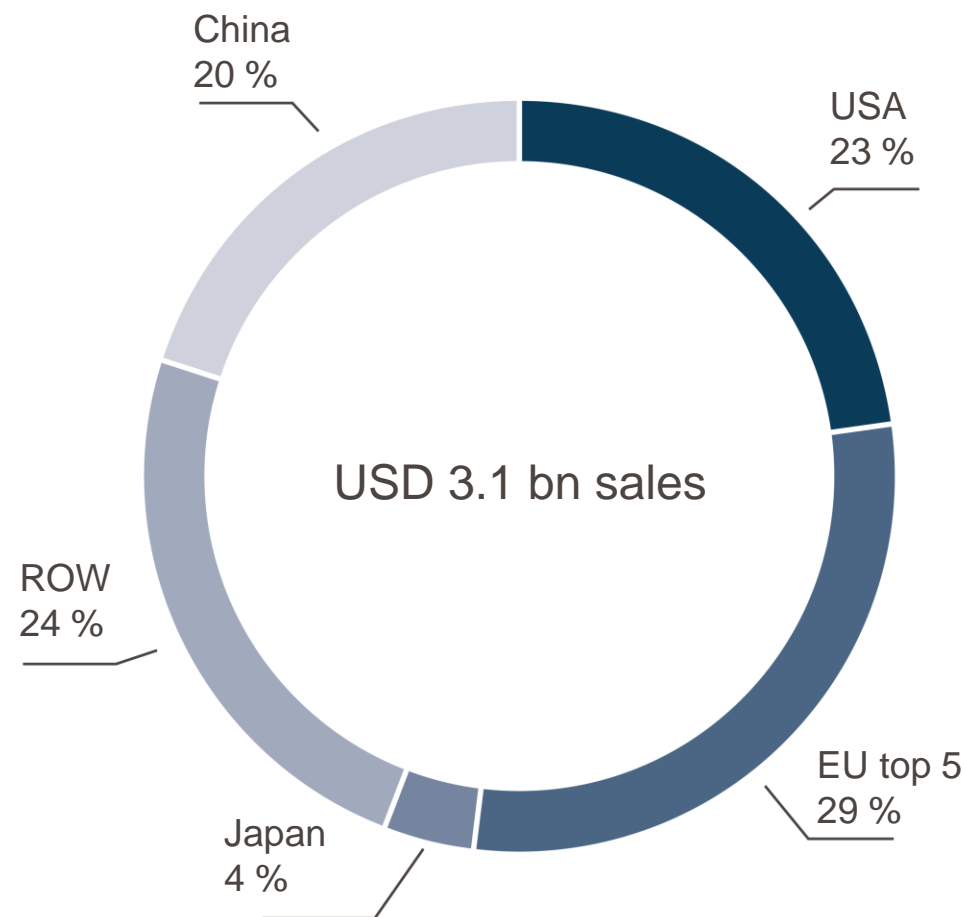
Second half-year



Note: Consolidated figures in conformity with U.S. GAAP; rounding applied consistently

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

USD 3.1 bn sales of best-in-class antifungals\*  
(MAT Q2 2022)



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

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

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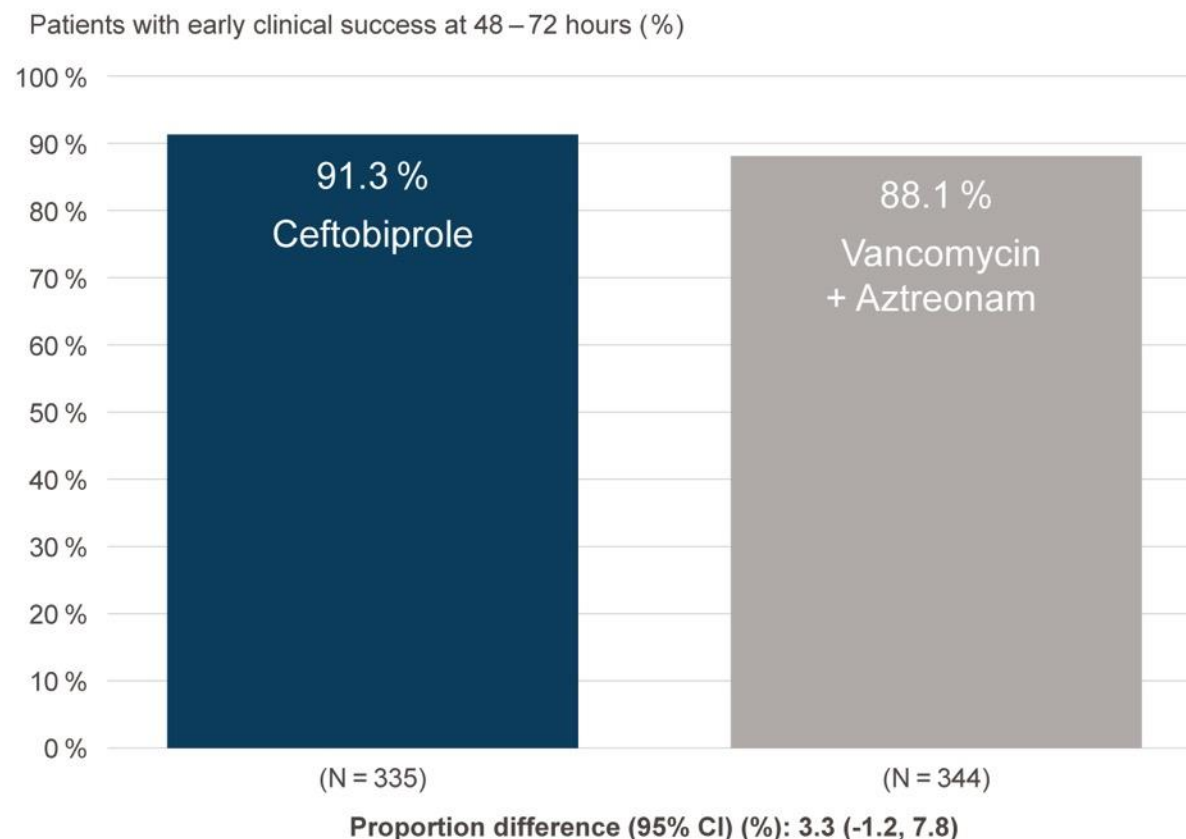
# Ceftobiprole — Positive phase 3 results reported in ABSSSI

Results showing non-inferiority of ceftobiprole to vancomycin plus aztreonam for the primary and secondary endpoints<sup>1</sup>



<sup>1</sup> Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

## 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 %

# Ceftobiprole — Positive phase 3 results reported in ABSSSI

Key topline study<sup>1</sup> results showing non-inferiority of ceftobiprole to vancomycin plus aztreonam for the primary and secondary endpoints

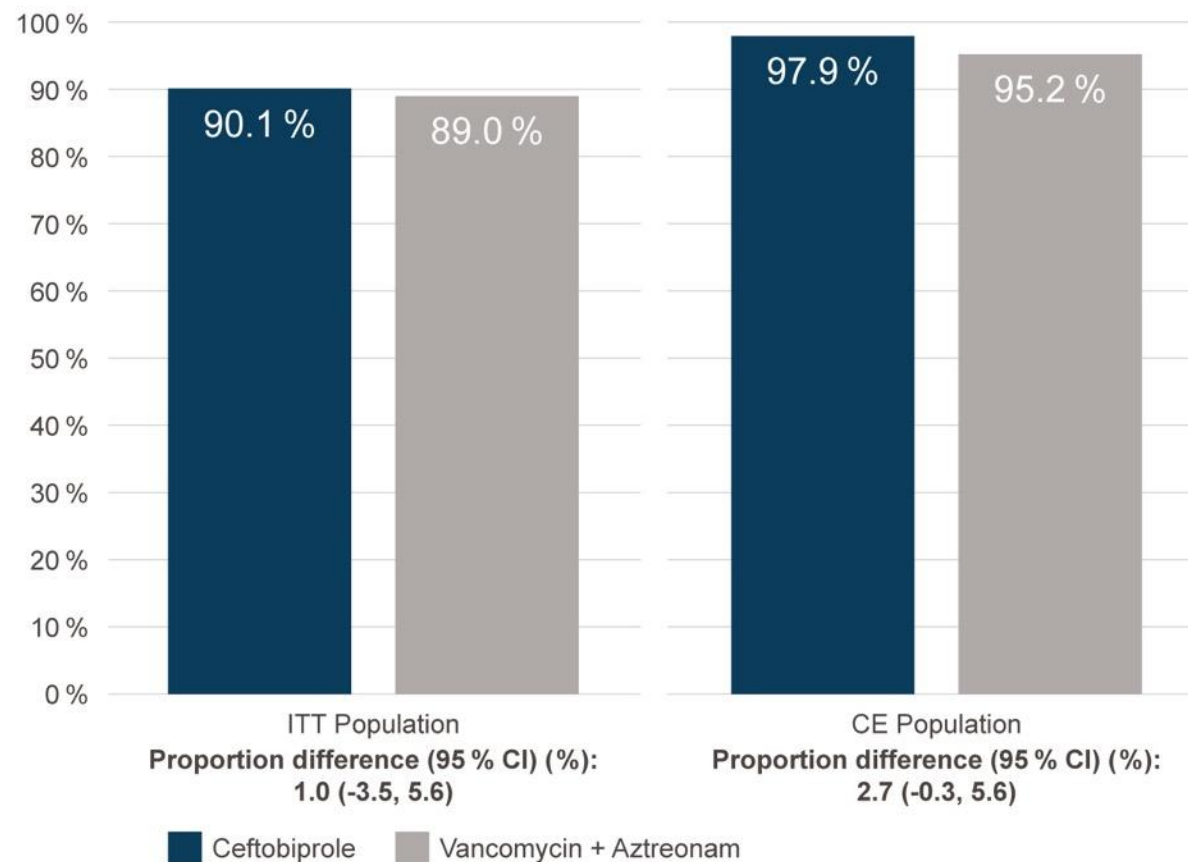


<sup>1</sup> NCT03137173

ABSSSI: Acute bacterial skin and skin structure infections

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

Patients with clinical success at the TOC visit (%)



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<sup>1</sup>
- Efficacy demonstrated in phase 3 clinical studies in acute bacterial skin and skin structure infections, and pneumonia<sup>1,2</sup>
- Superior activity profile in multiple in vivo models of serious infection compared to vancomycin and daptomycin<sup>3</sup>
- Low propensity for resistance development<sup>1</sup>
- Established safety profile consistent with the cephalosporin class, demonstrated in both adult and pediatric patients<sup>1,2,4</sup>

<sup>1</sup>Syed YY. Drugs. 2014;74:1523-1542.

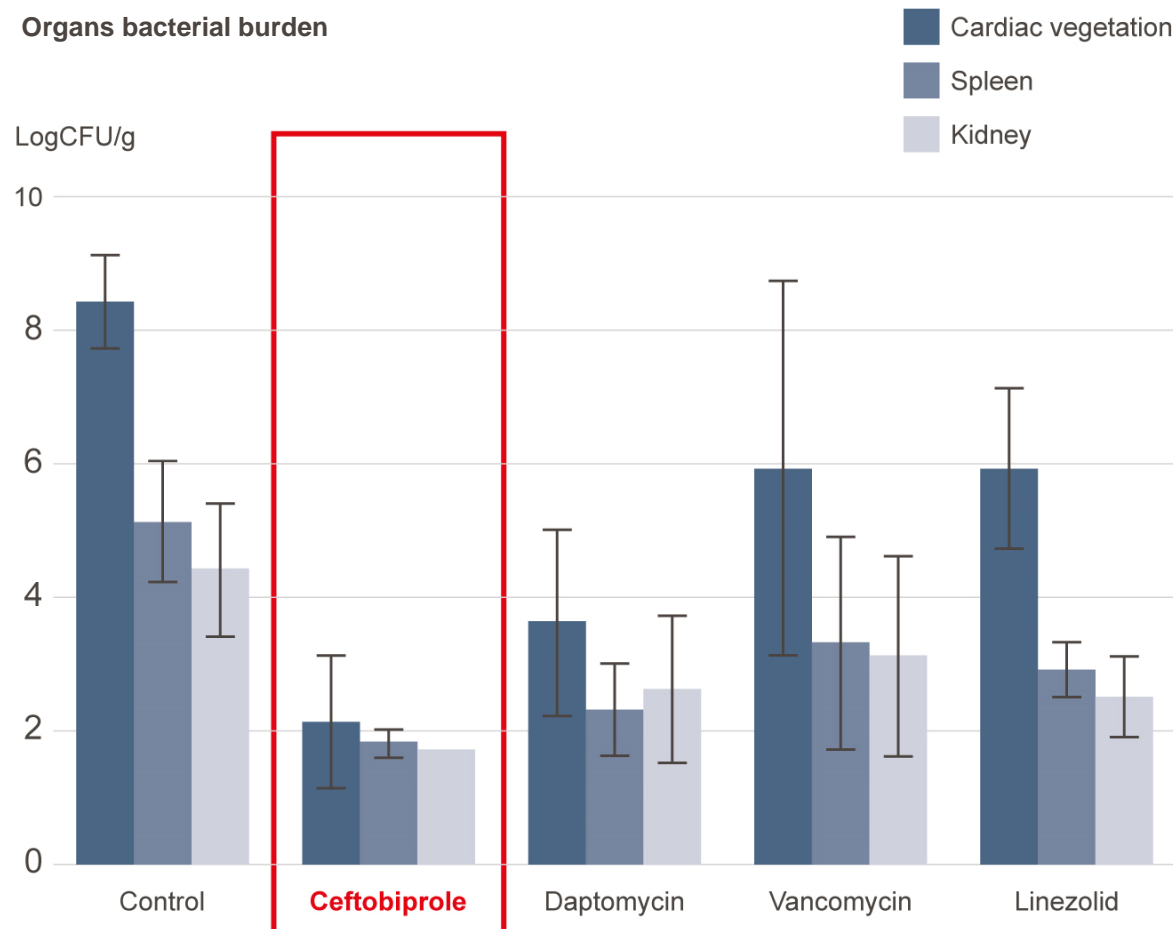
<sup>2</sup>Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

<sup>3</sup>Tatteen P et al. Antimicrob Agents Chemother. 2010;54:610-613.

<sup>4</sup>Rubino CM et al. Pediatr Infect Dis J. 2021;40:997-1003.

## Comparative efficacy in a rabbit model of endocarditis

Organs bacterial burden



Organism titers in cardiac vegetations, spleens and kidneys of untreated and antibiotic treated rabbits infected with MRSA<sup>3</sup>

# Glossary

–	ABSSSI:	<b>A</b> cute <b>b</b> acterial <b>s</b> kin and <b>s</b> kin <b>s</b> tructure <b>i</b> nfections
–	BARDA:	<b>B</b> iomedical <b>A</b> dvanced <b>R</b> esearch and <b>D</b> evelopment <b>A</b> uthority
–	CABP:	<b>C</b> ommunity-acquired <b>b</b> acterial <b>p</b> neumonia
–	CE:	<b>C</b> linically <b>e</b> valuable
–	CPA:	<b>C</b> hronic <b>p</b> ulmonary <b>a</b> spergillosis
–	CARB-X:	<b>C</b> ombating <b>A</b> ntibiotic- <b>R</b> esistant <b>B</b> acteria Biopharmaceutical <b>A</b> ccelerator
–	DRC:	<b>D</b> ata <b>r</b> eview <b>c</b> ommittee
–	HABP:	<b>H</b> ospital-acquired <b>b</b> acterial <b>p</b> neumonia
–	ITT:	<b>I</b> ntent- <b>T</b> o- <b>T</b> reat
–	i.v.:	<b>I</b> ntravenous
–	mITT:	<b>M</b> odified <b>i</b> ntent- <b>t</b> o- <b>t</b> reat
–	MSSA:	<b>M</b> ethicillin- <b>s</b> usceptible <i><b>S</b>ta<del>ph</del>yl<b>o</b>coccus <b>a</b>ureus</i>
–	MRSA:	<b>M</b> ethicillin- <b>r</b> esistant <i><b>S</b>ta<del>ph</del>yl<b>o</b>coccus <b>a</b>ureus</i>
–	NDA:	<b>N</b> ew <b>d</b> rug <b>a</b> pplication
–	OR:	<b>O</b> dds <b>r</b> atio
–	PTE:	<b>P</b> ost- <b>t</b> reatment <b>e</b> valuation
–	QIDP:	<b>Q</b> ualified <b>I</b> nfectious <b>D</b> isease <b>P</b> roduct
–	SAB:	<i><b>S</b>ta<del>ph</del>yl<b>o</b>coccus <b>a</b>ureus</i> <b>b</b> acteremia
–	SPA:	<b>S</b> pecial <b>P</b> rotocol <b>A</b> ssessment
–	U.S. GAAP:	<b>U</b> nited <b>S</b> tates <b>G</b> enerally <b>A</b> ccepted <b>A</b> ccounting <b>P</b> riniples
–	VAP:	<b>V</b> entilator-associated <b>p</b> neumonia

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