



**Focused on
Growth and Innovation**

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

Investor presentation

January 24, 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

2009



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

2010



**Gerrit
Hauck**
Ph.D. CTO

2018



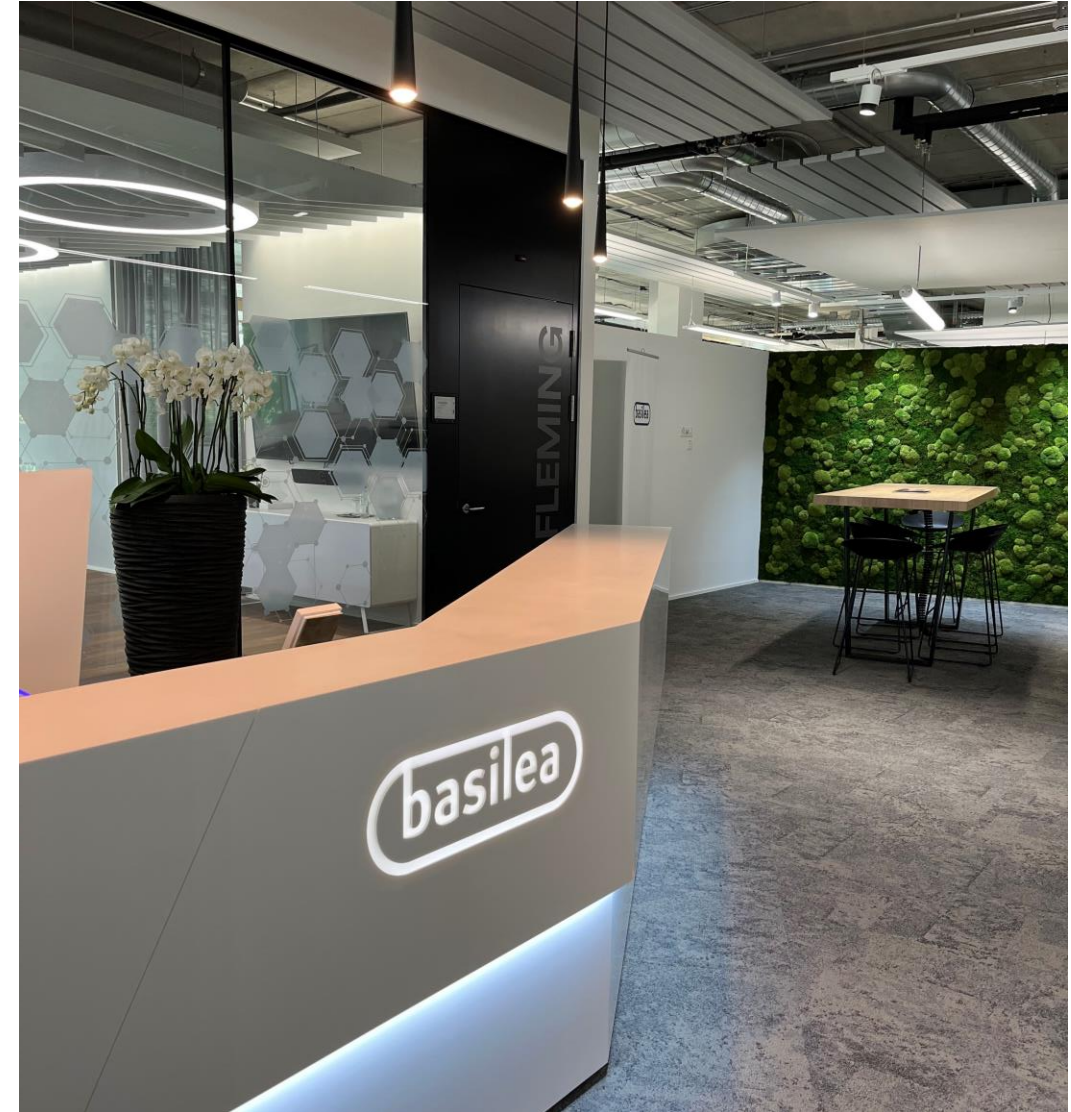
**Laurenz
Kellenberger**
Ph.D. CSO

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
- Reported preliminary profitability for 2022
- Listed on SIX Swiss Stock Exchange, SIX: BSLN
- Located in the Basel area life sciences hub, Switzerland

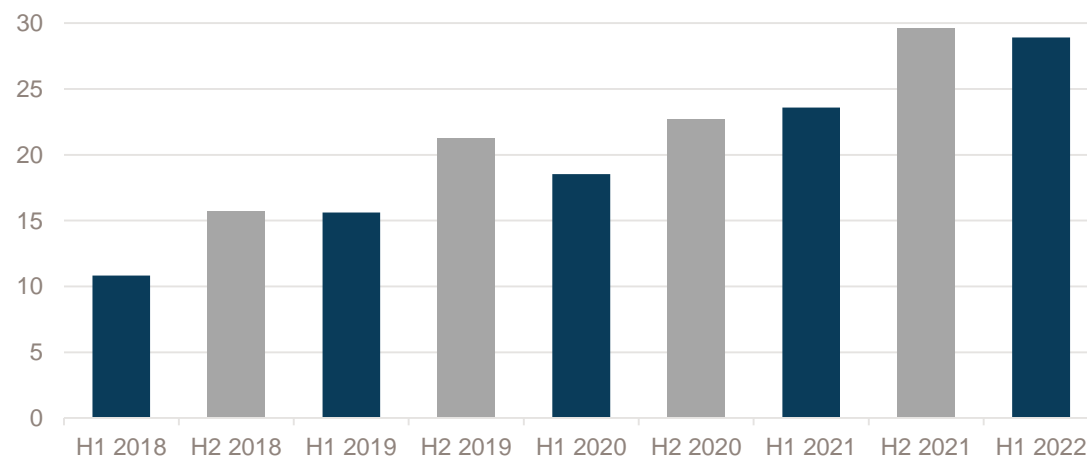


Uniquely positioned to create sustainable value in an area of increasing unmet medical need

Cresemba

- > USD 363 mn global in-market sales in 12-months to September 2022
- Launched in China mid-2022 and regulatory approval granted in Japan in December 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

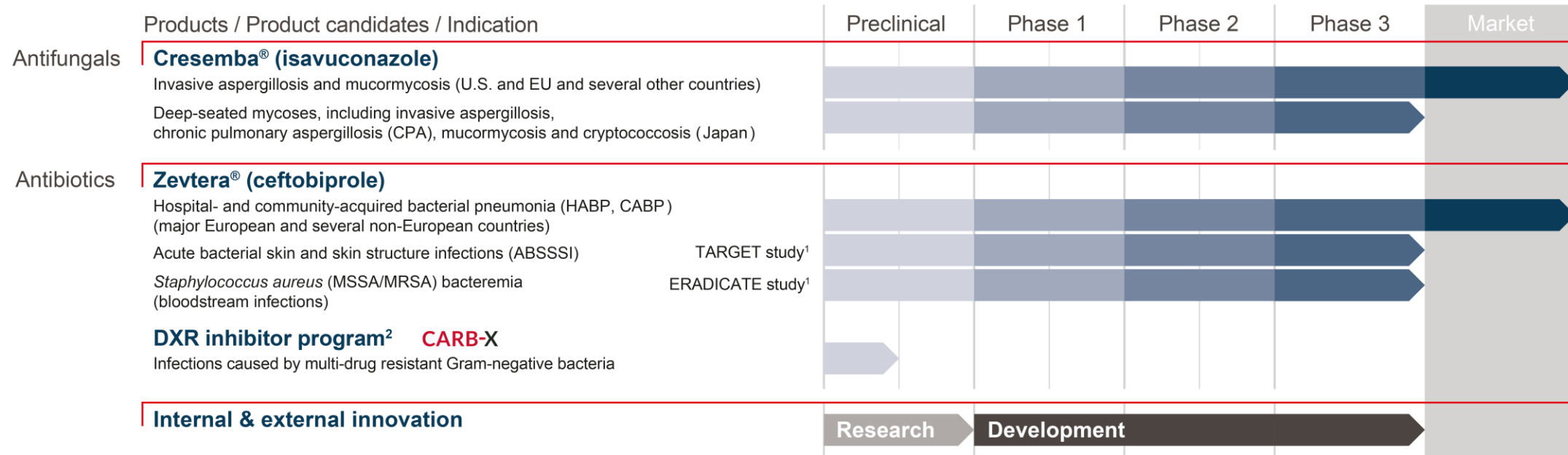
Zevtera

- Successful ERADICATE and TARGET phase 3 studies
- Preparing to access the U.S. market: NDA submission expected in March/April 2023
- 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
- 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

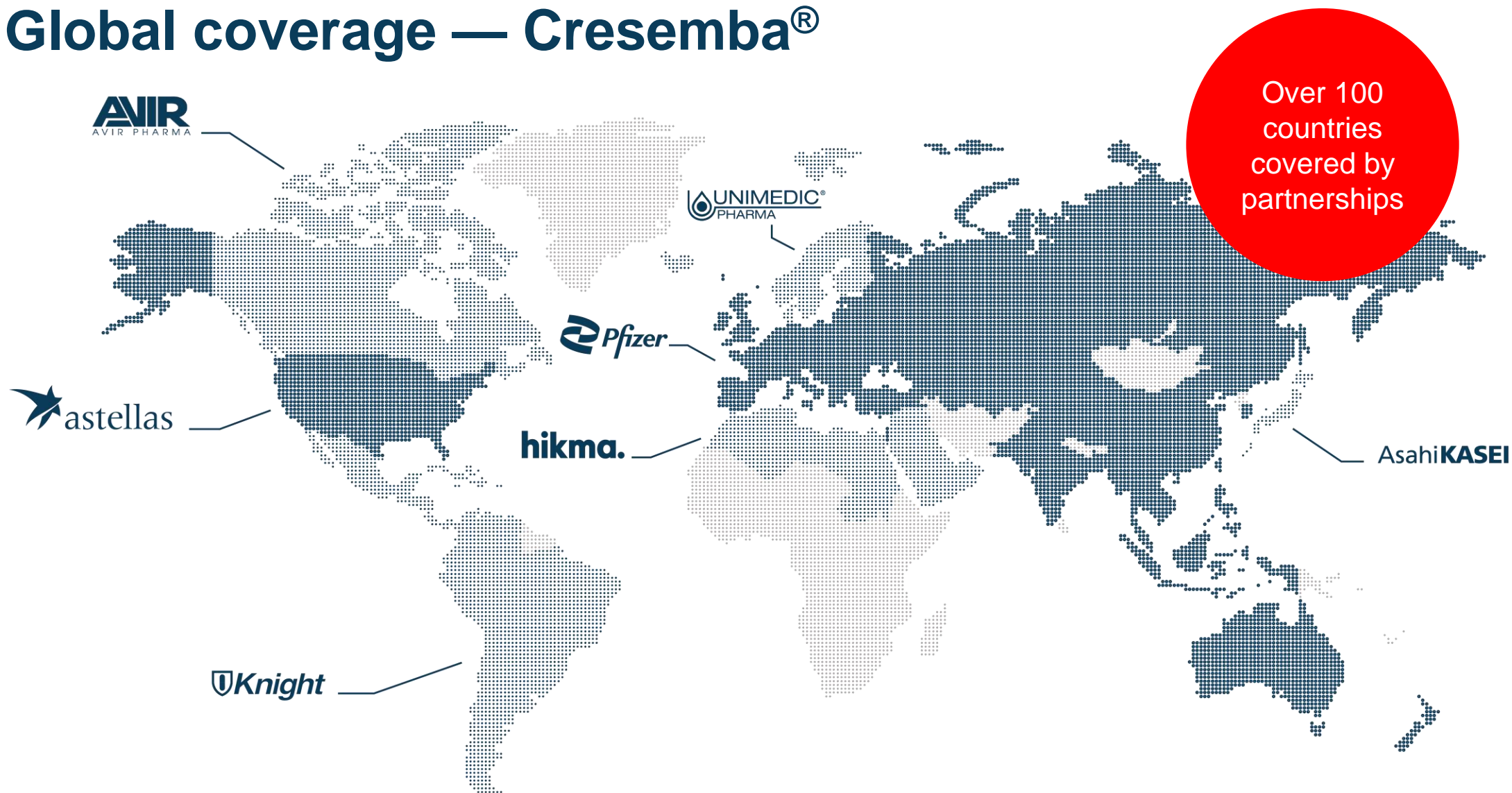


¹ Studies to support U.S. NDA. Phase 3 program is funded in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA).

² 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®)

AsahiKASEI

Japan (Cresemba®)



China (Zevtera®)

Distribution partners

ADVANCE
PHARMA

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

hikma.

MENA region
(Cresemba® and Zevtera®)

Knight

LatAm
(Cresemba® and Zevtera®)

UNIMEDIC
PHARMA

Nordics
(Cresemba® and Zevtera®)

AVIR
PHARMA

Canada
(Cresemba® and Zevtera®)

LANCET

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)

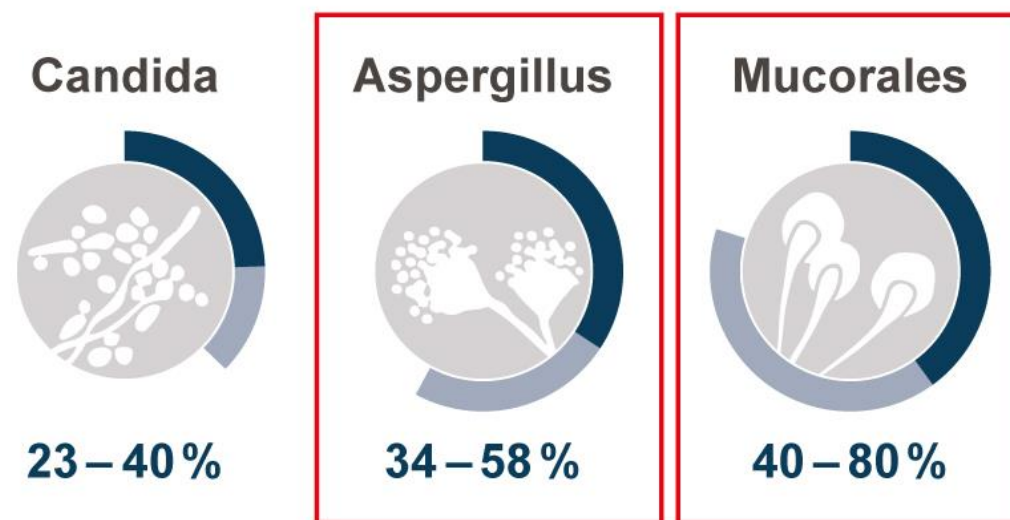
Invasive mold infections



The market — Invasive fungal infections

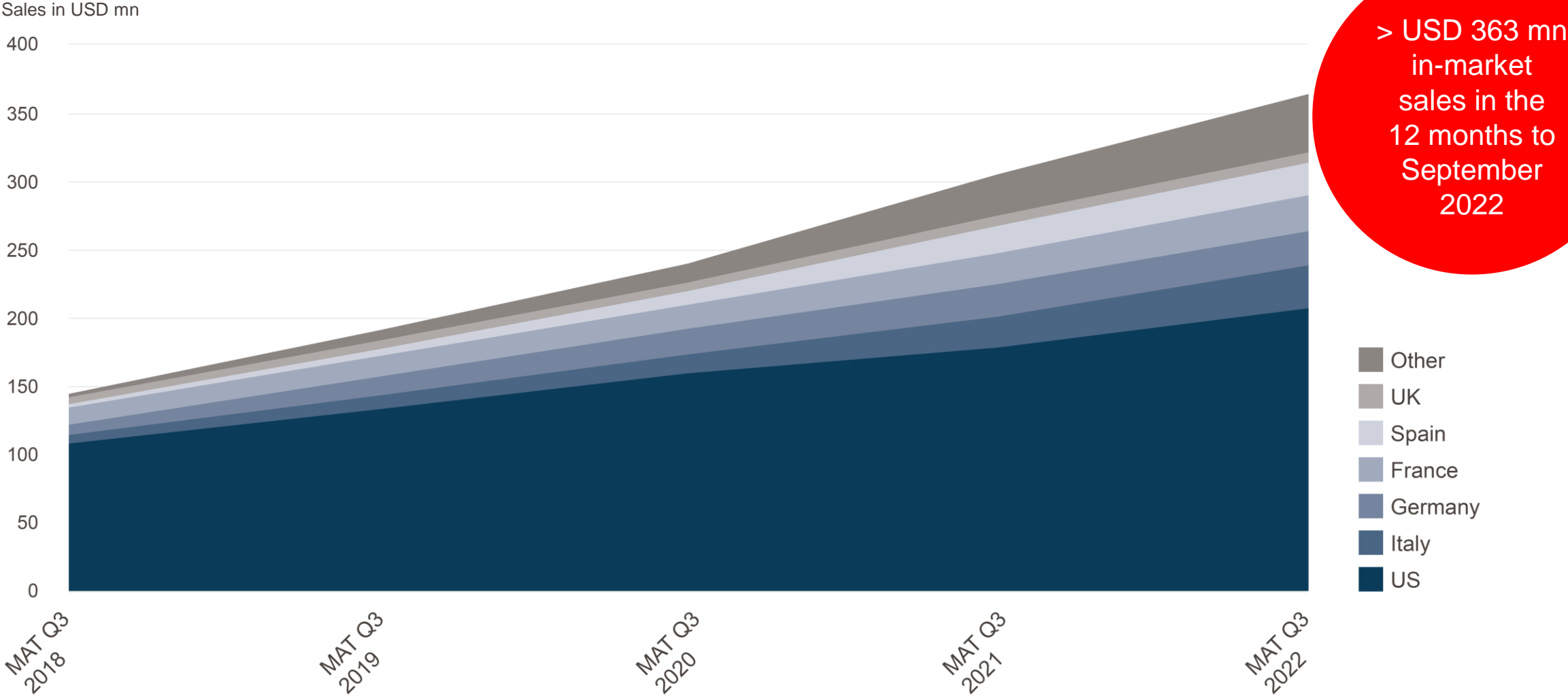
- Severe, potentially life-threatening infections mainly affecting immunocompromised patients
- An important cause of morbidity and mortality in cancer patients undergoing intensive chemotherapy regimens
- Rising number of immunocompromised patients (cancer and transplantations) driving therapeutic demand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

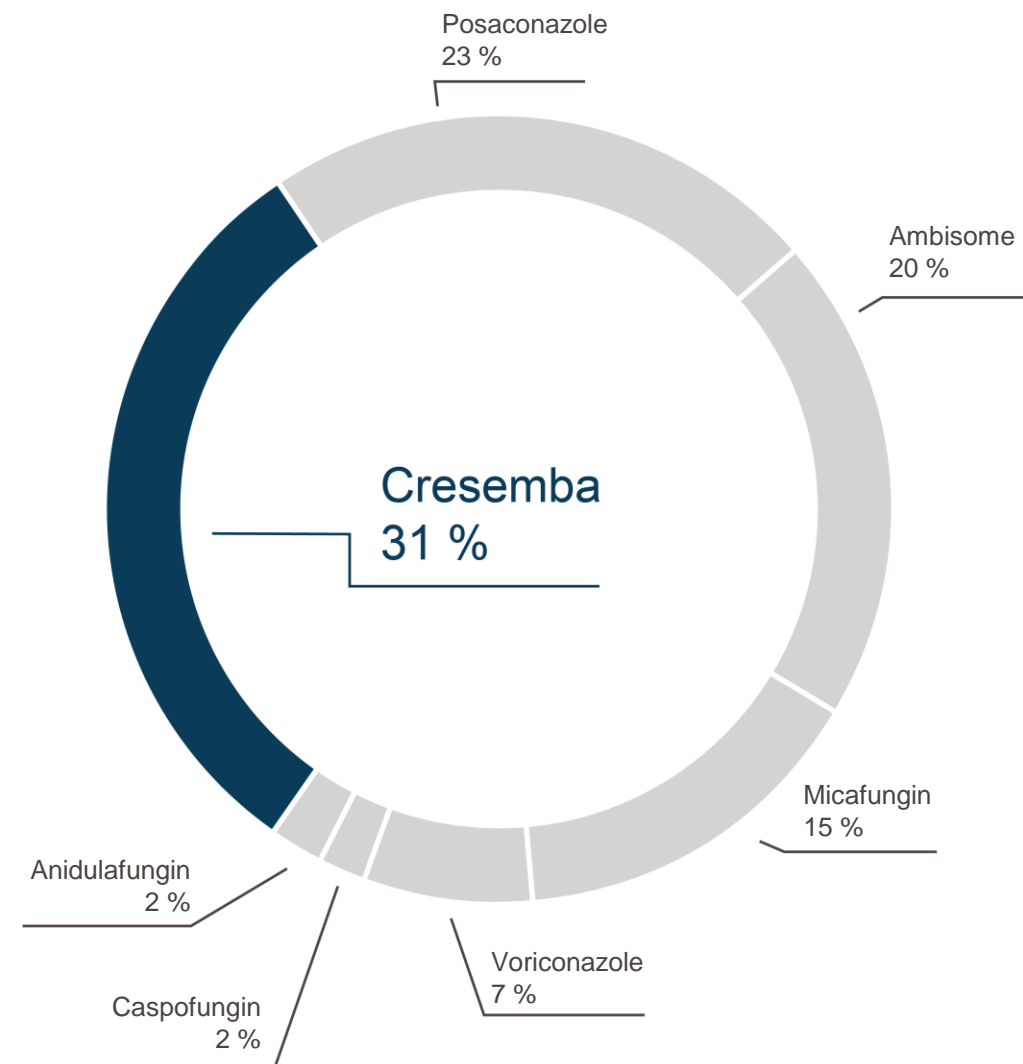


MAT: Moving annual total; Source: IQVIA Analytics Link, September 2022

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 31% by September 2022**

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



**Market share based on MAT Q3 2022, in-market sales reported as moving annual target (MAT) in U.S. dollar; rounding consistently applied. Source: IQVIA Analytics Link, September 2022

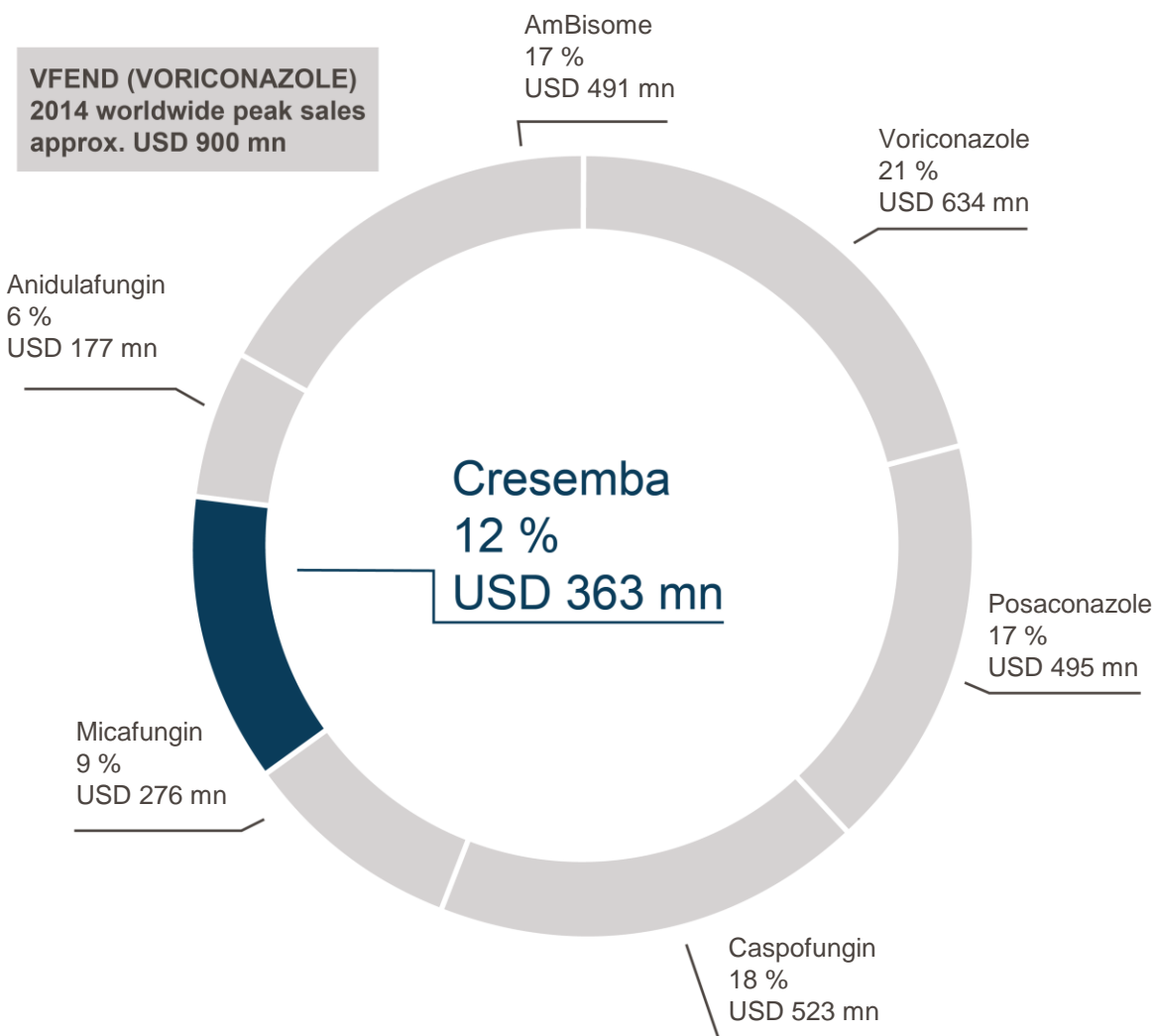
Sales of best-in-class antifungals* by product

USD 3.0 bn sales (MAT Q3 2022)

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

- Launched in 63 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, September 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 development¹
 - 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
- U.S. 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 (CAPB). Not approved in the U.S.

MENA: Middle East and North Africa



Focused on Growth and Innovation



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

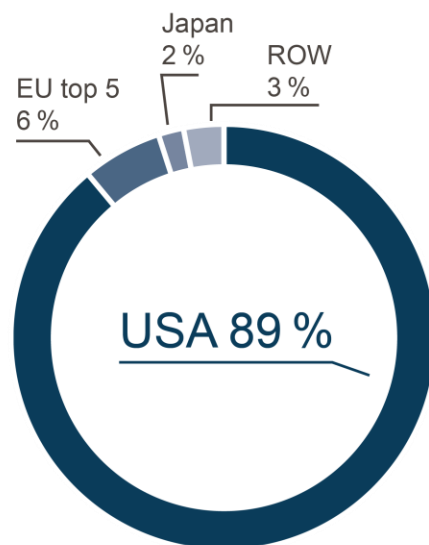
² Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

³ Holland TL et al. IDWeek 2022, LB2302

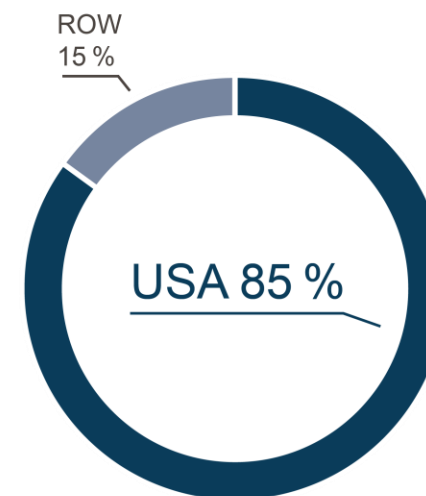
⁴ Rubino CM et al. Pediatr Infect Dis J. 2021;40:997-1003.

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 Q3 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, September 2022

Ceftobiprole — Strategy for accessing the U.S. market

- Planned U.S. NDA submission in March/April 2023 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)¹
 2. *Staphylococcus aureus* bacteremia (SAB)²
- 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



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

² Holland TL et al. IDWeek 2022, LB2302

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 U.S. (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 mortality²
- 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

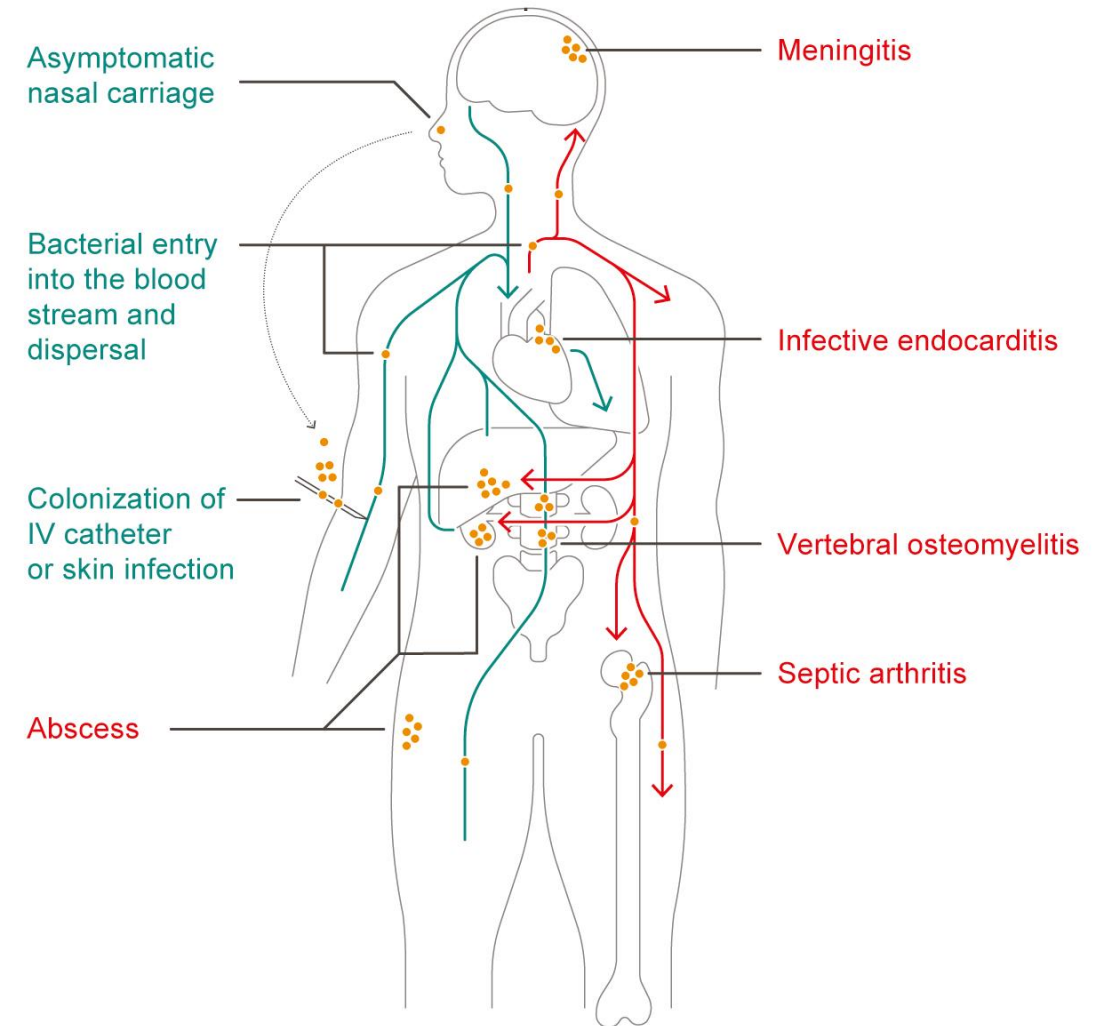
¹ MMWR, 2019;68:214–219.

² Hamed K et al. Future Microbiol. 2020;15:35-48.

MRSA: methicillin-resistant *Staphylococcus aureus*

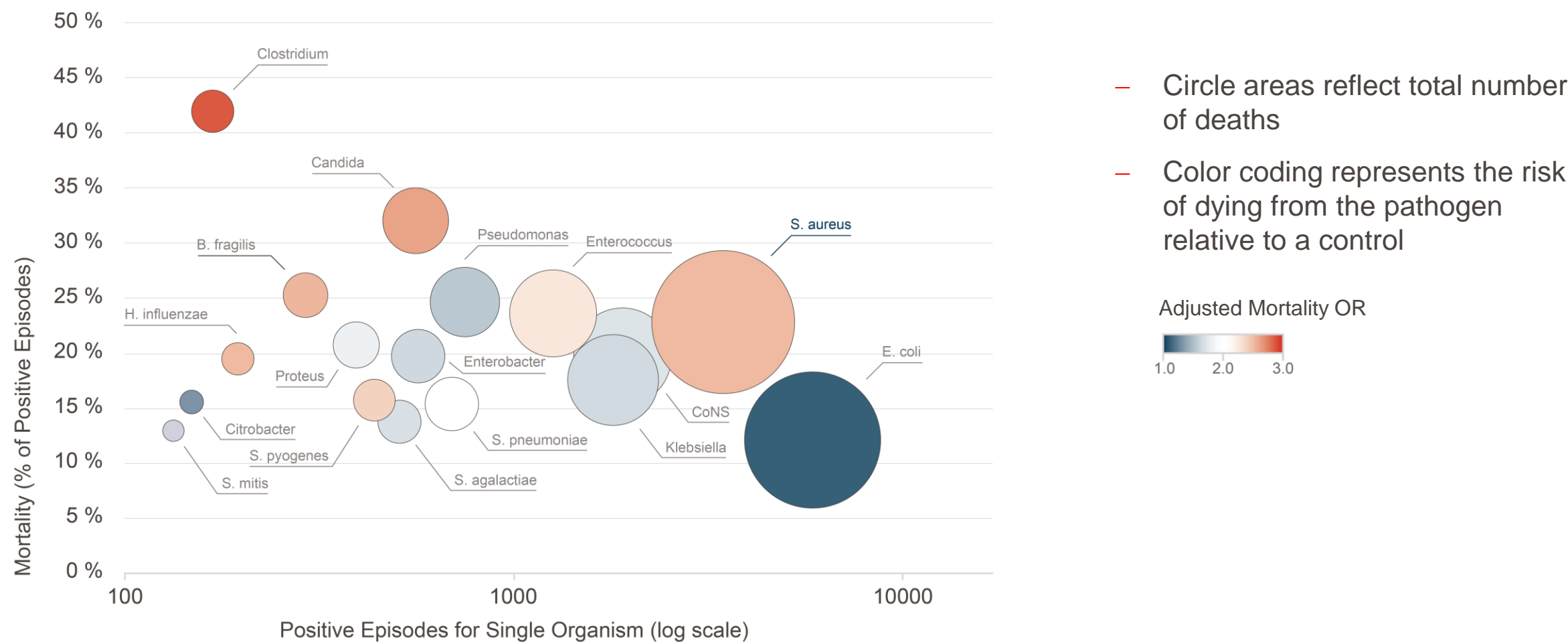
MSSA: methicillin-susceptible *Staphylococcus aureus*

Causes and consequences of SAB



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

SAB — Highest disease burden among bloodstream infections

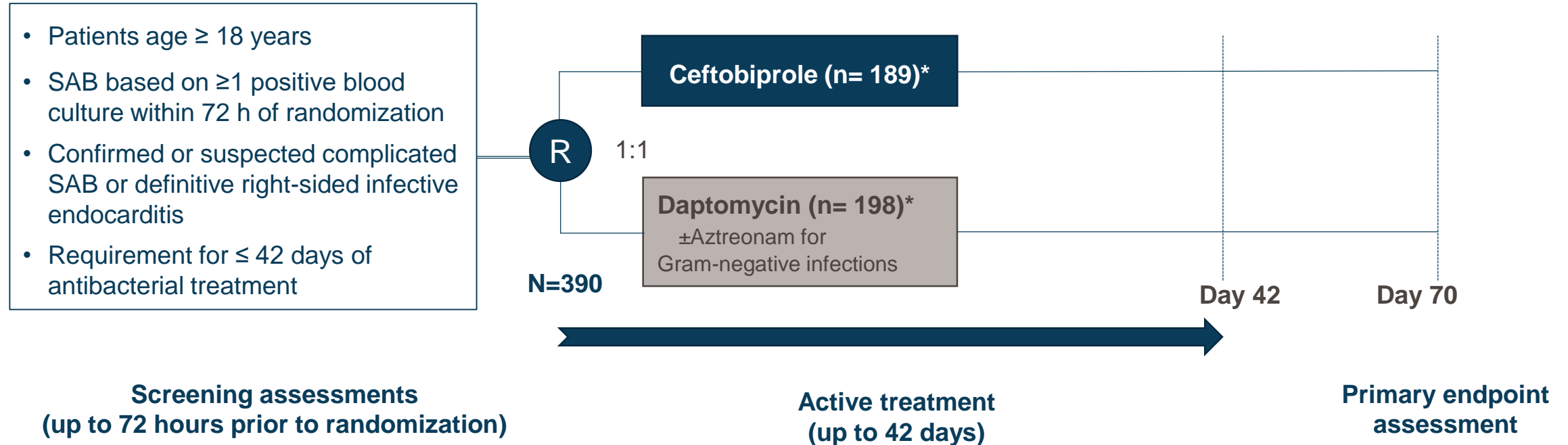


Adapted from: Verway M et al. J Clin Microbiol. 2022;60:e0242921.

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



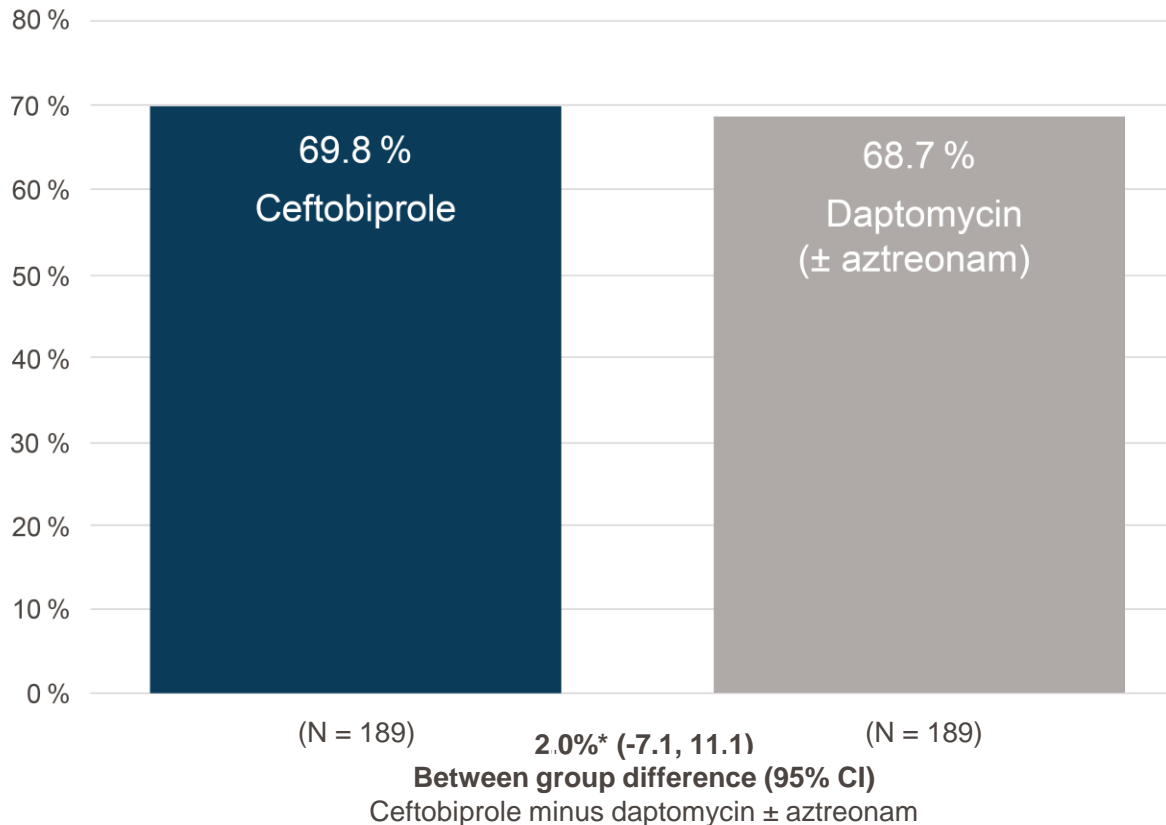
Adapted from Hamed K et al. Future Microbiol. 2020;15:35-48

*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

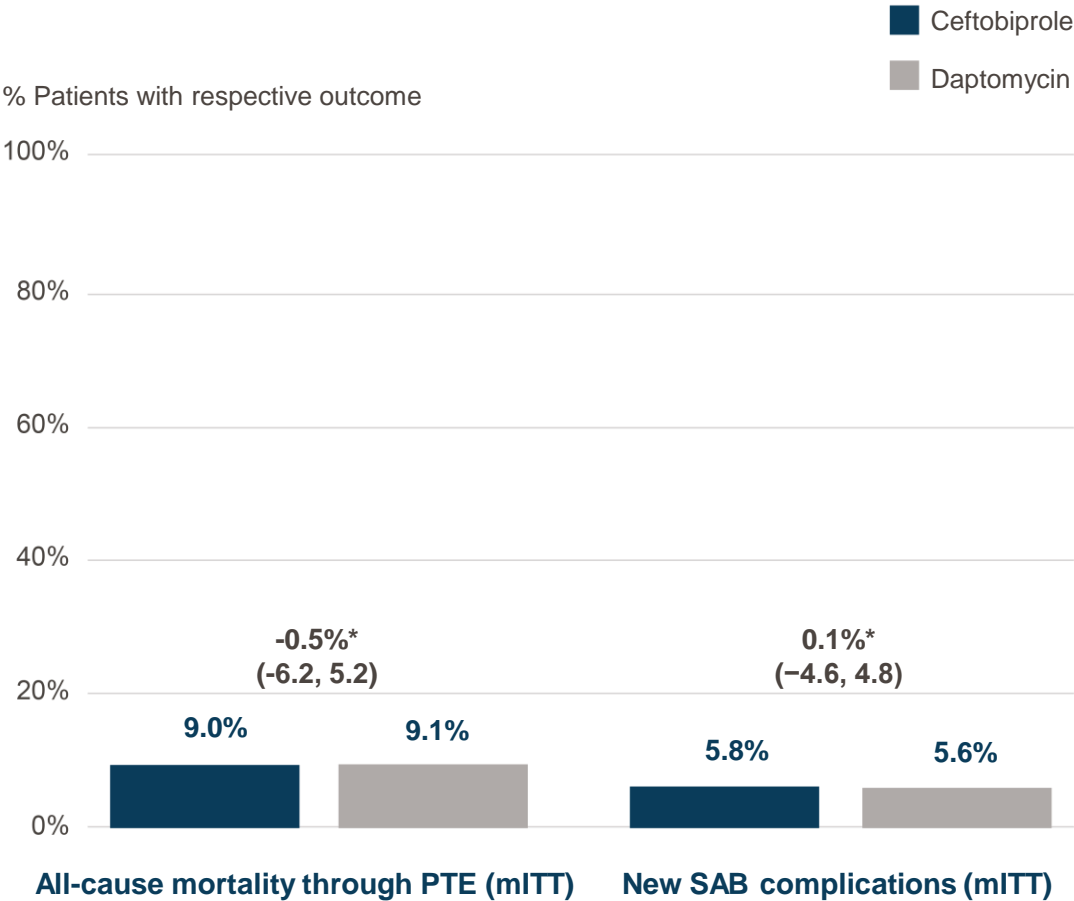
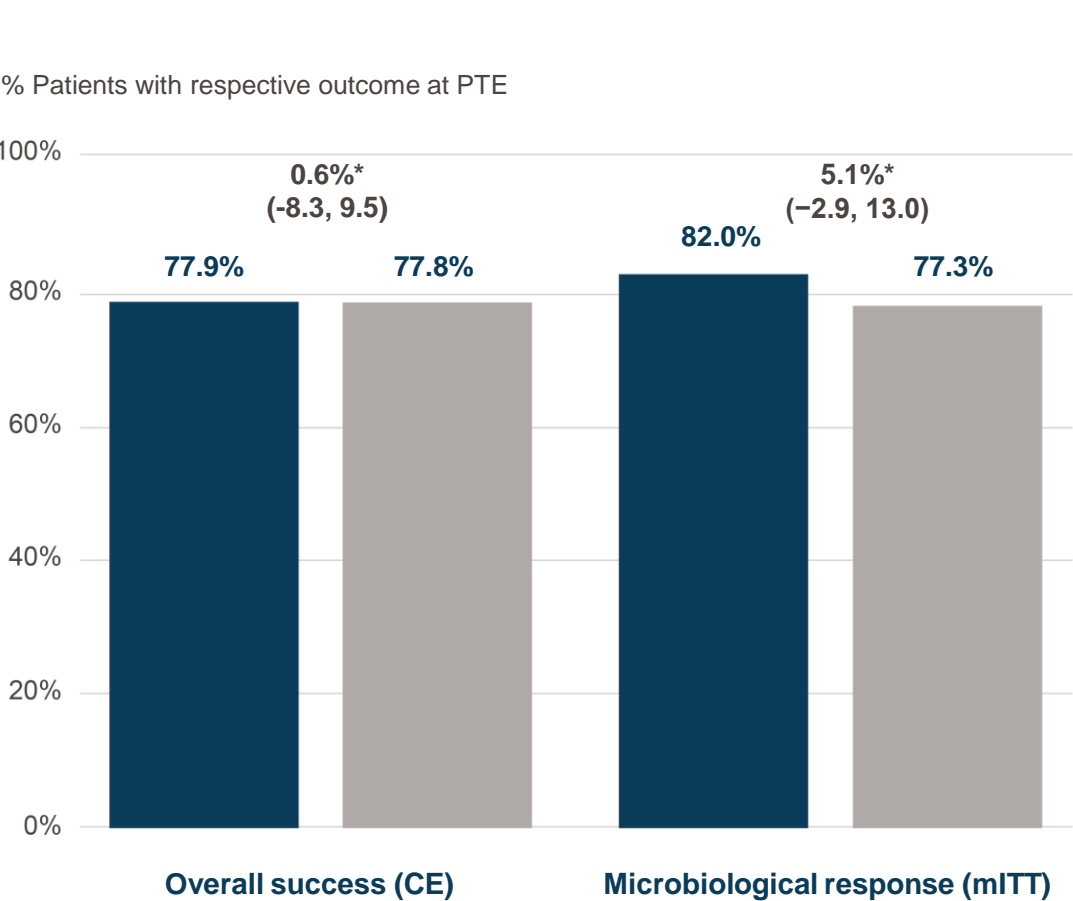


- Non-inferiority demonstrated based on the pre-defined non-inferiority margin of 15%
- Consistent results in key subgroups and various categories of underlying conditions:
 - MSSA or MRSA bloodstream infections at baseline
 - Skin and skin structure infections
 - Abdominal abscesses
 - Chronic dialysis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



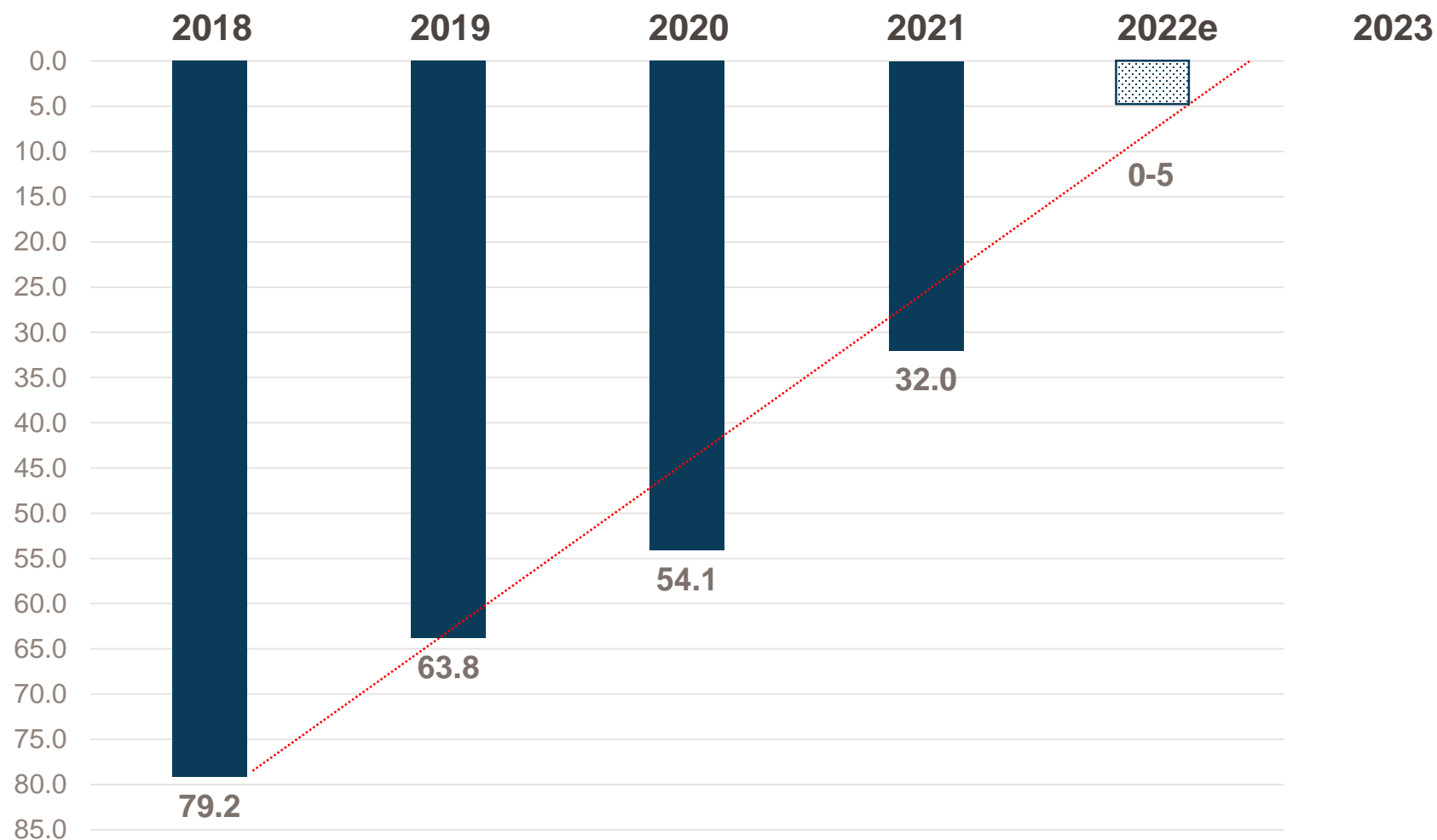
Preliminary revenue and operating result for 2022 exceed guidance

In CHF mn	FY 2023e (guidance)	FY 2022*	FY 2022e (guidance)	FY 2021
Cresemba & Zevtera related revenue	-	~122	98 – 104	131.4
Royalty income	-	-	~59	53.2
Total revenue	-	~148	116 – 122	148.1
Cost of products sold Operating expenses	- -30% vs. 2022	-	21 – 24 ~110	24.1 122.9
Operating (loss)/profit	> 0	~18	(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 milestone payments

* The audited financial statements as well as the annual report 2022 will be published on February 14, 2023.
The final audited revenue and operating result for 2022 may differ from the preliminary numbers reported so far

Net cash used in operating activities



Key milestones

Product	H1 2022	H2 2022	H1 2023
Ceftobiprole (Zevtera)	Completed patient enrolment in phase 3 SAB study (ERADICATE) ✓		
	Positive results of phase 3 SAB study (ERADICATE) ✓		U.S. NDA submission (March/April)
Isavuconazole (Cresemba)	Marketing approvals in China ✓	Marketing approval in Japan ✓	
		Launched in 63 countries ✓	

Successfully completed transactions of oncology assets

Increasing Cresemba & Zevtera revenue

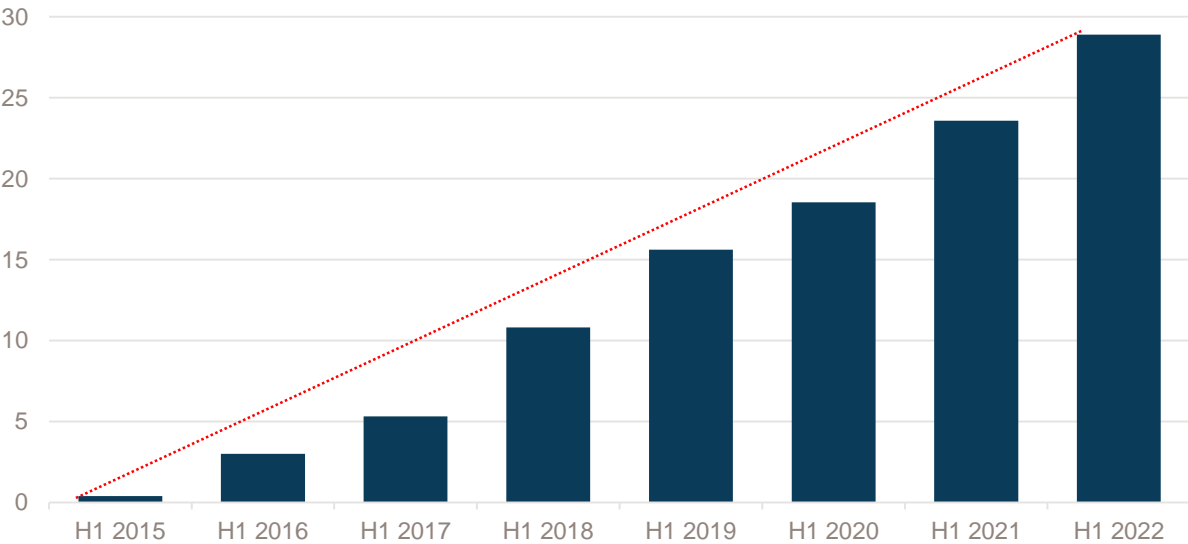
Advancement of preclinical anti-infective assets

In-licensing of anti-infectives

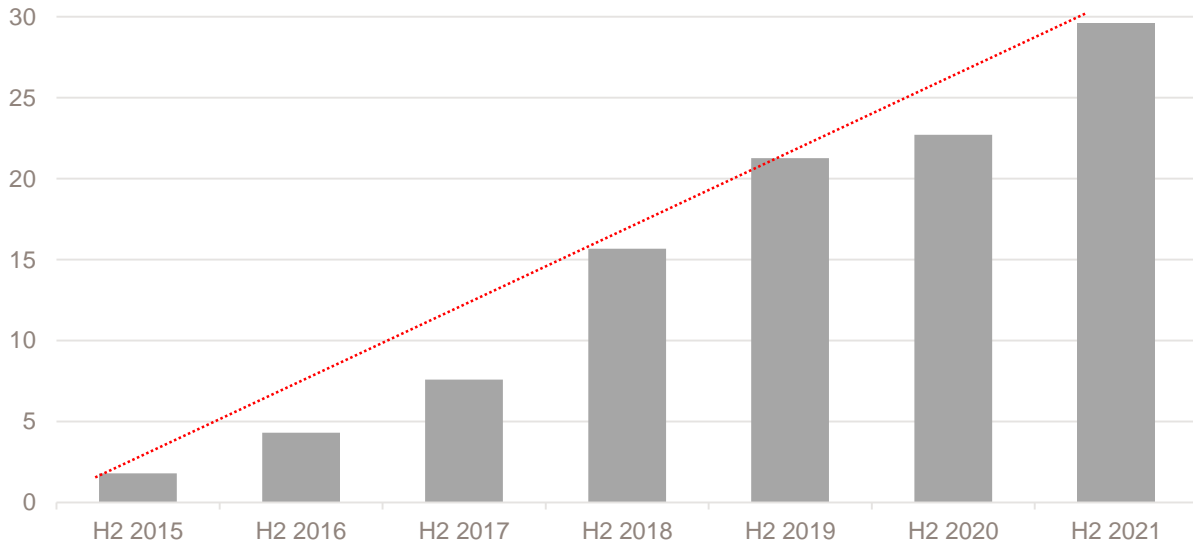
Appendix

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

First half-year



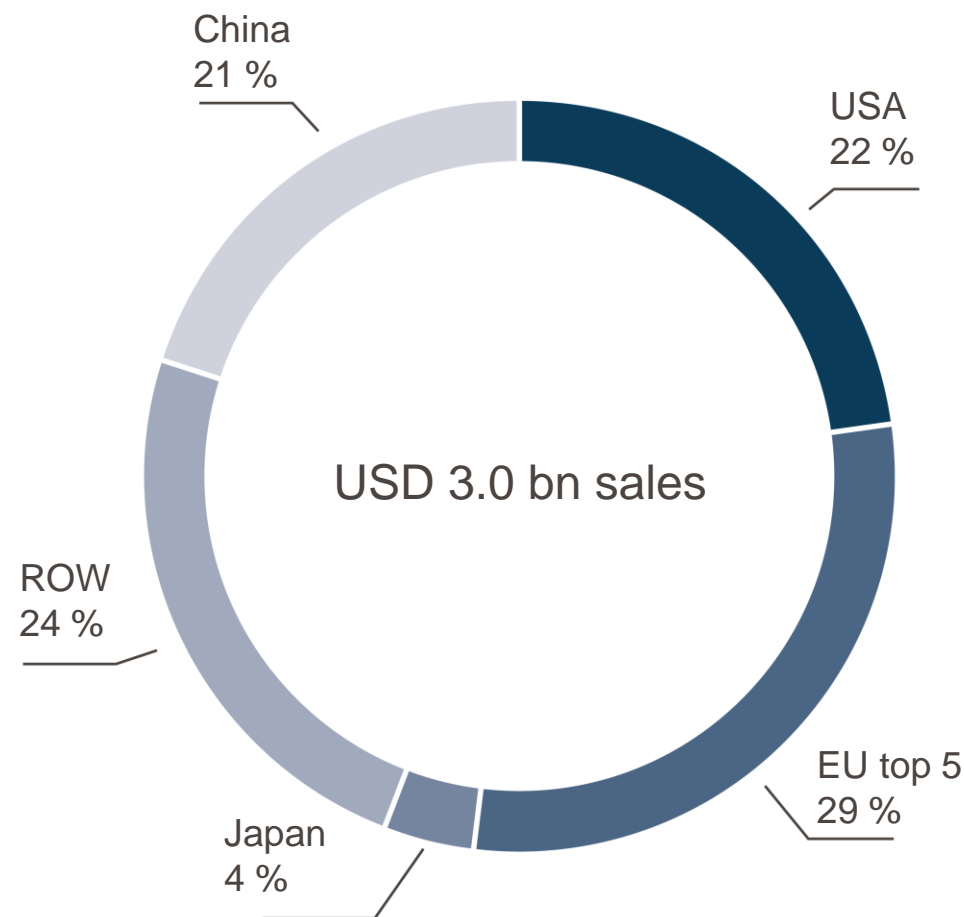
Second half-year



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 3.0 bn sales of best-in-class antifungals*
(MAT Q3 2022)



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

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

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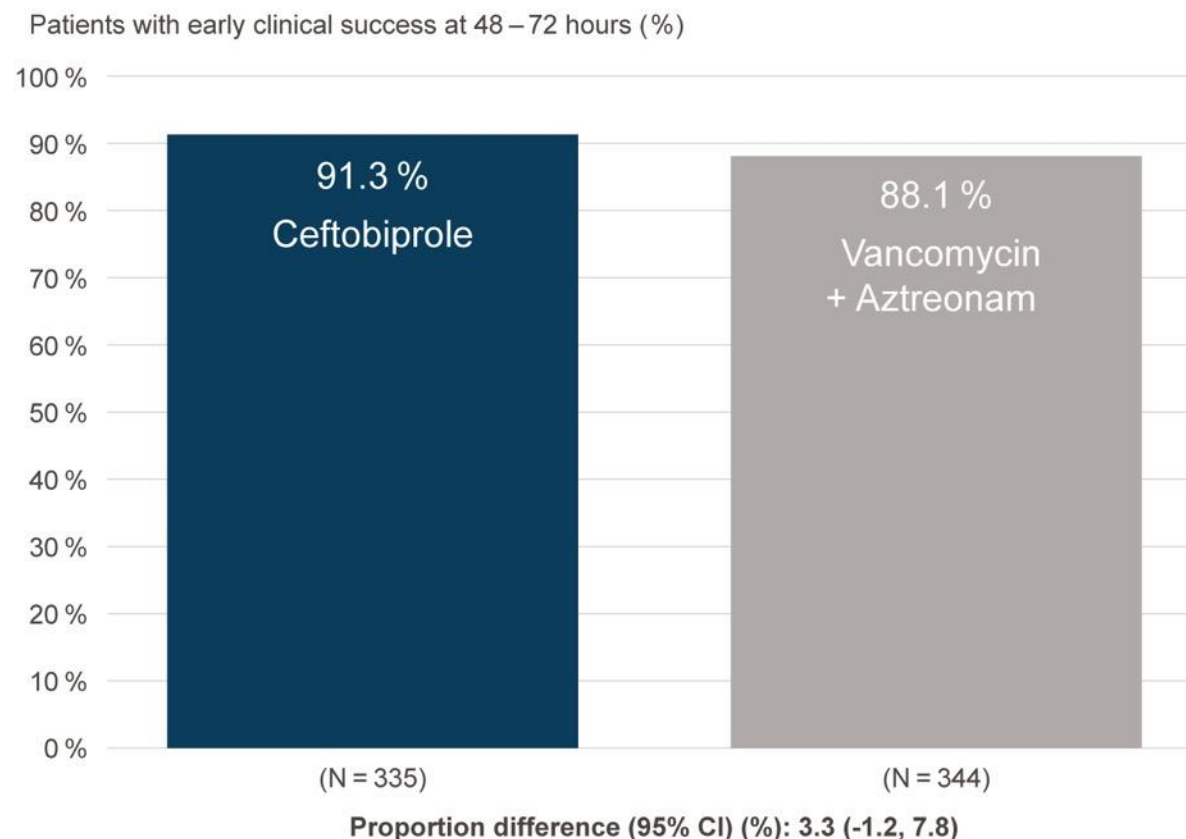
Ceftobiprole — Positive phase 3 results reported in ABSSSI

Results showing non-inferiority of ceftobiprole to vancomycin plus aztreonam for the primary and secondary endpoints¹



¹ 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 study¹ results showing non-inferiority of ceftobiprole to vancomycin plus aztreonam for the primary and secondary endpoints

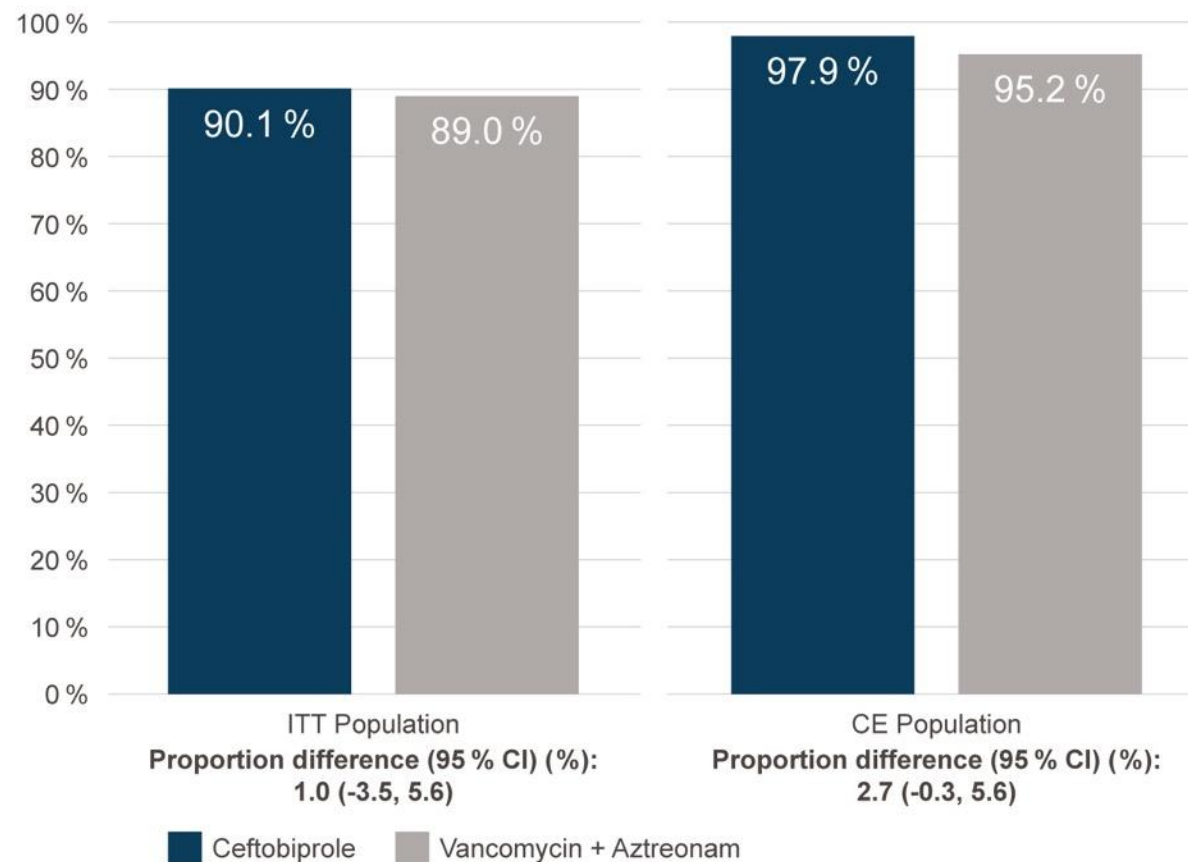


¹ NCT03137173

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 organisms¹
- 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 serious infection compared to vancomycin and daptomycin³
- Low propensity for resistance development¹
- Established safety profile consistent with the cephalosporin class, demonstrated in both adult and pediatric patients^{1,2,4}

¹Syed YY. Drugs. 2014;74:1523-1542.

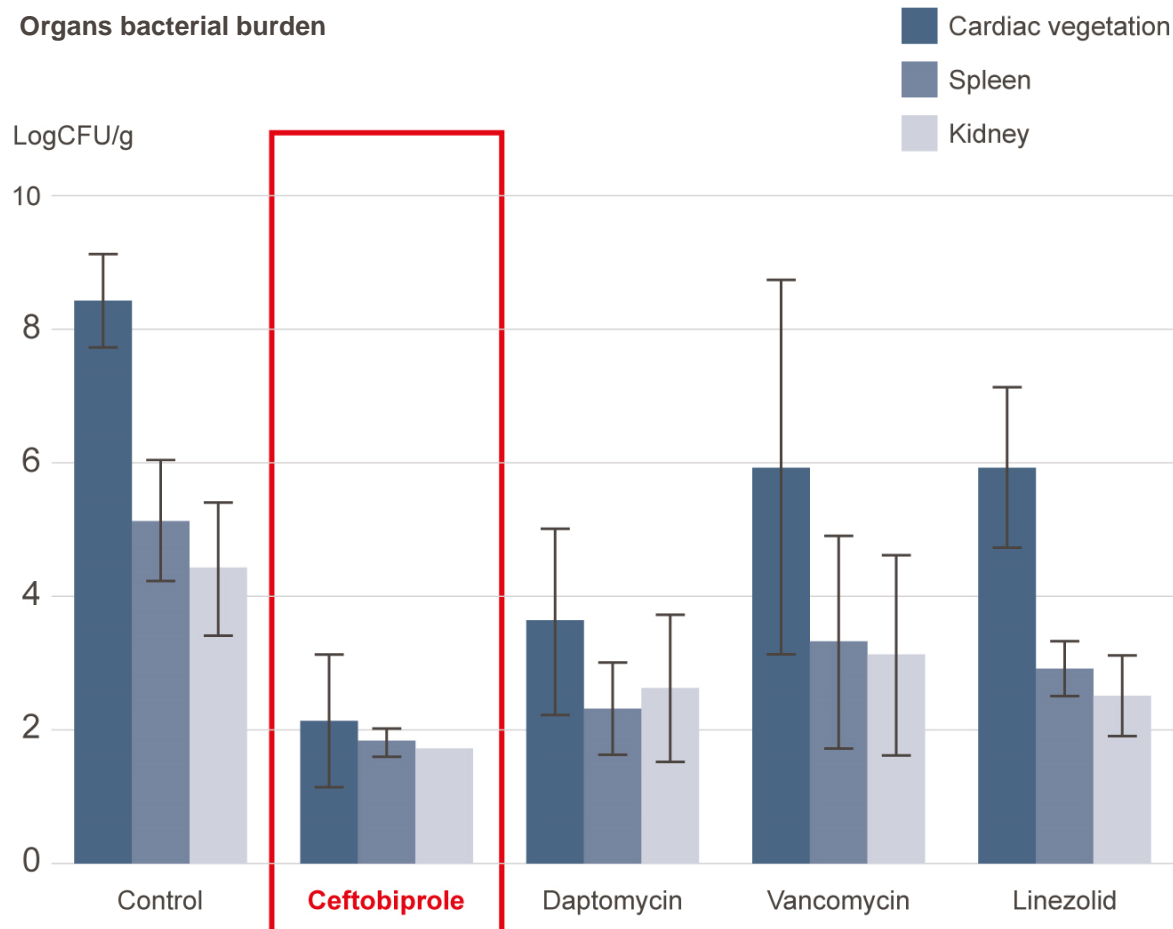
²Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

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

⁴Rubino 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 MRSA³

Glossary

–	ABSSSI:	Acute 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-acquired b acterial p neumonia
–	CE:	C linically e valuable
–	CPA:	C hronic p ulmonary a spergillosis
–	CARB-X:	C ombating A ntibiotic- R esistant B acteria Biopharmaceutical A ccelerator
–	DRC:	D ata r eview c ommittee
–	HABP:	H ospital-acquired b acterial p neumonia
–	ITT:	I ntent- T o- T reat
–	i.v.:	I ntravenous
–	mITT:	M odified i ntent- t o- t reat
–	MSSA:	M ethicillin- s usceptible <i>Staphylococcus aureus</i>
–	MRSA:	M ethicillin- r esistant <i>Staphylococcus aureus</i>
–	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:	<i>Staphylococcus aureus</i> b acteremia
–	SPA:	S pecial P rotocol A ssessment
–	U.S. GAAP:	U nited S tates G enerally A ccepted A ccounting P riniples
–	VAP:	V entilator-associated p neumonia

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Focused on Growth and Innovation

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