



**Focused on
Growth and Innovation**

Half-year results 2022

August 16, 2022

Webcast presentation



David Veitch

Chief Executive Officer

Introduction



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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. Derazantinib, lisavanbulin, BAL0891 and their uses are investigational and have not been approved by a regulatory authority for any use. Efficacy and safety have not been established. The information presented should not be construed as a recommendation for use. The relevance of findings in nonclinical/preclinical studies to humans is currently being evaluated.

Speakers



David Veitch
CEO



Adesh Kaul
CFO



Dr. Marc Engelhardt
CMO

Key achievements



Strong financial results

- 22.5% y-o-y increase of royalty income
- Positive improvement operating cash flow
- CHF 142 mn cash, restricted cash and investments
- FY 2022 guidance confirmed and continue to expect sustainable profitability from 2023

Reported positive results of ERADICATE phase 3 study with ceftobiprole

- Preparing the U.S. NDA submission

Our new strategy

- Focus on anti-infectives

Pipeline expansion

- Licensing of a novel first-in-class antifungal program

Continued commercial success of Cresemba

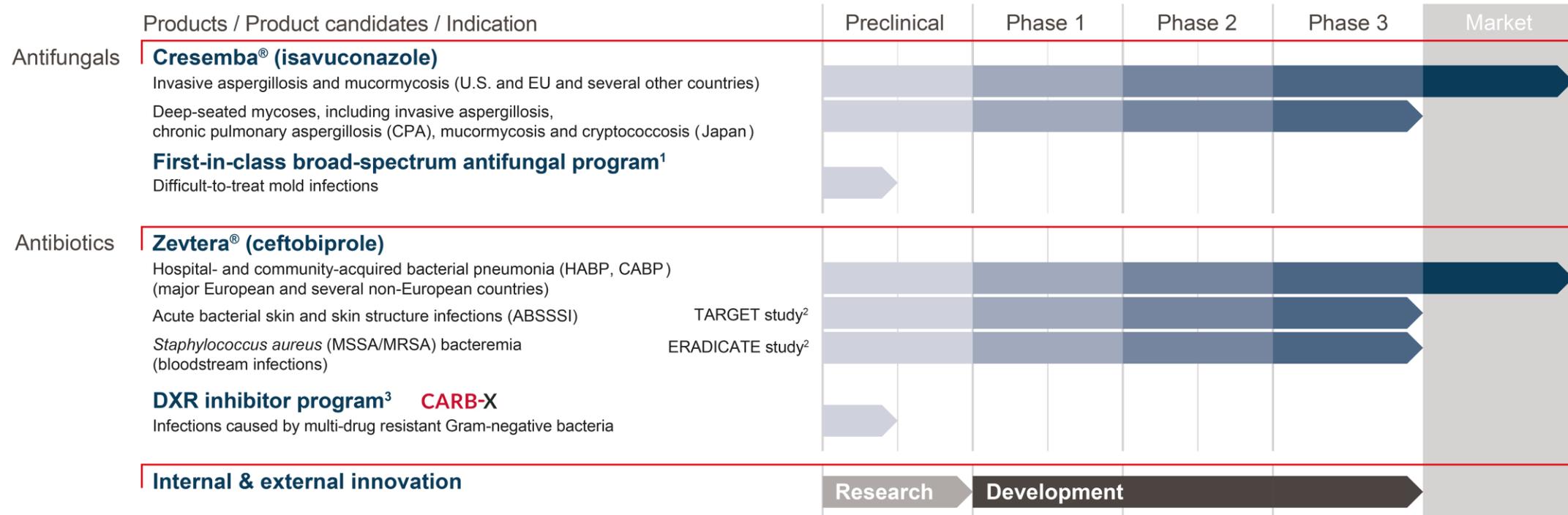
- 31% increase of global in-market sales to >USD 344 mn*

Accessing new markets

- Launch of Cresemba in China

* MAT Q1/2021 vs. MAT Q2/2022; MAT: Moving annual total; Source: IQVIA Analytics Link, March 2022

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



¹ Licensed from FCCDC

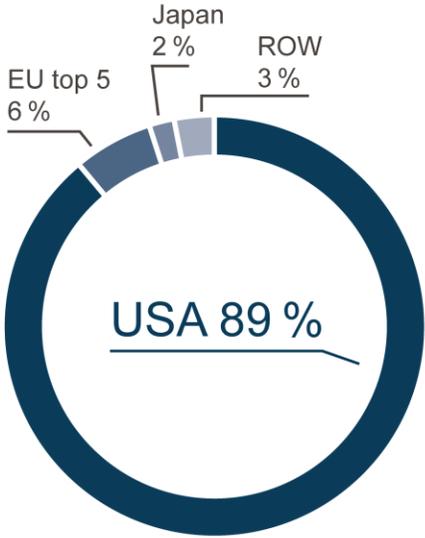
² Studies to support U.S. NDA

³ 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.

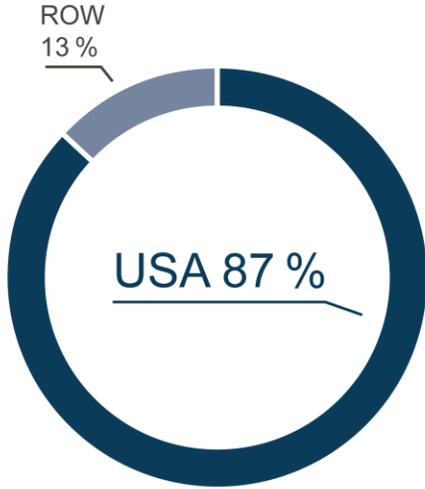
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The hospital anti-MRSA antibiotic market — A USD 2.8 bn market* with the U.S. being the most important region

Daptomycin sales by region (2015, before LOE)



Ceftaroline sales by region (MAT Q1 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, March 2022

Adesh Kaul

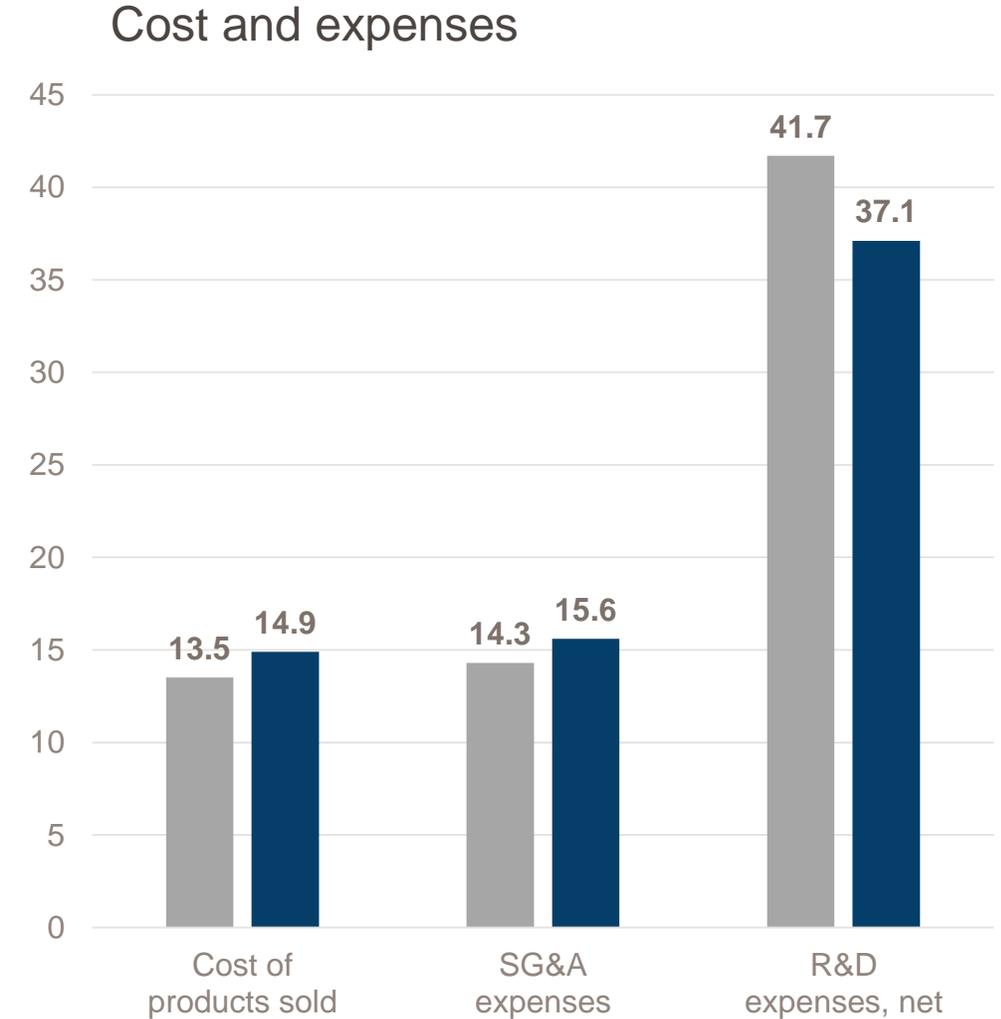
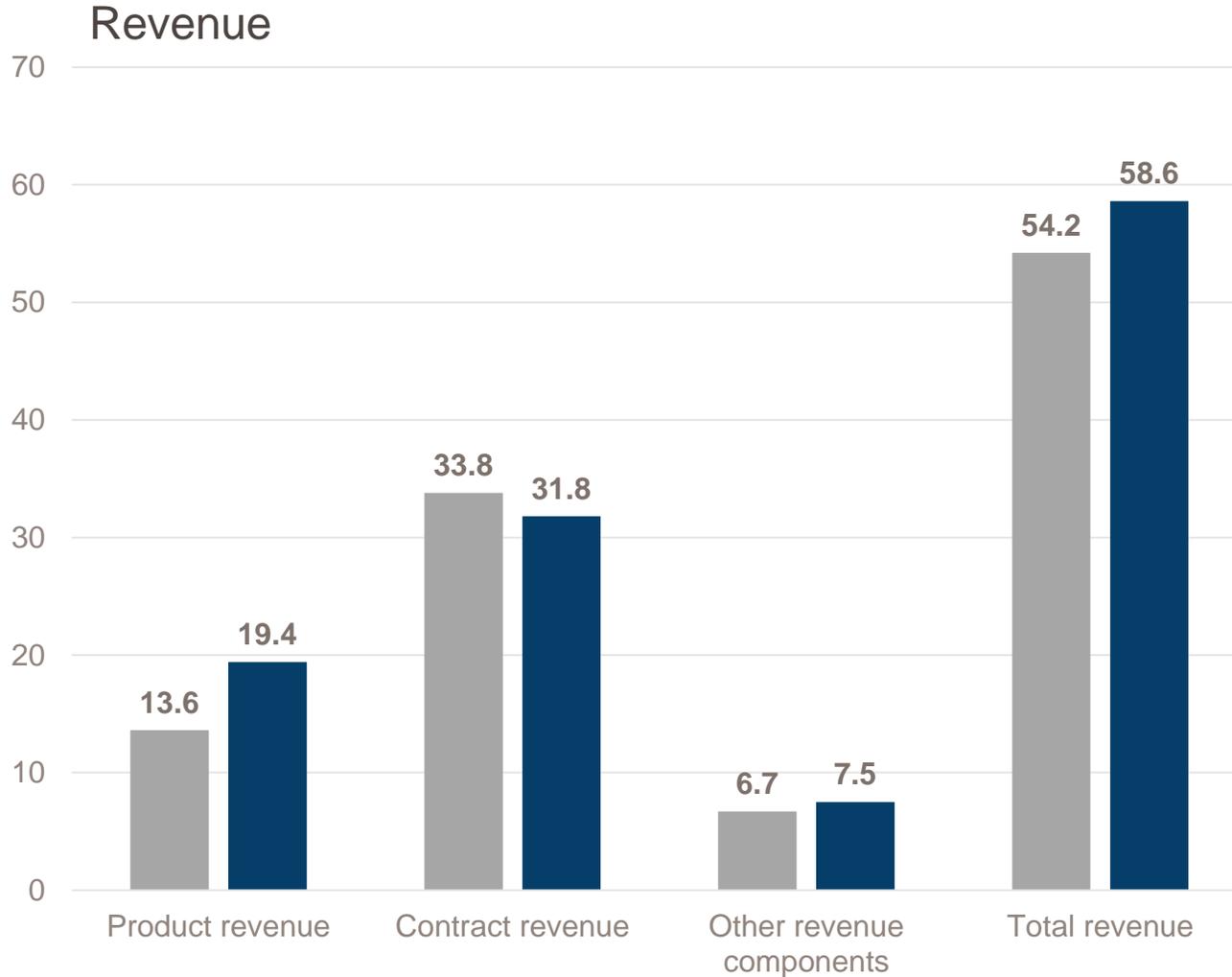
Chief Financial Officer

Financial update



Financial summary, in CHF mn (1/2)

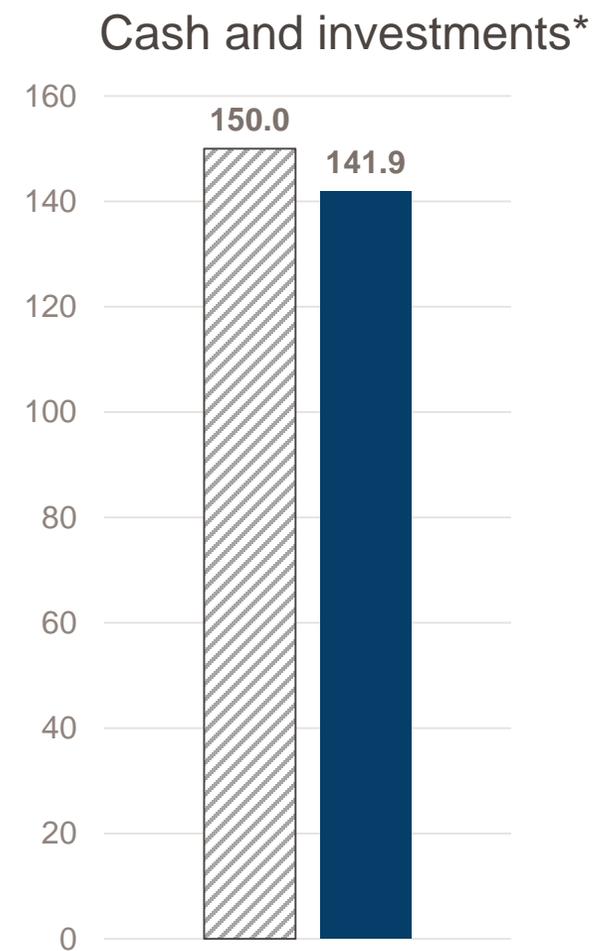
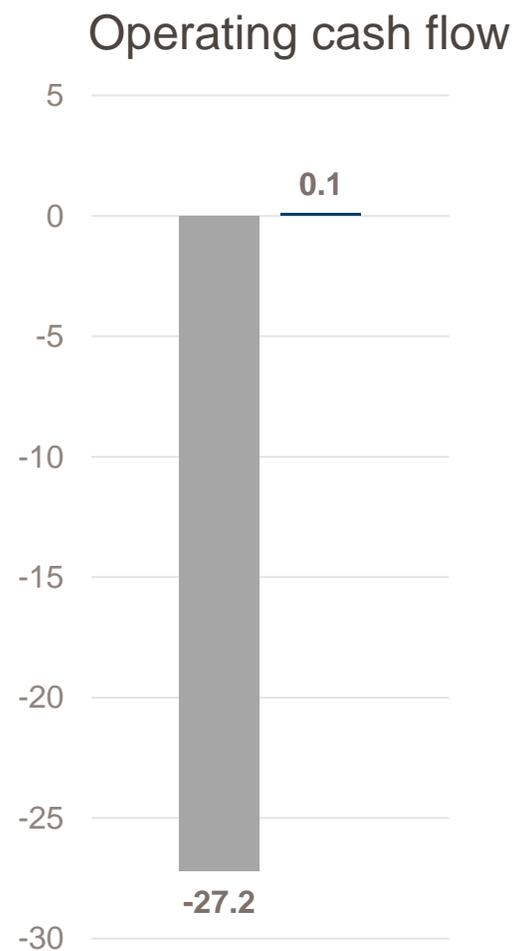
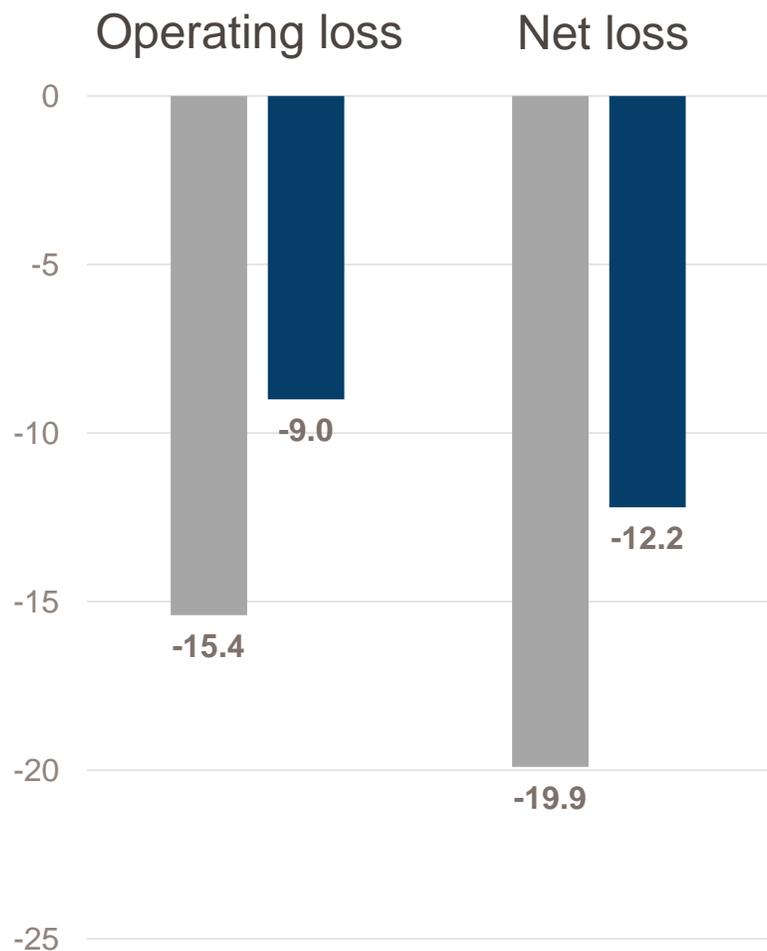
■ HY 2021
■ HY 2022



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

Financial summary, in CHF mn (2/2)

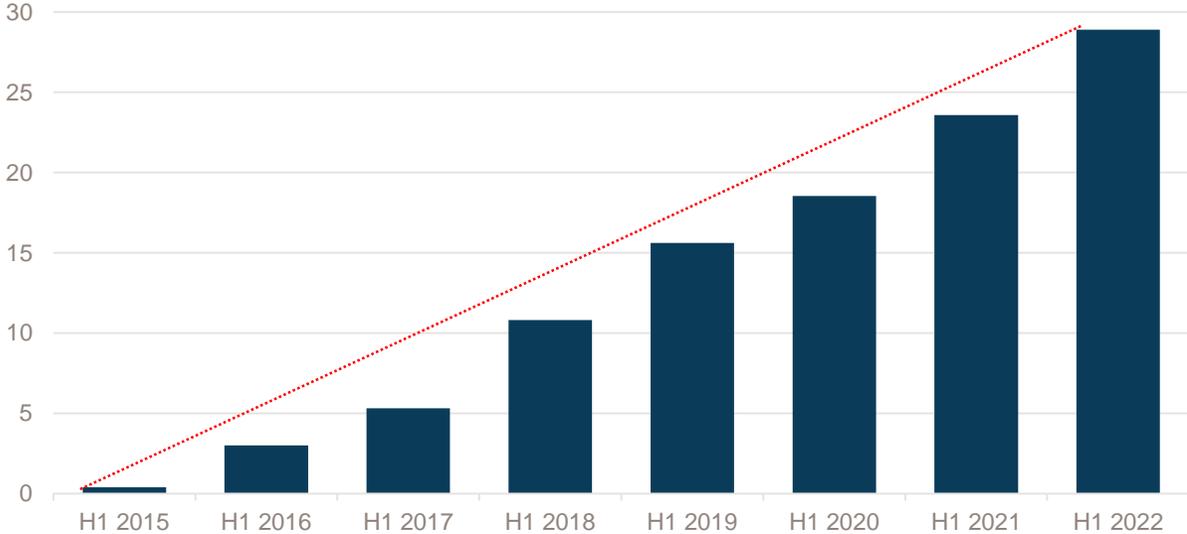
- HY 2021
- HY 2022
- ▨ FY 2021



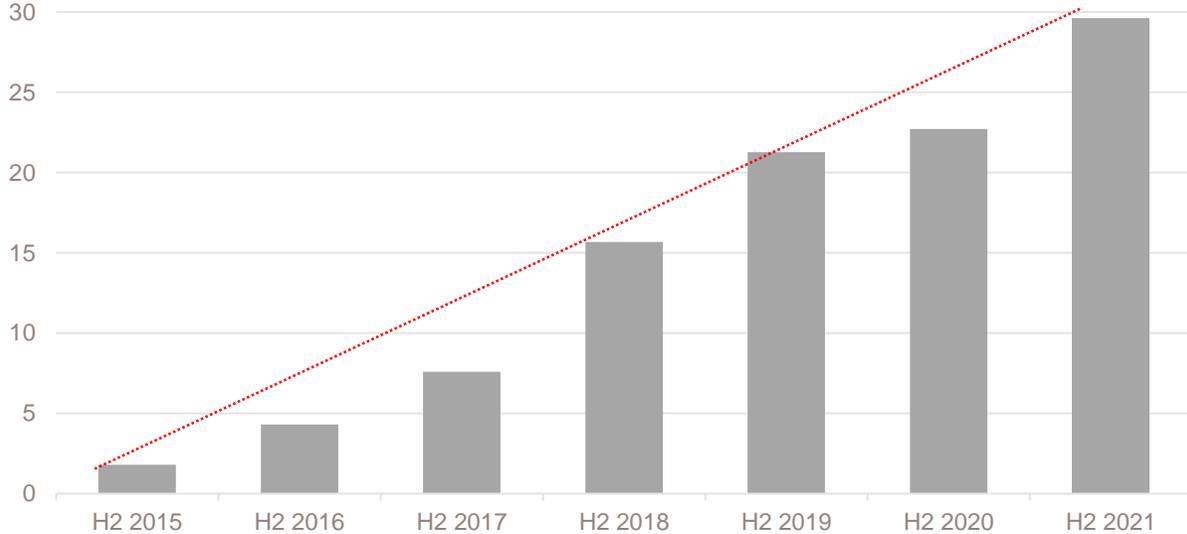
Note: Consolidated figures in conformity with U.S. GAAP; rounding applied consistently, *Cash, cash equivalents, restricted cash and investments

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

First half-year

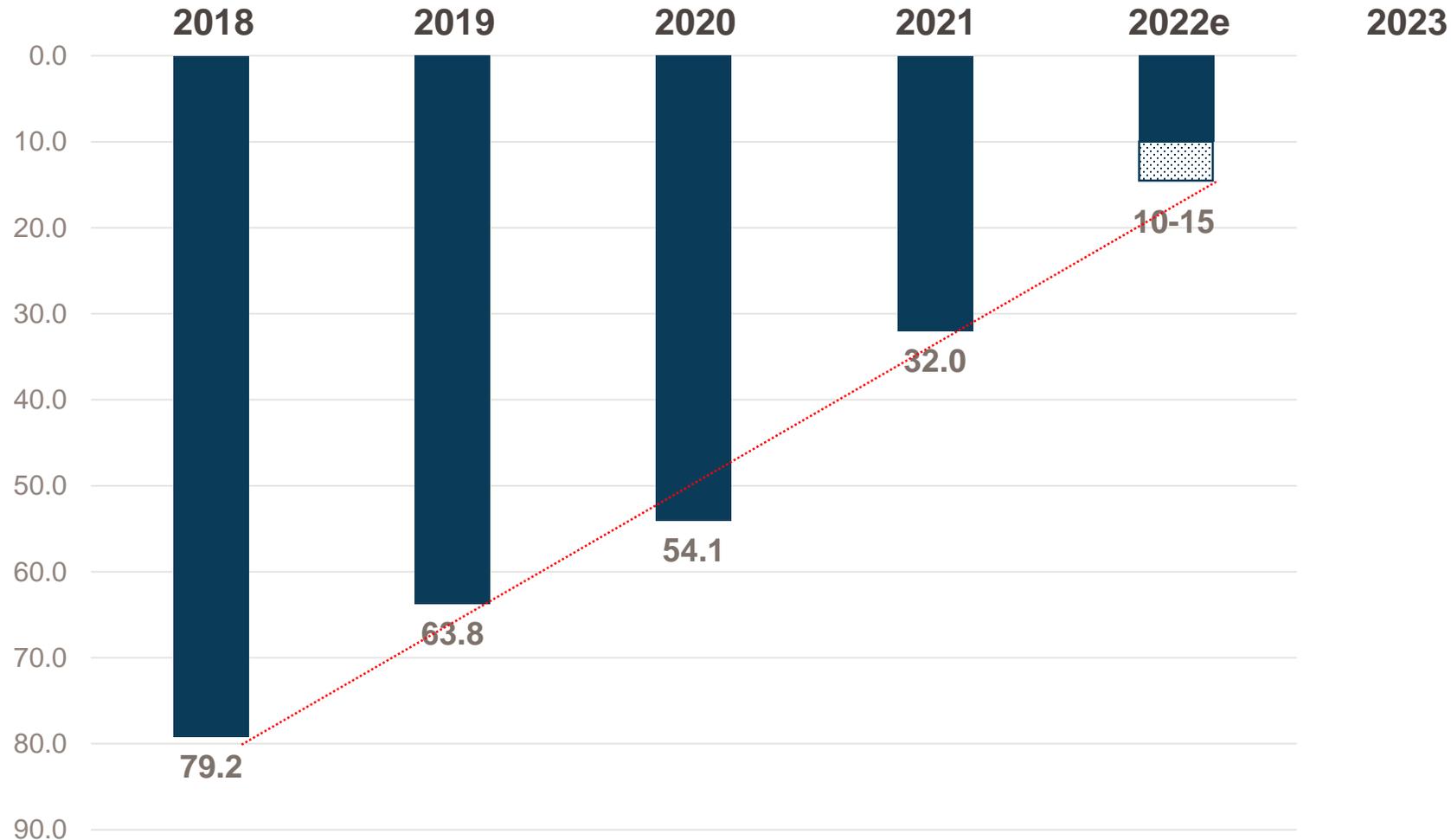


Second half-year



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

Net cash used in operating activities



**Sustainable
profitability from 2023
onwards**

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	-	106 – 112	148.1
Cost of products sold	-	21 – 24	24.1
Operating expenses	-30% vs. 2022	~ 110	122.9
Operating (loss)/profit	> 0	(20 – 25)	1.2
Net cash used in operating activities	Cash flow positive	10 – 15	32.0

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

* 2022 guidance does not include the potential impact from strategic transactions on the oncology assets

Dr. Marc Engelhardt

Chief Medical Officer

Development
update



Ceftobiprole — Strategy for accessing the U.S. market

- Two cross-supportive phase 3 studies under FDA Special Protocol Assessment (SPA)
 1. Acute bacterial skin and skin structure Infections (ABSSSI)¹, successfully completed
 2. *Staphylococcus aureus* bacteremia (SAB)², successfully completed (topline results reported)
- New Drug Application (NDA) submission planned around year-end 2022
- Qualified Infectious Disease Product (QIDP) designation extends U.S. market exclusivity to 10 years from approval
- Commercialization planned through partnership



- Phase 3 study in community-acquired bacterial pneumonia (CABP) previously completed³
 - Additionally explore the possibility of gaining approval for CABP as a third indication



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

² Hamed K et al. Future Microbiol. 2020;15:35-48. (NCT03138733)

³ Nicholson SC et al. International Journal of Antimicrobial Agents 2012 (39), 240-246

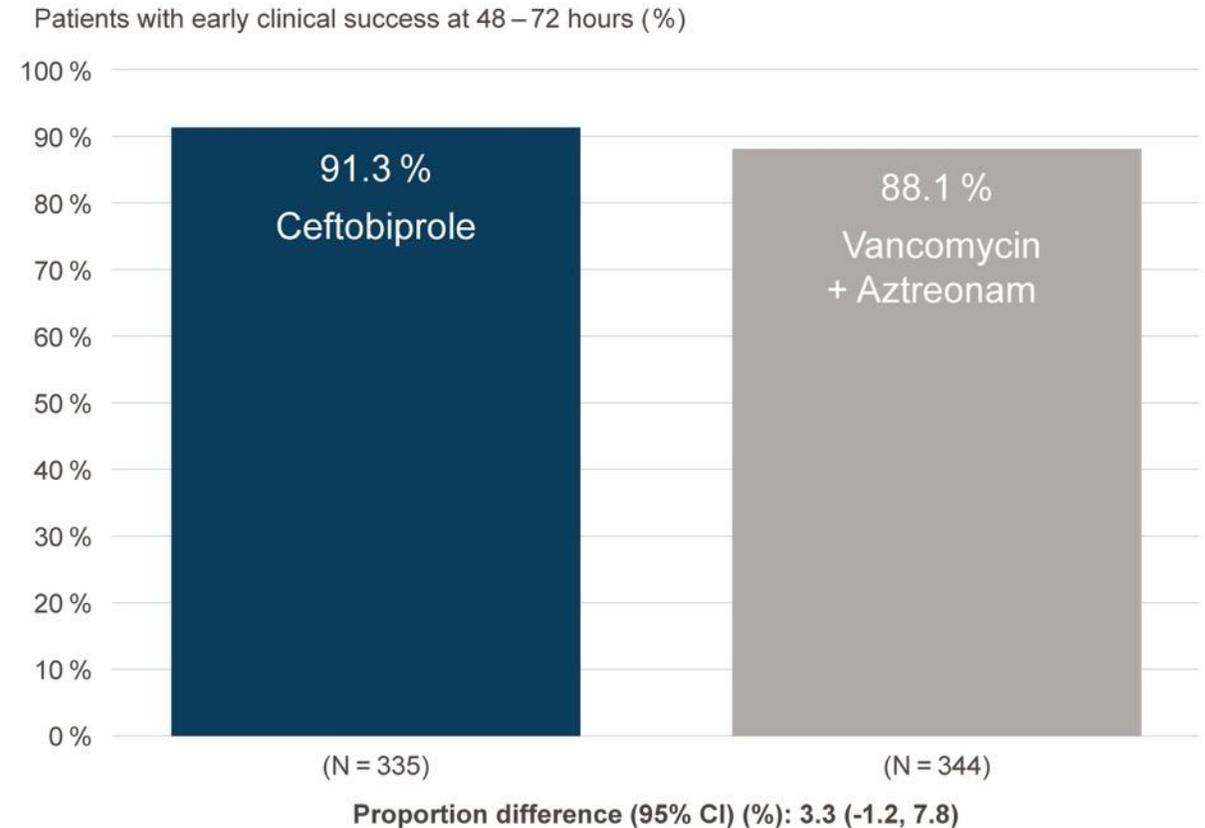
Ceftobiprole — Positive phase 3 results reported in ABSSSI

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 %

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

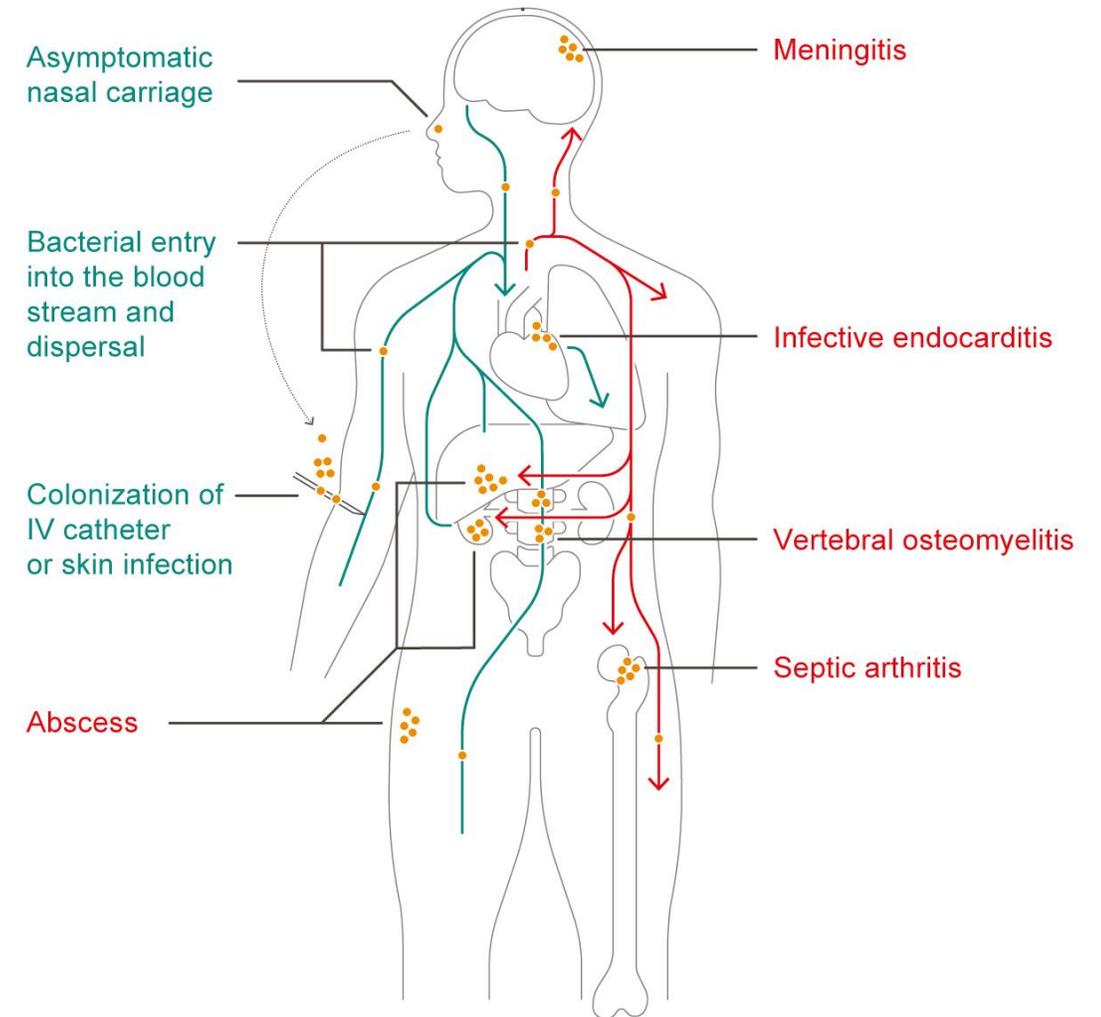
¹ MMWR, 2019;68:214–219.

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

MRSA: methicillin-resistant *Staphylococcus aureus*

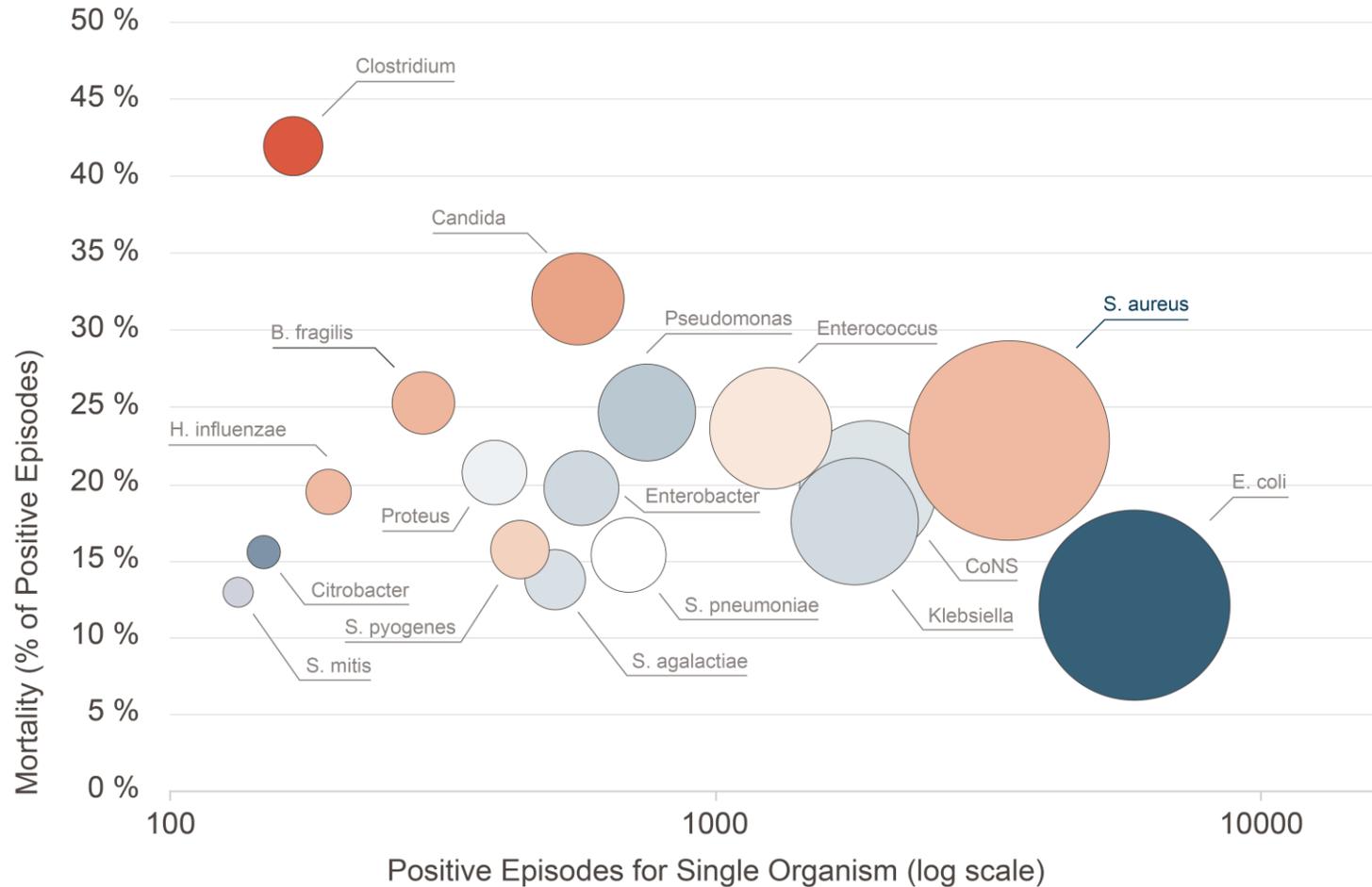
MSSA: methicillin-susceptible *Staphylococcus aureus*

Causes and consequences of SAB



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

SAB — Highest disease burden among bloodstream infections



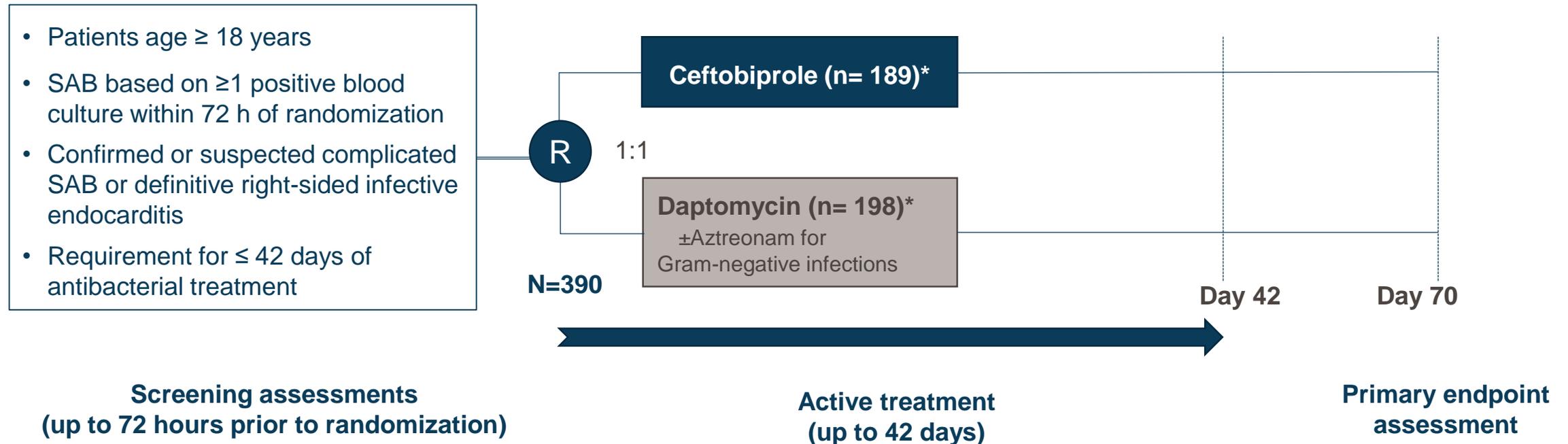
- Circle areas reflect total number of deaths
- Color coding represents the risk of dying from the pathogen relative to a control



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

Phase 3 study with ceftobiprole in the treatment of patients with SAB

ERADICATE (390 patients) is the largest randomized study conducted for registrational purposes of a new antibiotic treatment in *Staphylococcus aureus* bacteremia



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

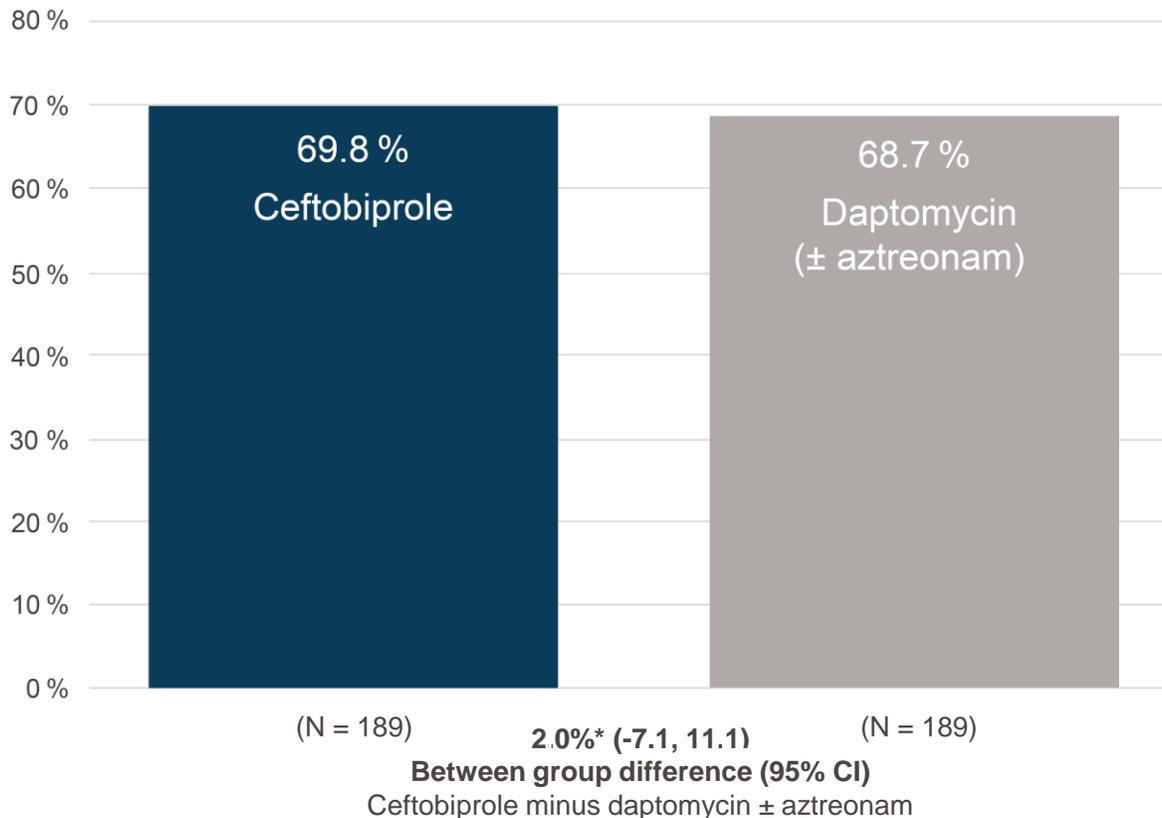
*Ceftobiprole was administered 500 mg q6h on Day 1-8 and 500 mg q8h from Day 9 onwards. Daptomycin was administered at 6mg/kg up to 10 mg/kg q24h.

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%

DRC: Data review committee; PTE: Post-treatment evaluation

*Cochran-Mantel-Haenszel (CMH) weights method adjusted for actual stratum (dialysis status and prior antibacterial treatment use)

ERADICATE — Secondary objectives

- Secondary efficacy endpoints including all-cause mortality, new complications of SAB in the mITT population and overall success in the clinically evaluable population were consistent with the primary study outcome
- Ceftobiprole was well tolerated and the overall rate of adverse events was similar between the two treatment groups
- The observed safety and tolerability profile was consistent with previous phase 3 studies and the post-marketing experience with ceftobiprole
 - As expected, gastrointestinal side effects were more frequent with ceftobiprole

Ceftobiprole — 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

David Veitch

Chief Executive Officer

Outlook



Key milestones

Product	H1 2022	H2 2022
Ceftobiprole (Zevtera)	Completed patient enrolment in phase 3 SAB study (ERADICATE) ✓	
	Topline 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



Q & A



Thank you

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
- CPA: **C**hronic **p**ulmonary **a**spergillosis
- CARB-X: **C**ombating **A**ntibiotic-**R**esistant **B**acteria Biopharmaceutical **A**ccelerator
- DRC: **D**ata review **c**ommittee
- HABP: **H**ospital-**a**cquired **b**acterial **p**neumonia
- ITT: **I**ntent-**t**o-**t**reat
- i.v.: **I**ntravenous
- mITT: **M**odified intent-**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 ratio
- 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
- U.S. GAAP: **U**nited **S**tates **G**enerally **A**ccepted **A**ccounting **P**inciples



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