# Focused on Growth and Innovation

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

**Investor presentation**

August 16, 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

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

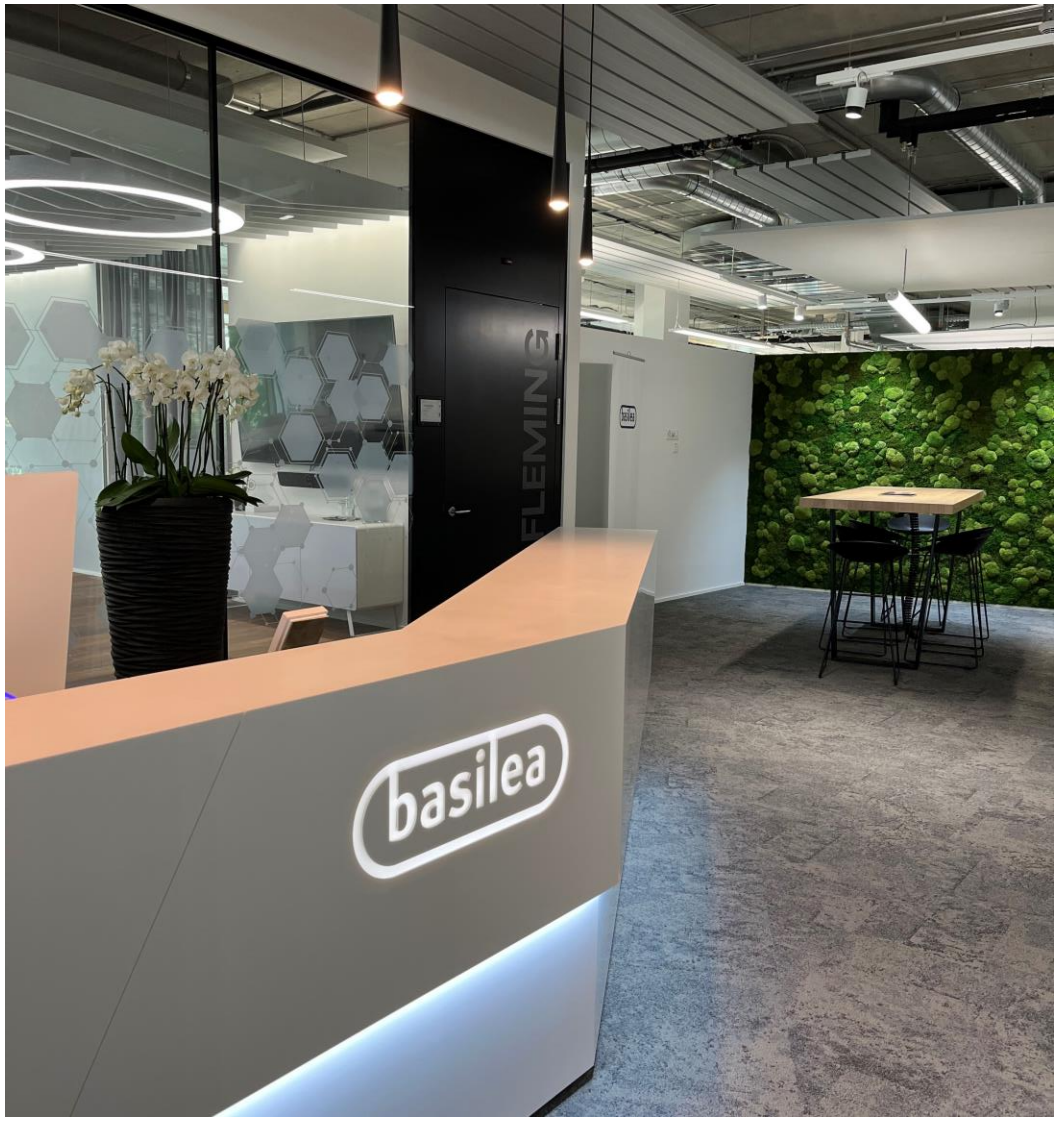
**Laurenz Kellenberger Ph.D.** CSO

Joined: 2000

Previous roles: UNIVERSITY OF CAMBRIDGE; Roche

# At a glance

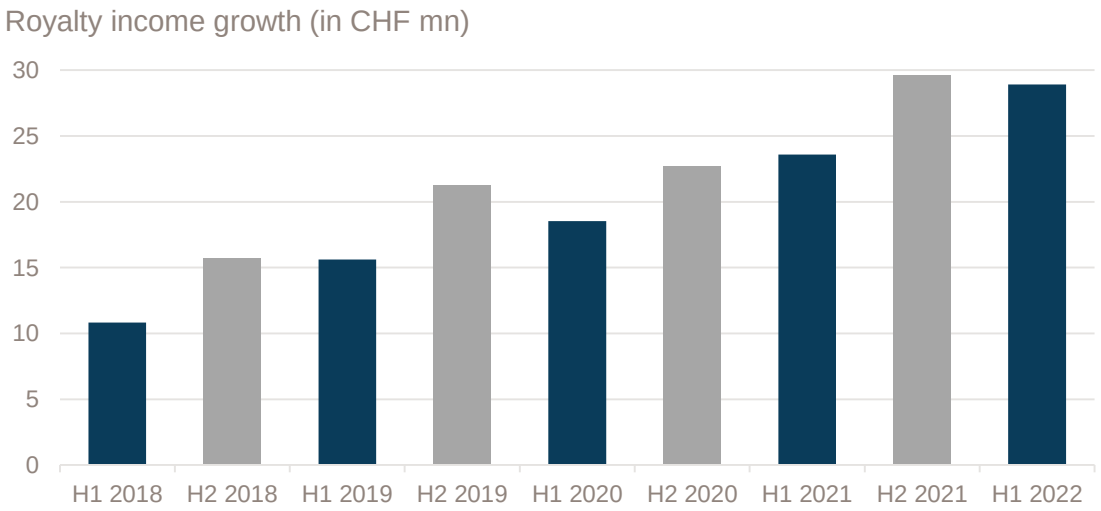
- Focus on the treatment of serious bacterial and fungal infections
- Recognized ability to establish and manage partnerships in both the development and commercial phase, providing access to international markets
- Cresemba® and Zevtera® – two revenue generating hospital anti-infective brands
- Commercial 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 344 mn global in-market sales in 12-months to March 2022
- Recently launched in China and in H2 2022 regulatory decision expected in Japan
- 22.5% royalty income growth in H1 2022




## Zevtera

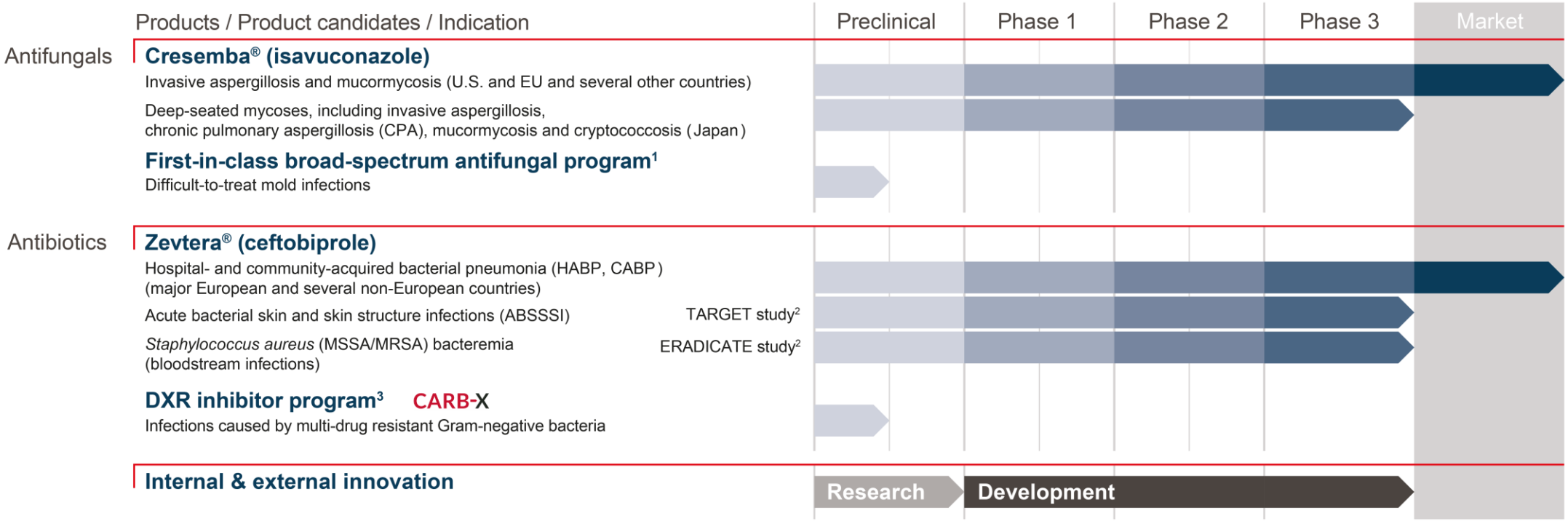
- Positive topline results of ERADICATE study
- Preparing to access the U.S. market: submission of an NDA expected around year-end
- U.S. represents ~ 80–90% of global commercial potential for branded MRSA hospital antibiotics

## 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

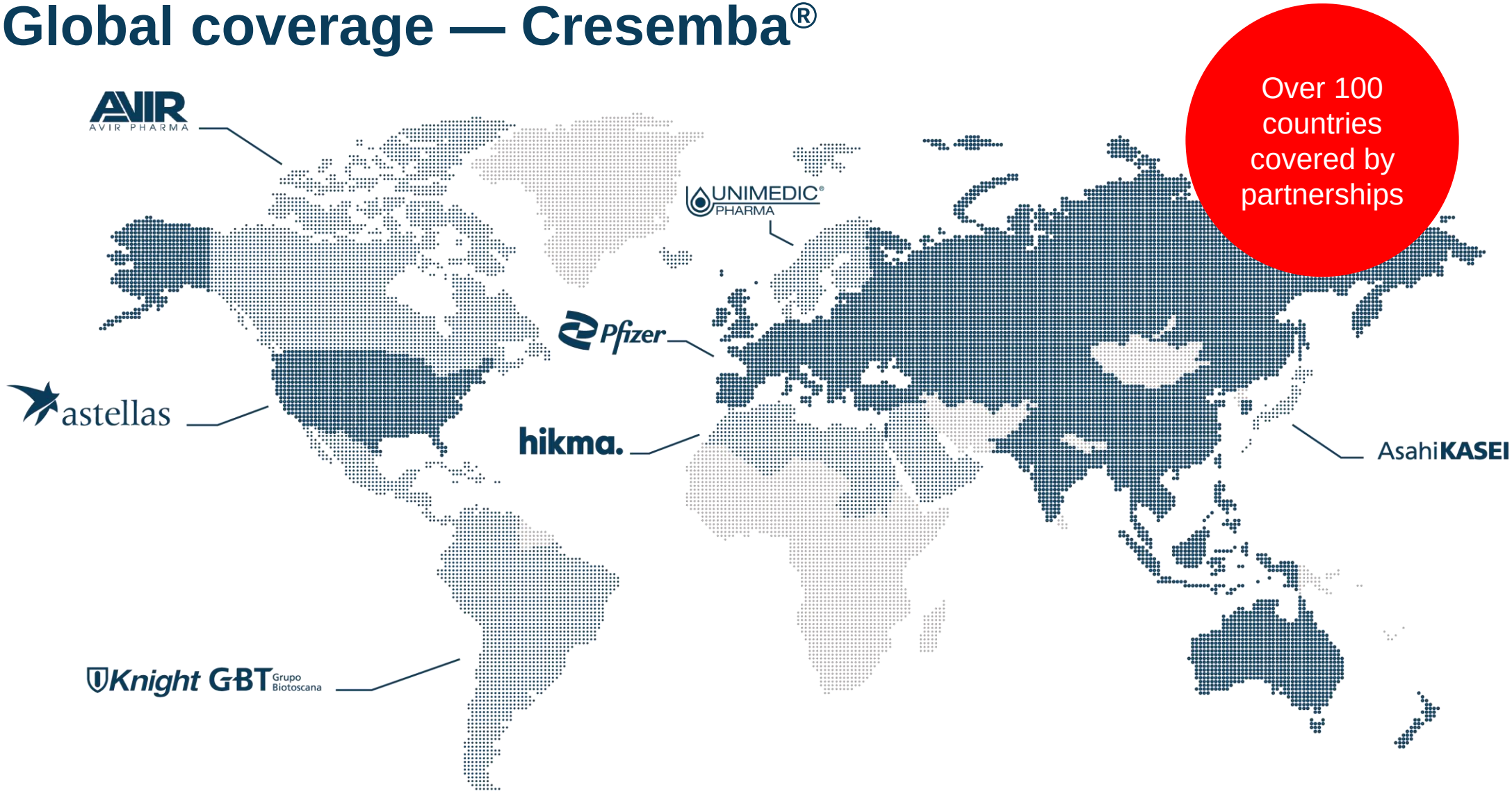
Note: Consolidated figures in conformity with U.S. GAAP; rounding applied consistently

# 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. 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

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

**astellas**
U.S. (Cresemba®)

**AsahiKASEI**
Japan (Cresemba®)

**CR Gosun**
China (Zevtera®)

## Distribution partners

**ADVANZ PHARMA**
Europe (excl. Nordics), Israel (Zevtera®)

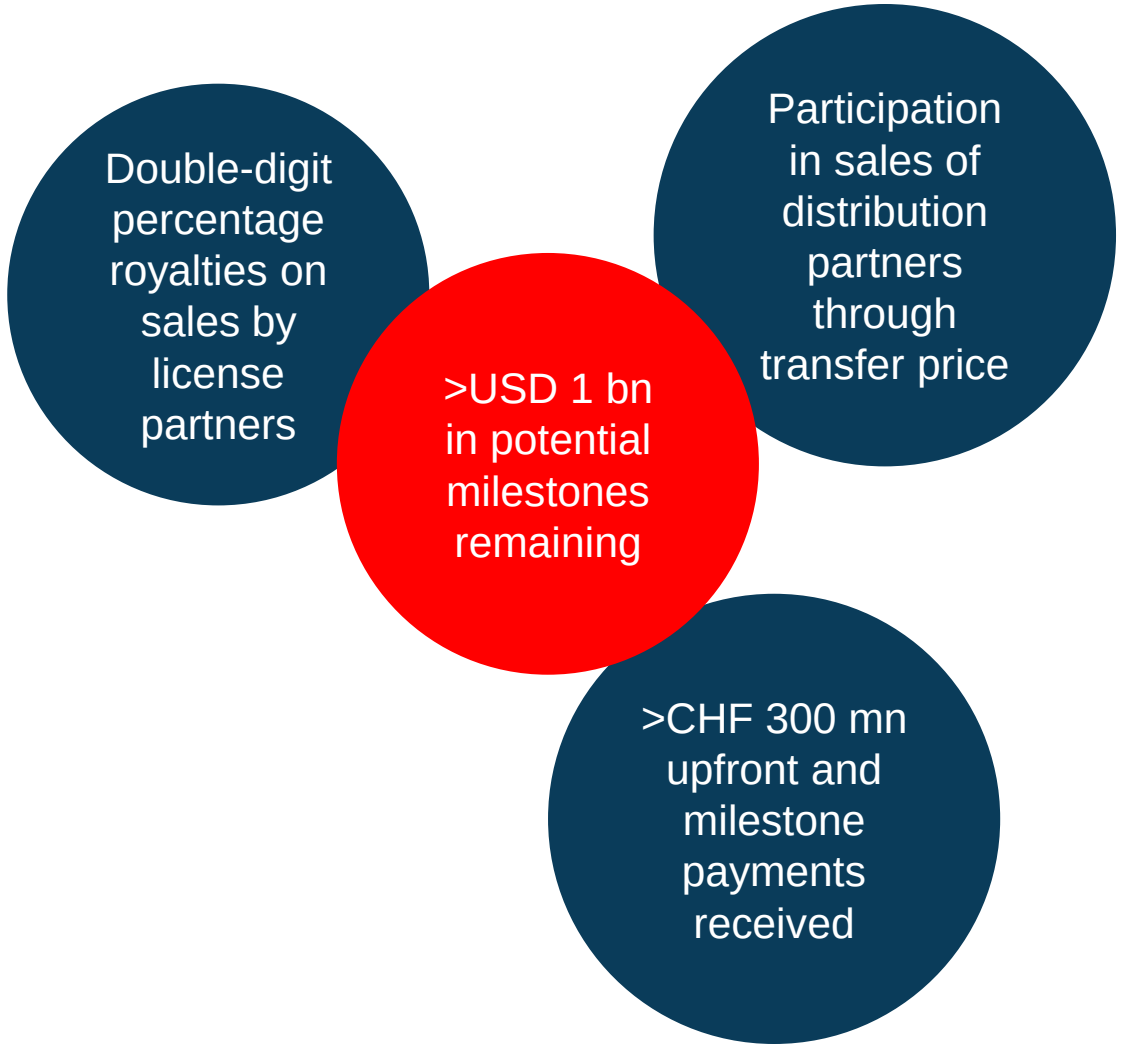
**hikma.**
MENA region (Cresemba® and Zevtera®)

**Knight GBT Grupo Biotoscana**
LatAm (Cresemba® and Zevtera®)

**UNIMEDIC PHARMA**
Nordics (Cresemba® and Zevtera®)

**AVIR PHARMA**
Canada (Cresemba® and Zevtera®)

**LANCET**
Russia and the Eurasian Economic Union (Zevtera®)



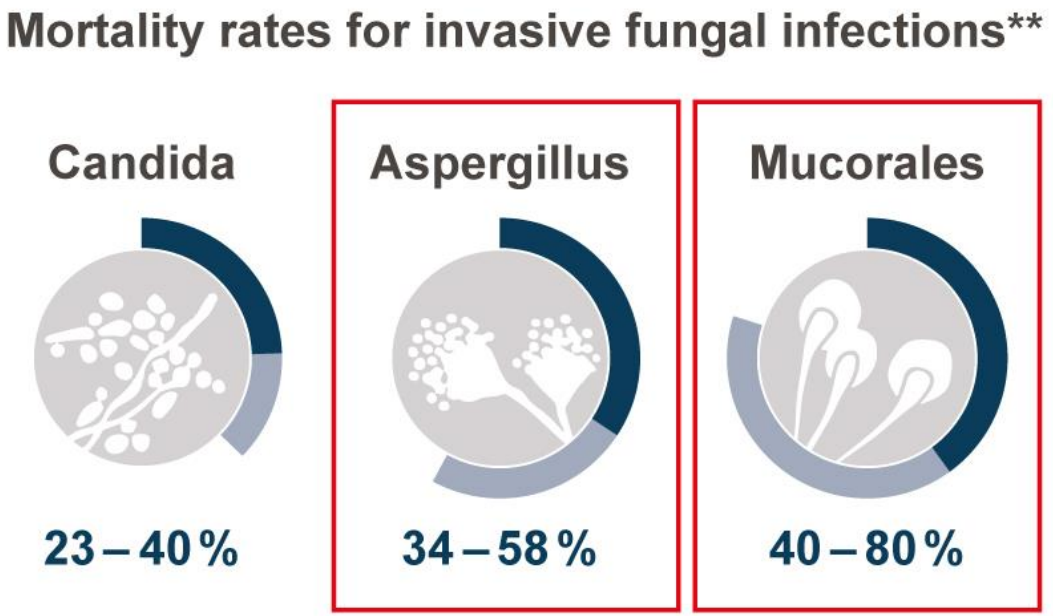
Antifungal

# Cresemba® (isavuconazole)

Invasive mold infections

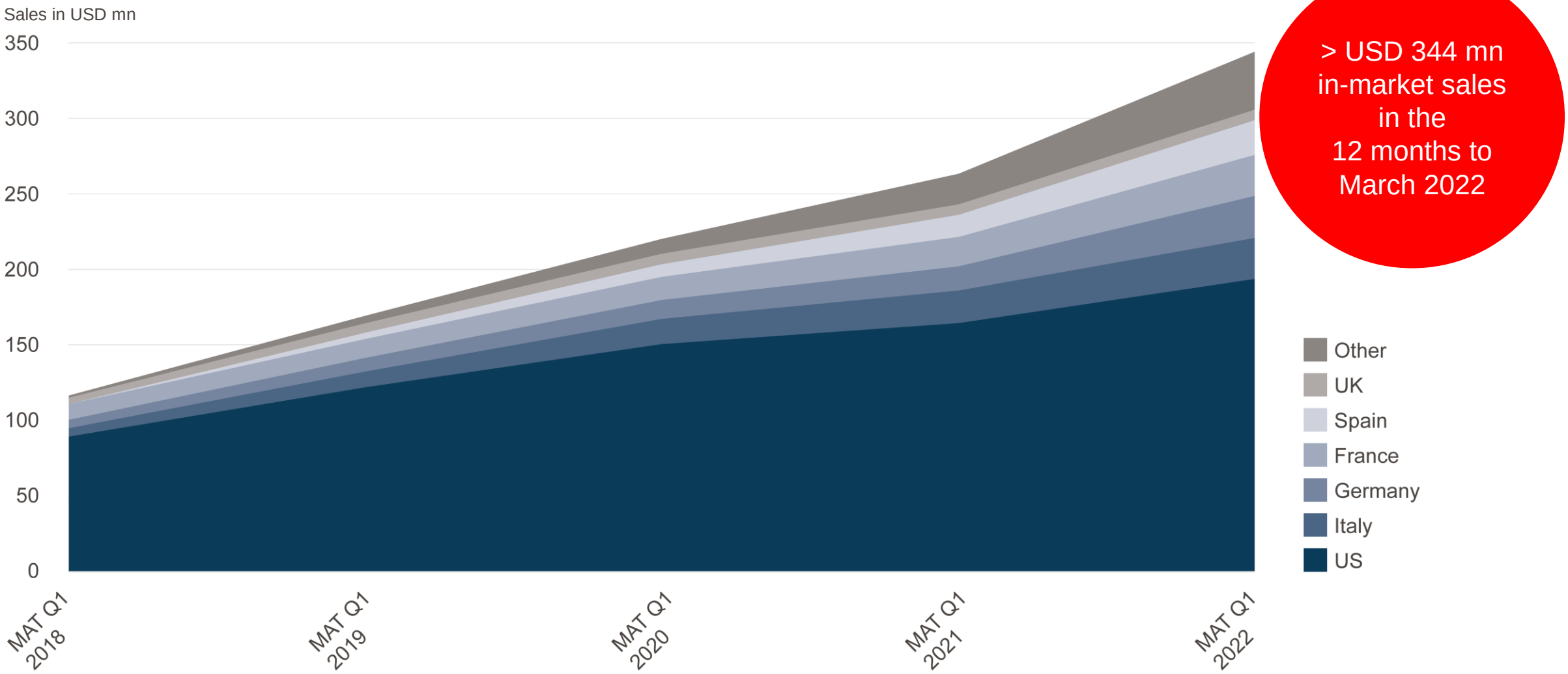
# The market — Invasive fungal infections

- 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

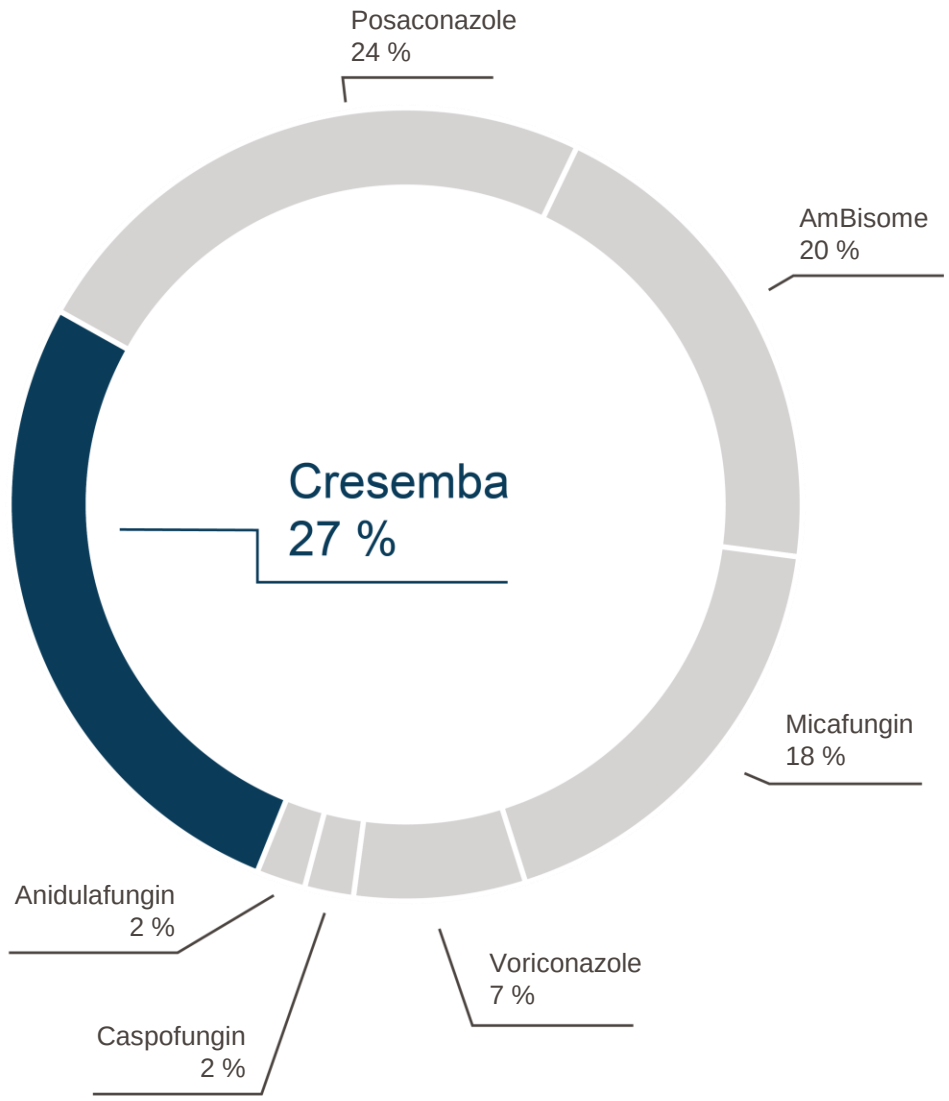



> USD 344 mn in-market sales in the 12 months to March 2022

MAT: Moving annual total; Source: IQVIA Analytics Link, March 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 27% by March 2022**




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

**Market share based on MAT Q1 2022, in-market sales reported as moving annual target (MAT) in U.S. dollar; rounding consistently applied. Source: IQVIA Analytics Link, March 2022

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

**USD 3.2 bn sales (MAT Q1 2022)**

Potential to increase Cresemba® (isavuconazole) 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, March 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.

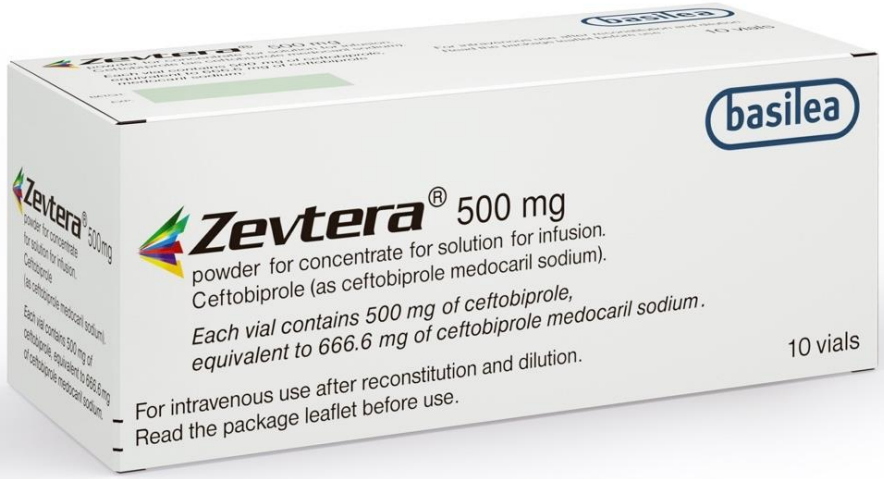
Antibacterial

# 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
  - Cephalosporin class safety profile
  - Early improvement in HABP, particularly in patients with MRSA, and CABP, including high-risk patients
- Marketed in selected countries in Europe, Latin America, the MENA-region and Canada
- Expected launch in China in 2022
- U.S. NDA for SAB and ABSSSI expected to be submitted around year-end 2022; exploring CABP as additional indication




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 U.S.

MENA: Middle East and North Africa

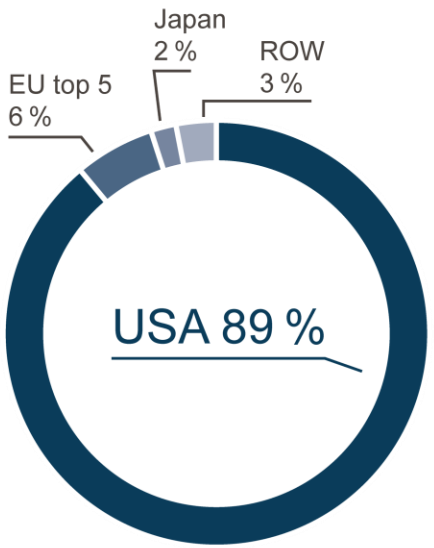
# Zevtera — Key attributes

- 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 *Staphylococcus aureus* bacteremia, acute bacterial skin and skin structure infections, and pneumonia[1, 2]
- Low propensity for resistance development[1]
- Established safety profile consistent with the cephalosporin class, demonstrated in both adult and pediatric patients[1, 2, 3]

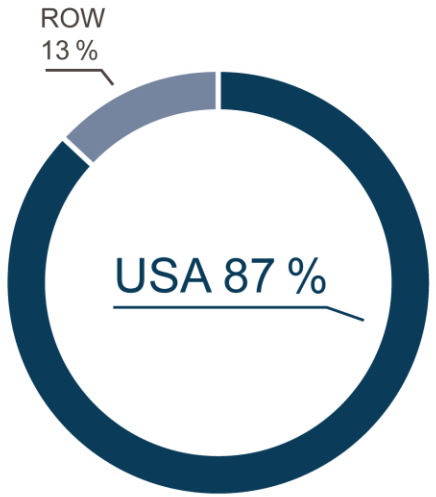
[1] Syed YY. Drugs. 2014;74:1523-1542 and Basilea data on file.
[2] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.
[3] Rubino CM et al. Pediatr Infect Dis J. 2021;40:997-1003.

# 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

# 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)

TARGET ABSSSI Study

ERADICATE SAB Study

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

- 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

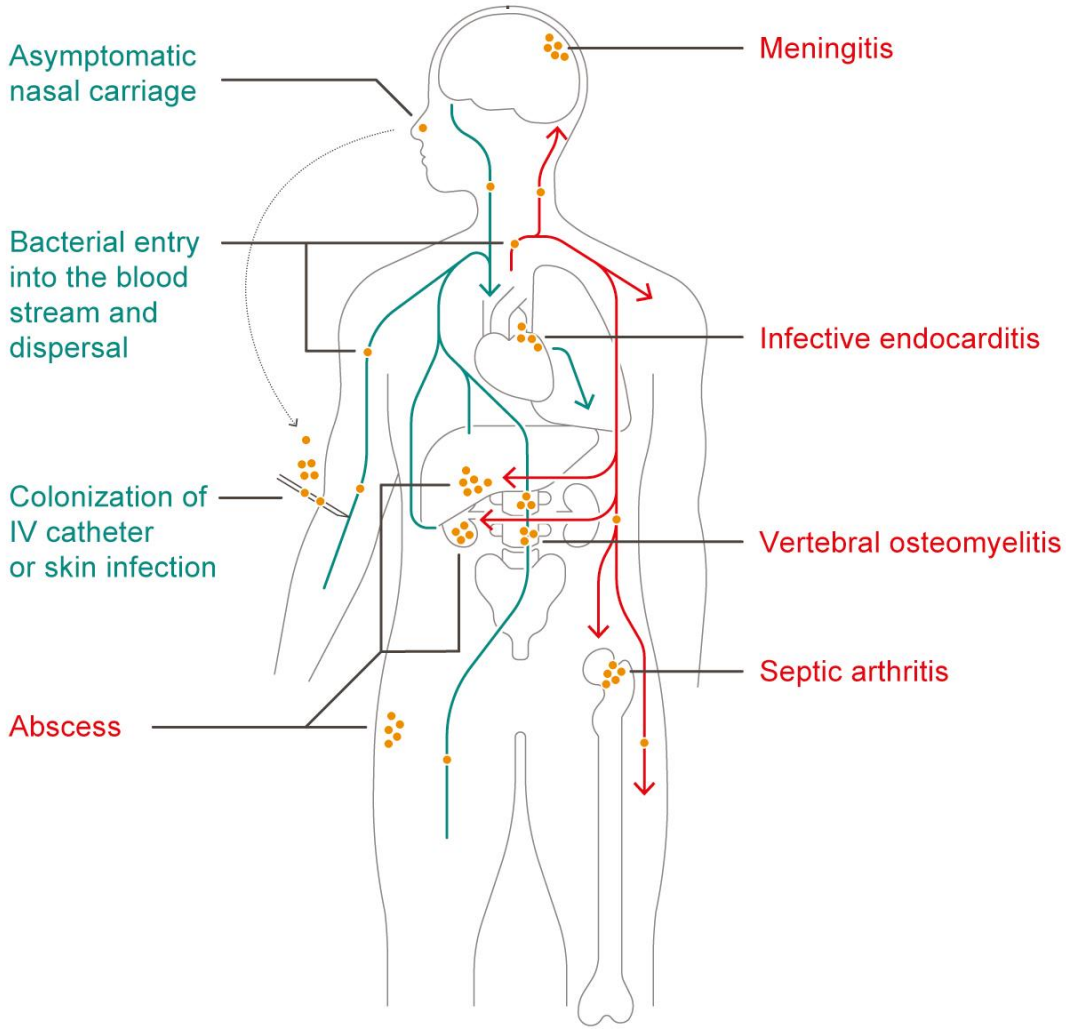
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
BARDA

[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

# 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 mortality[2]
- 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

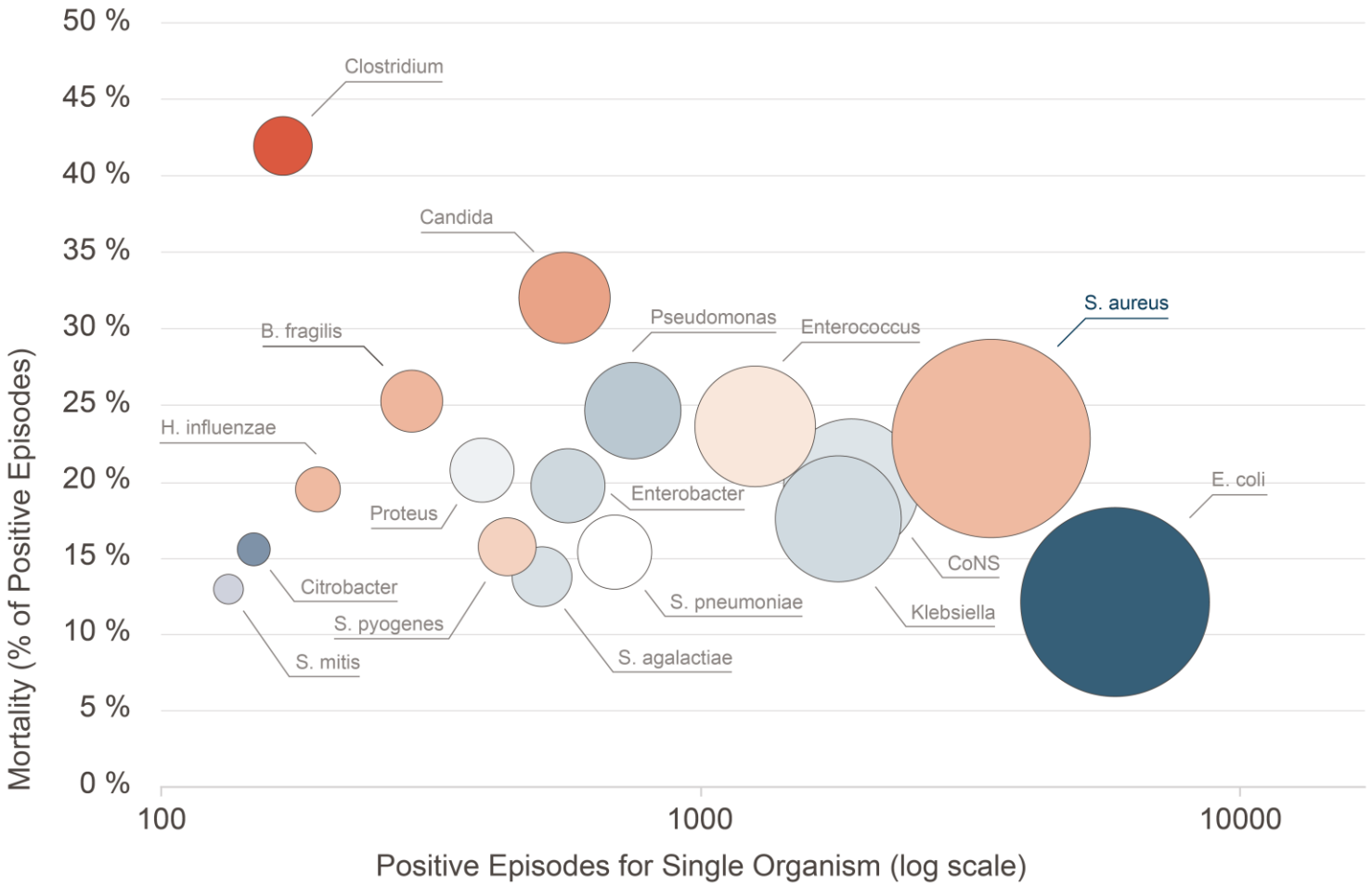
**Causes and consequences of SAB**




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

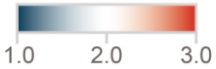
[1] MMWR, 2019;68:214–219.
[2] Hamed K et al. Future Microbiol. 2020;15:35-48.
MRSA: methicillin-resistant *Staphylococcus aureus*
MSSA: methicillin-susceptible *Staphylococcus aureus*

# 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

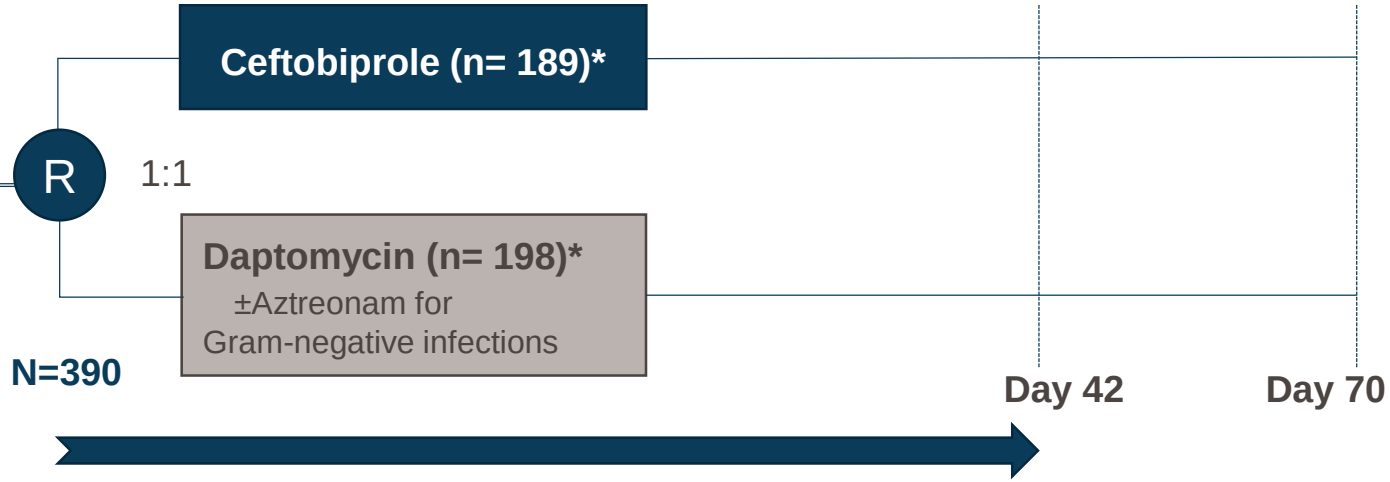



Adapted from: Verway M et al. J Clin Microbiol. 2022;60:e0242921.

# 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

- 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)**

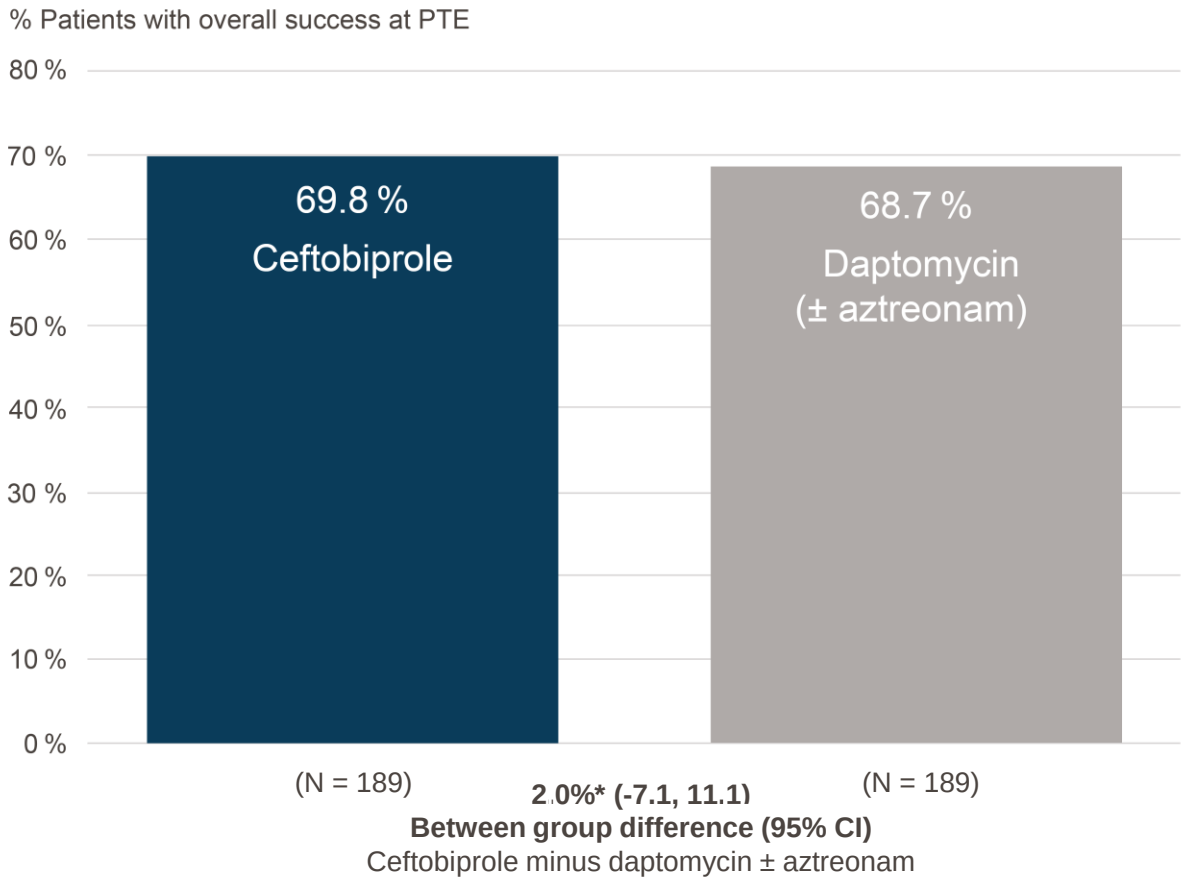
**Active treatment (up to 42 days)**

**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 is achieved**
## DRC assessed overall success at PTE in mITT population




**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

# 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

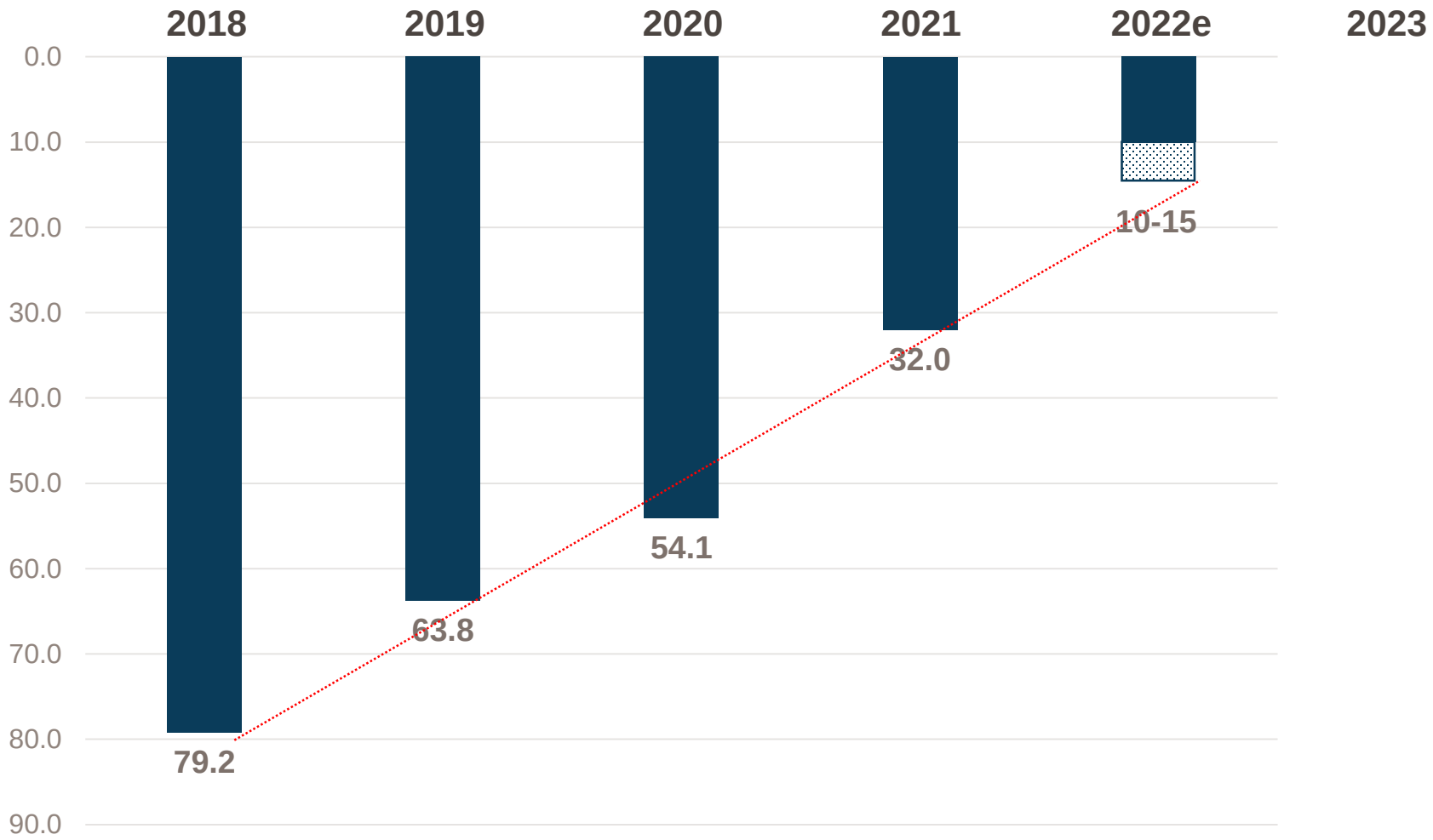
# Guidance: Sustainable profitability from FY 2023 expected

| In CHF mn | FY 2023e | FY 2022e* | FY 2021 |
|---|---|---|---|
| Cresemba & Zevtera related revenue | - | 98 – 104 | 131.4 |
| Royalty income | - | ~ 59 | 53.2 |
| Total revenue | - | 106 – 112 | 148.1 |
| Cost of products sold<br>Operating expenses | -<br>-30% vs. 2022 | 21 – 24<br>~ 110 | 24.1<br>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

# Net cash used in operating activities




**Sustainable profitability from 2023 onwards**

# 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

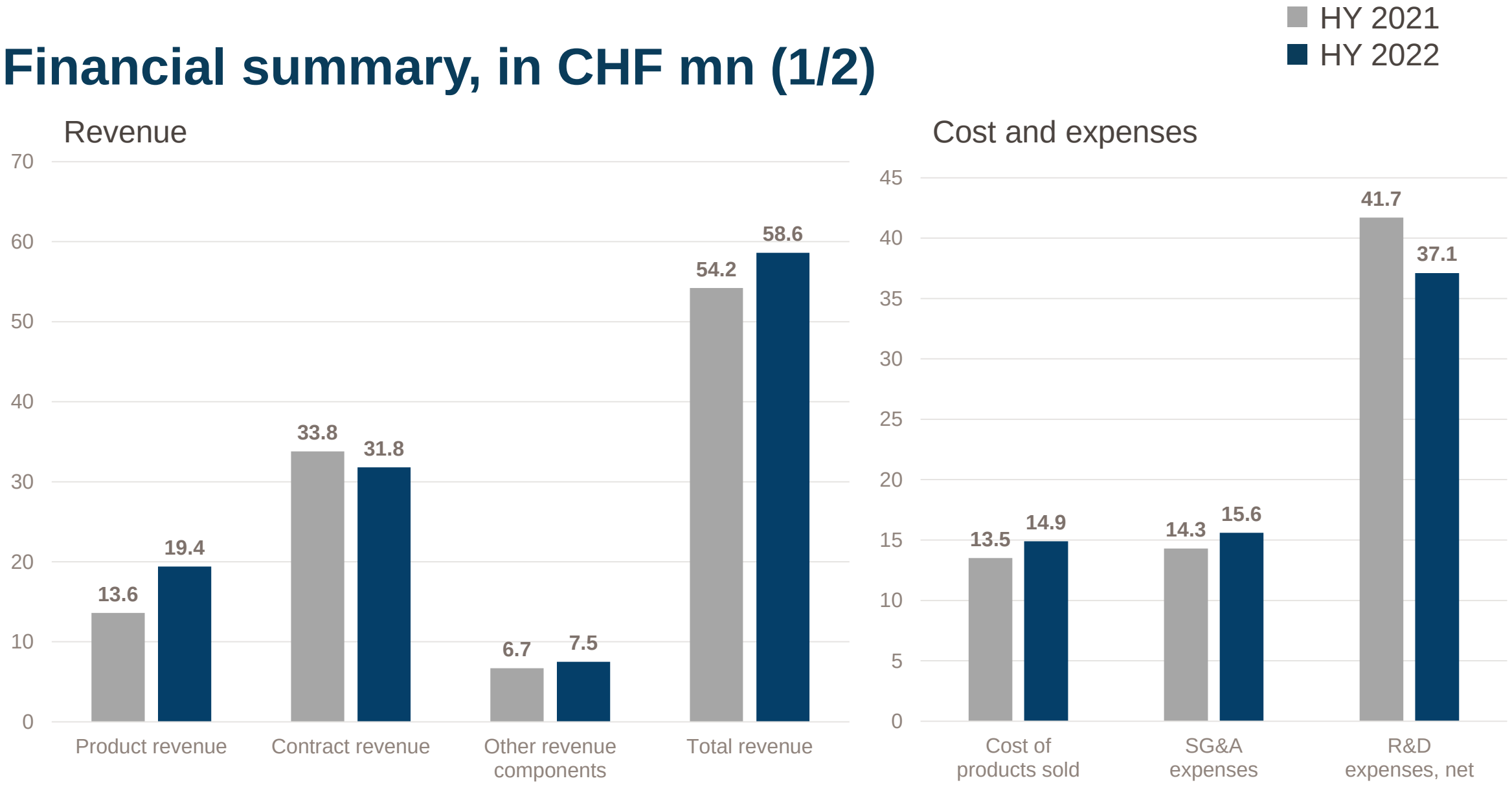
Increasing Cresemba & Zevtera revenue

Advancement of preclinical anti-infective assets

In-licensing of anti-infectives

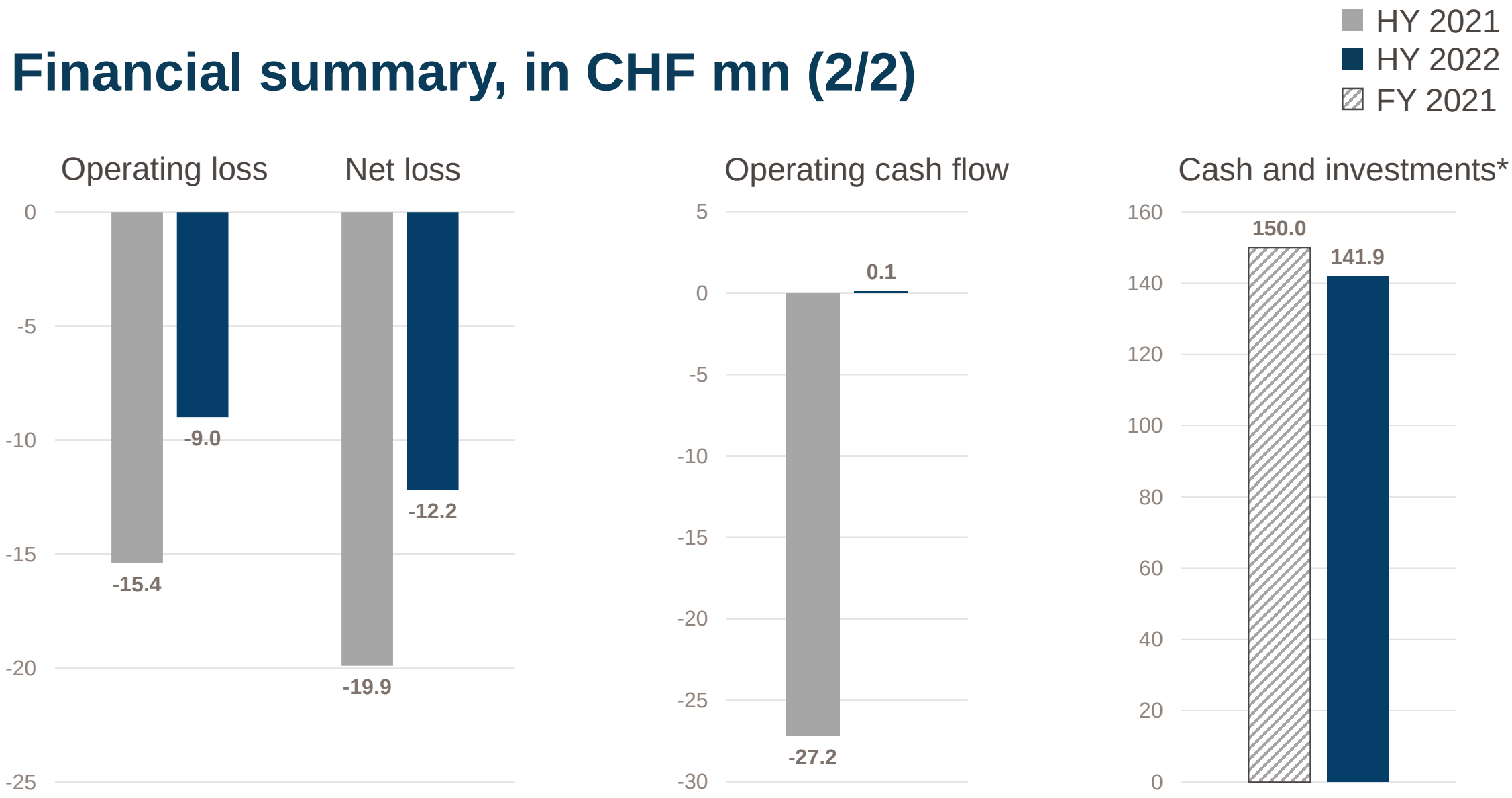
# Appendix

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



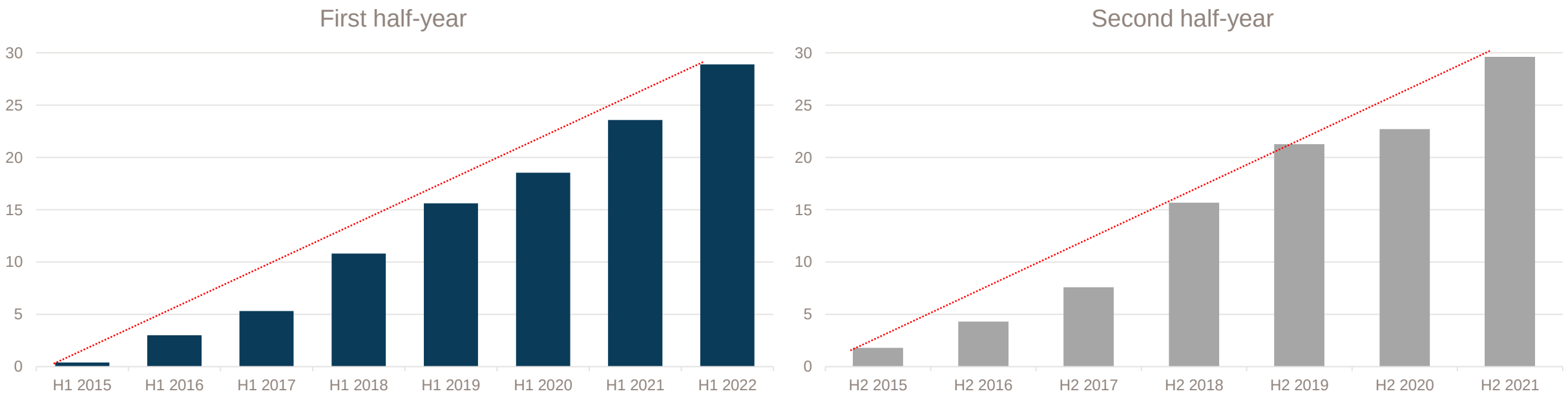

Note: Consolidated figures in conformity with U.S. GAAP; rounding applied consistently

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




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

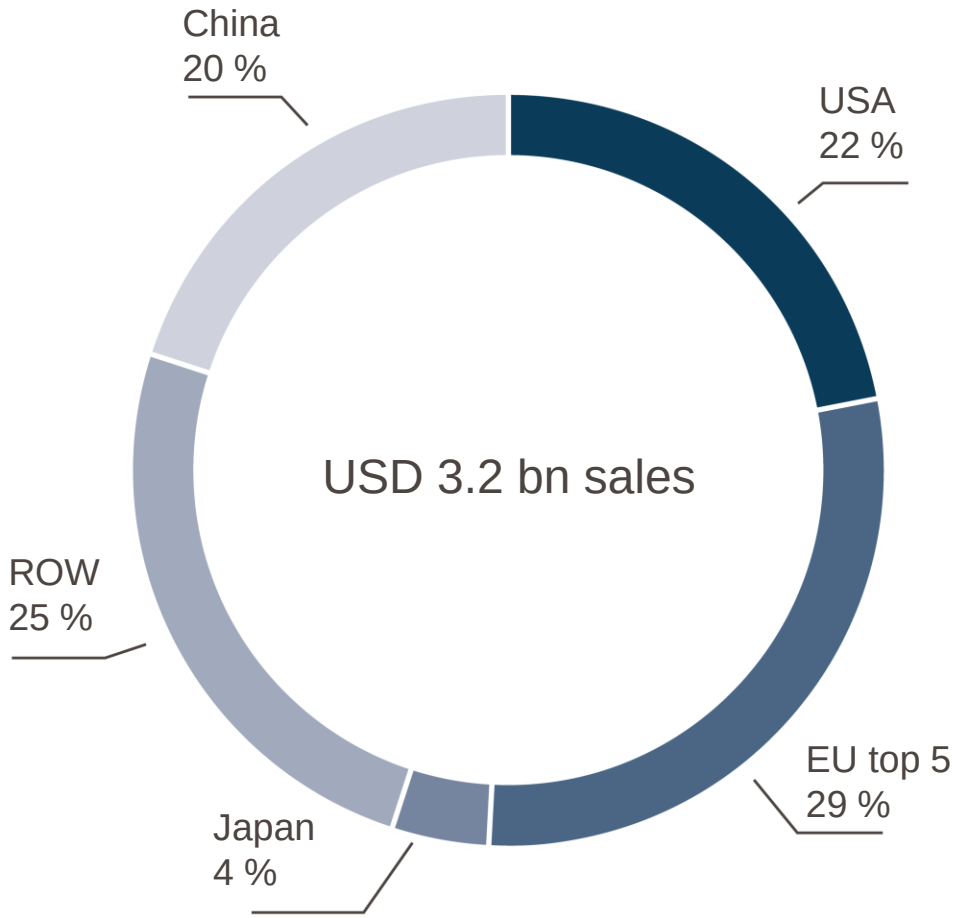
# Cresemba royalty income growth reflects continued commercial success in key territories (in CHF mn)




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 3.2 bn sales of best-in-class antifungals*
(MAT Q1 2022)




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

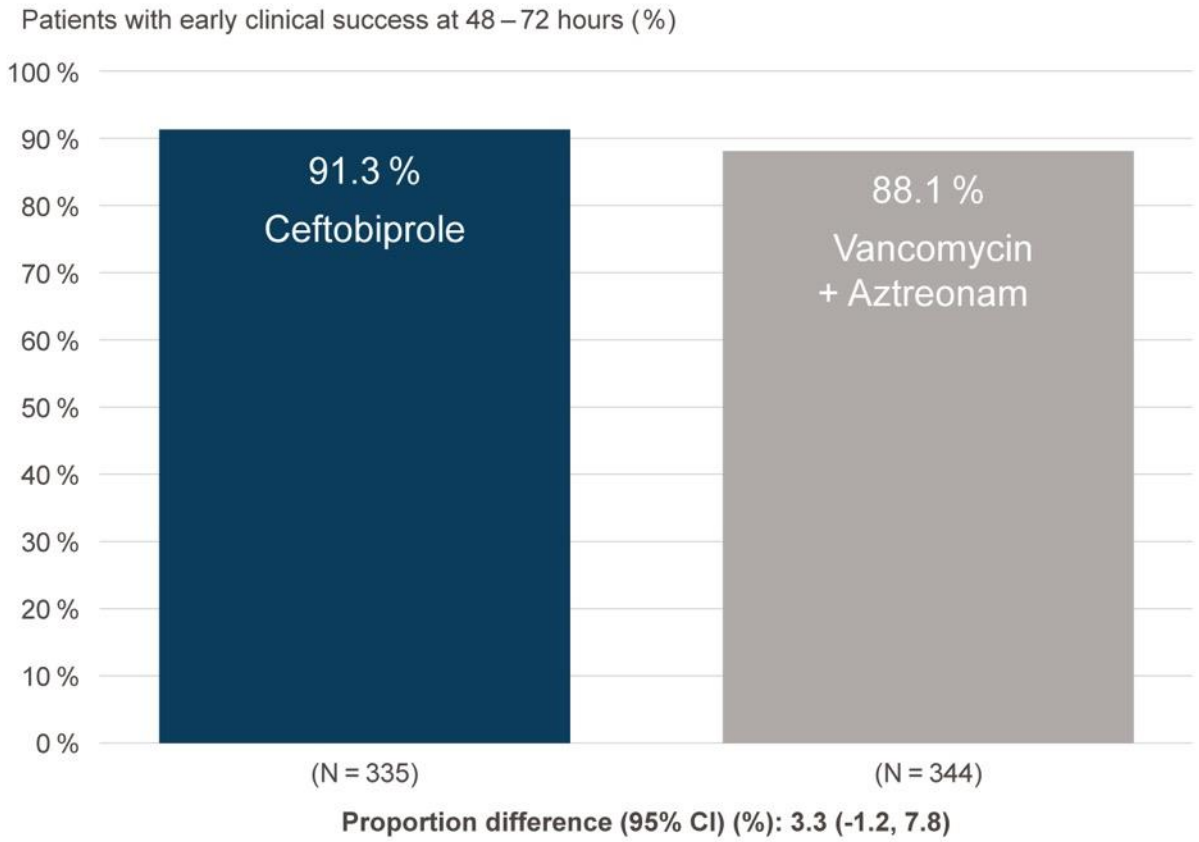
MAT: Moving annual total; Source: IQVIA Analytics Link, March 2022

# 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 %

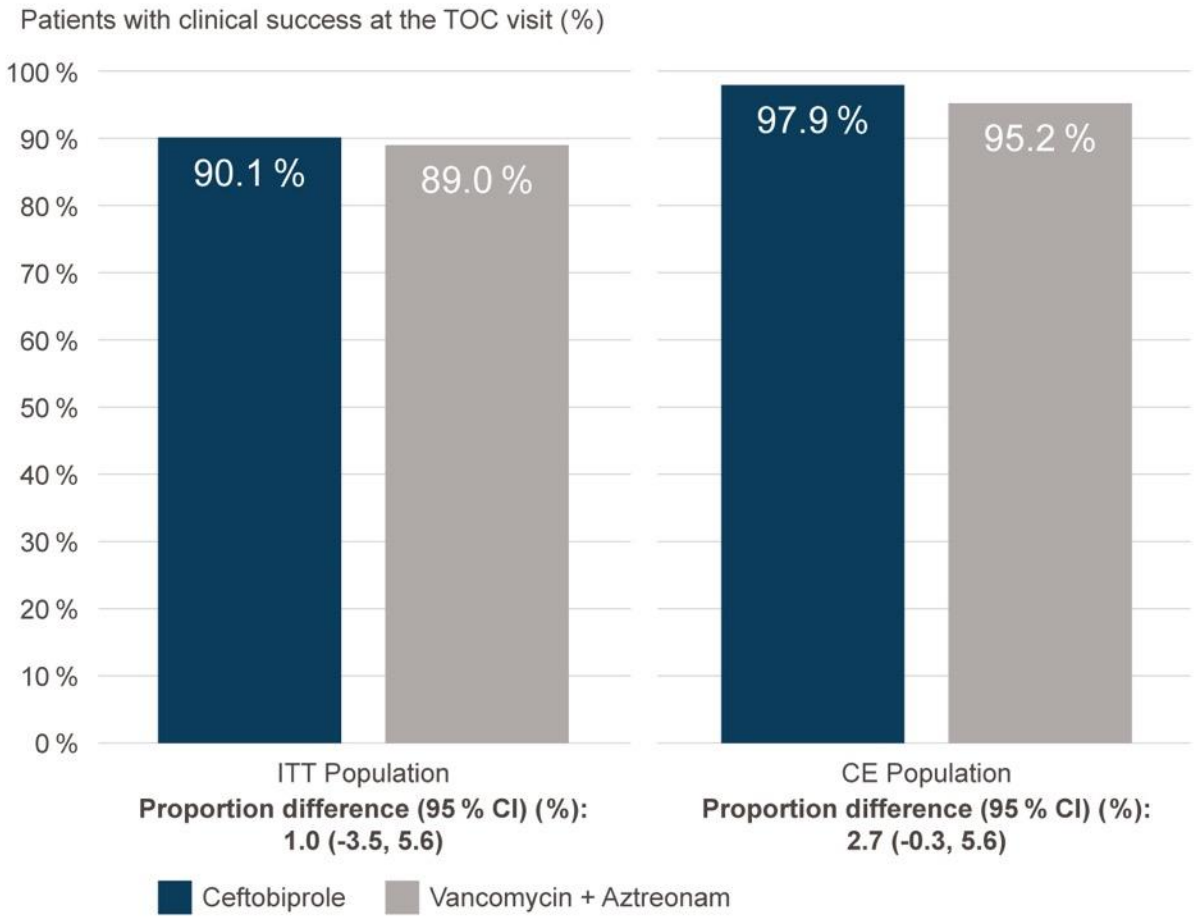
[1] Overcash JS et al. Clin Infect Dis. 2021;73:e1507-e1517.

# 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

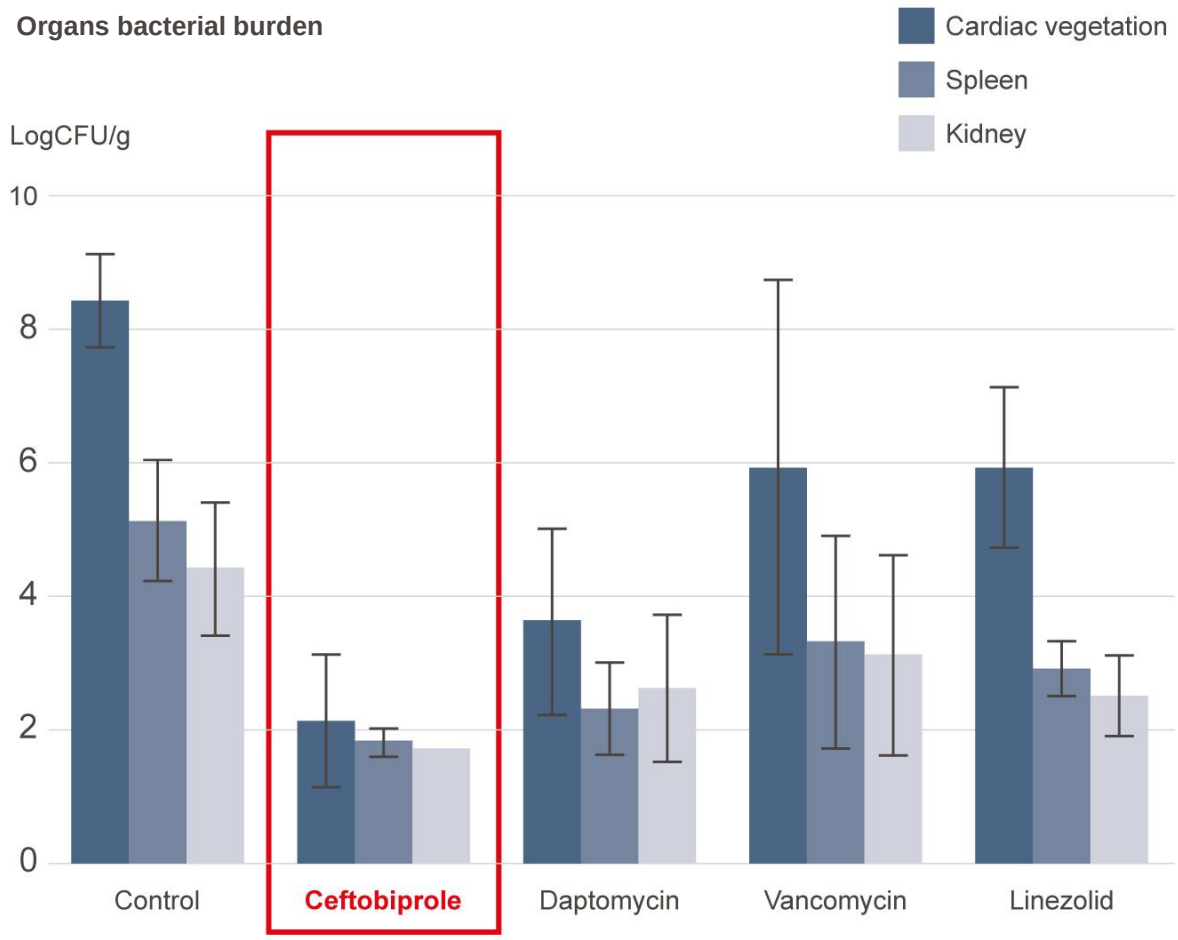
CE: clinically evaluable; ITT: intent-to-treat

# 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 serious 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]

[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.

## 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]

# 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 **Accelerator**
- DRC: **D**ata **r**eview **c**ommittee
- HABP: **H**ospital-**a**cquired **b**acterial **p**neumonia
- ITT: **I**ntent-**T**o-**T**reat
- ITT: **I**ntent-**t**o-**t**reat
- i.v.: **I**ntra**v**enous
- 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
- U.S. GAAP: **U**nited **S**tates **G**enerally **A**ccepted **A**ccounting **P**rinciples
- VAP: **V**entilator-**a**ssociated **p**neumonia

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**Focused on Growth and Innovation**

**Hegenheimermattweg 167b**
**4123 Allschwil**
**Switzerland**

**info@basilea.com**
**www.basilea.com**