



**Focused on
Growth and Innovation**

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

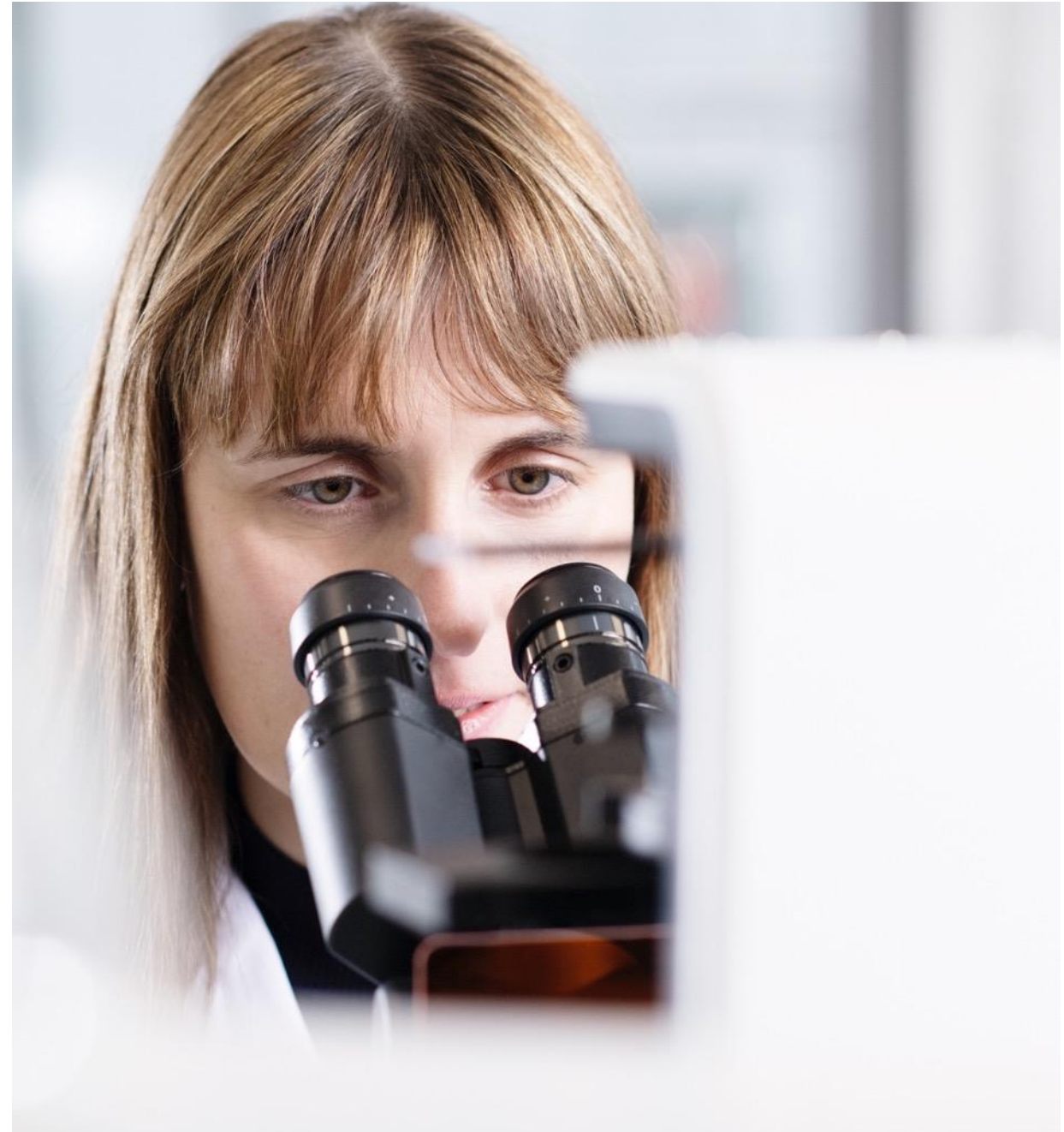
Investor presentation

June 28, 2022



Table of contents

- Executive summary
- Portfolio
 - Antifungal
 - Cresemba® (isavuconazole)
 - Antibiotic
 - Zevtera® (ceftobiprole)
- Financials & Outlook
- Appendix





Executive summary



Experienced leadership team



**David
Veitch** CEO

Joined
2014

Previous
roles:



**Adesh
Kaul** CFO

2009



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

2010



**Gerrit
Hauck**
Ph.D. CTO

2018



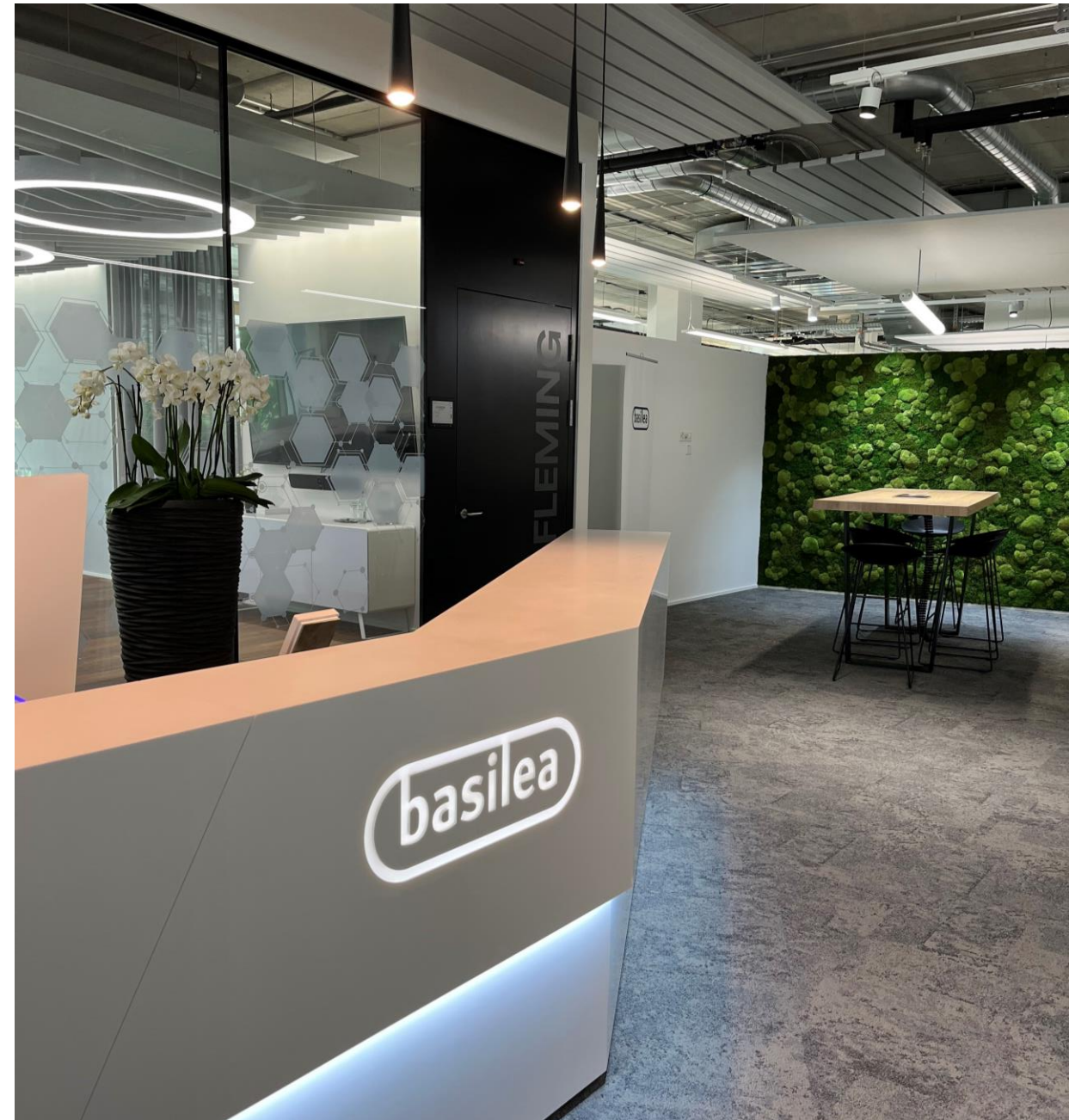
**Laurenz
Kellenberger**
Ph.D. CSO

2000



At a glance

- Focused on the treatment of serious bacterial and fungal infections
- Well funded, with two revenue generating hospital anti-infective brands, Cresemba® and Zevtera®, complemented by preclinical pipeline
- Recognized ability to establish and manage partnerships in both the development and commercial phase, providing access to international markets
- Experienced team with the proven expertise to take compounds from research to market
- Listed on SIX Swiss Stock Exchange, SIX: BSLN
- Based in the Basel area life sciences hub, Switzerland



Strategy focused on anti-infectives

Significantly growing cash revenues from Cresemba and Zevtera:

Cresemba

- 29% royalty income growth in 2021,
- > USD 324 mn global in-market sales in 12-months to December 2021
- 2022: launched in China and regulatory decision expected in Japan

Zevtera

- Preparing to file NDA for U.S. around year-end 2022
- U.S. is the most important MRSA market ~ 80–90% of global potential
- Qualified infectious disease product (QIDP) designation provides 10 years market exclusivity from approval
- Commercialization in U.S. planned with a partner

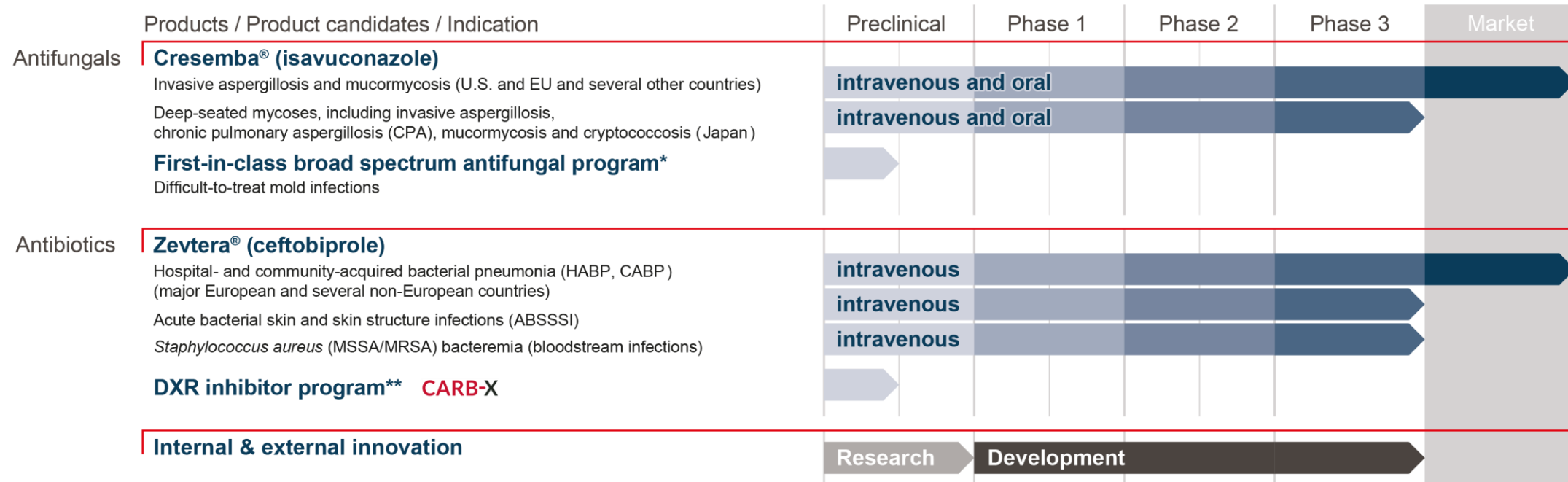
Preclinical assets

- A number of preclinical programs, including DXR inhibitor (CARB-X funded) and a potential first-in-class broad spectrum antifungal
- Focus on external sourcing of additional preclinical and clinical anti-infective compounds

Sustainable profitability from 2023

We are uniquely positioned to create sustainable value, in an area of increasing unmet medical need, with our proven ability to advance anti-infective compounds from research, through development, to commercialization.

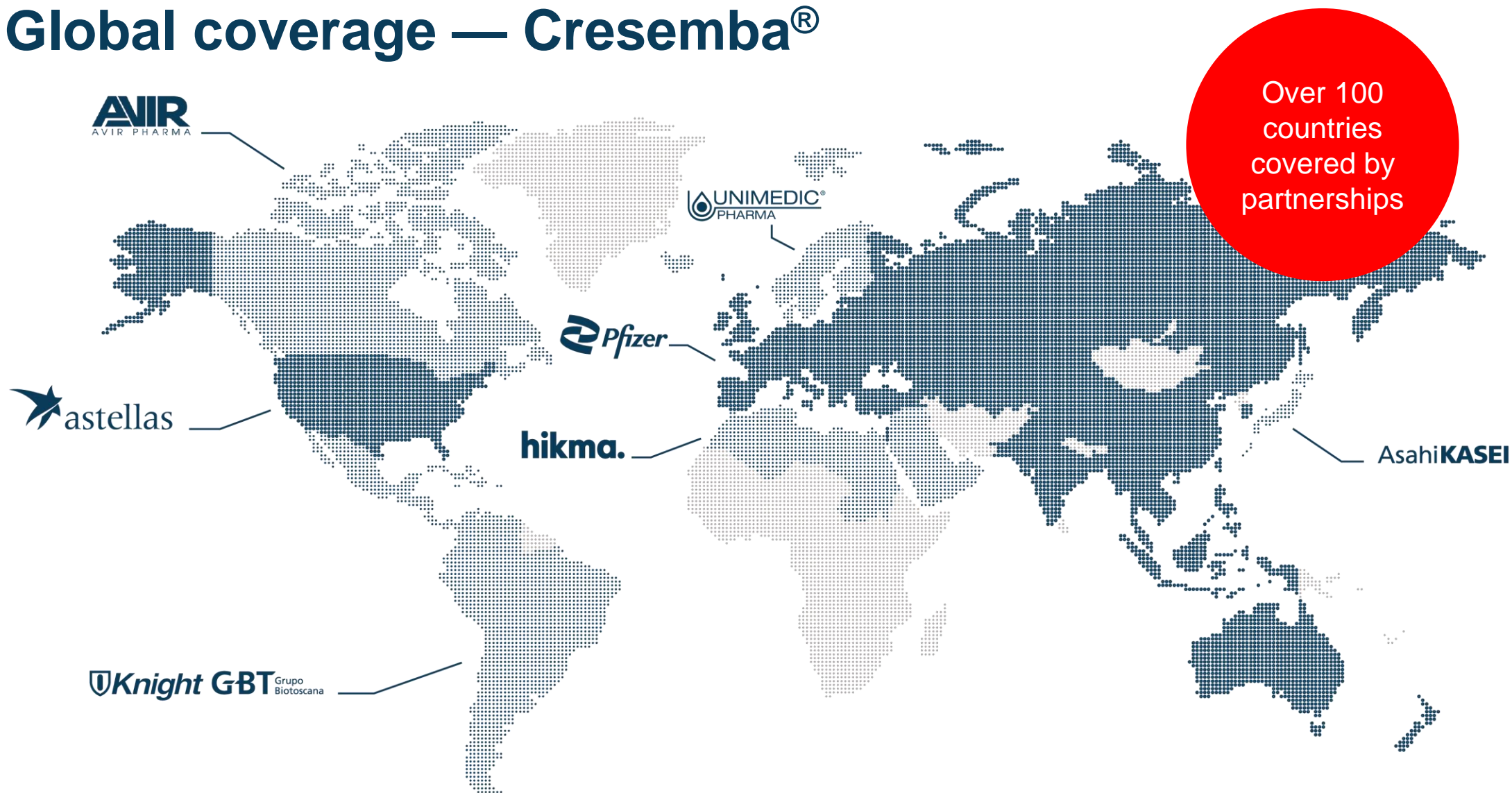
Potential for sustainable growth and value creation based on commercialized brands and innovative pipeline



* Licensed from FCCDC

** 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

>USD 295 mn
upfront and
milestone
payments
received

Exit from oncology to be completed in 2022

- Preparing separate transactions for BAL0891 (TTK/PLK1 kinase inhibitor) and preclinical oncology assets, to be concluded in H2 2022
- Returning derazantinib rights to Merck & Co., Inc. by year-end 2022
- Exploring partnering opportunities for lisavanbulin; no expansion of ongoing clinical studies

No material expenses related to oncology activities and sustainable profitability expected in 2023. Generating long-term value through separate transactions.



Antifungal

Cresemba® (isavuconazole)

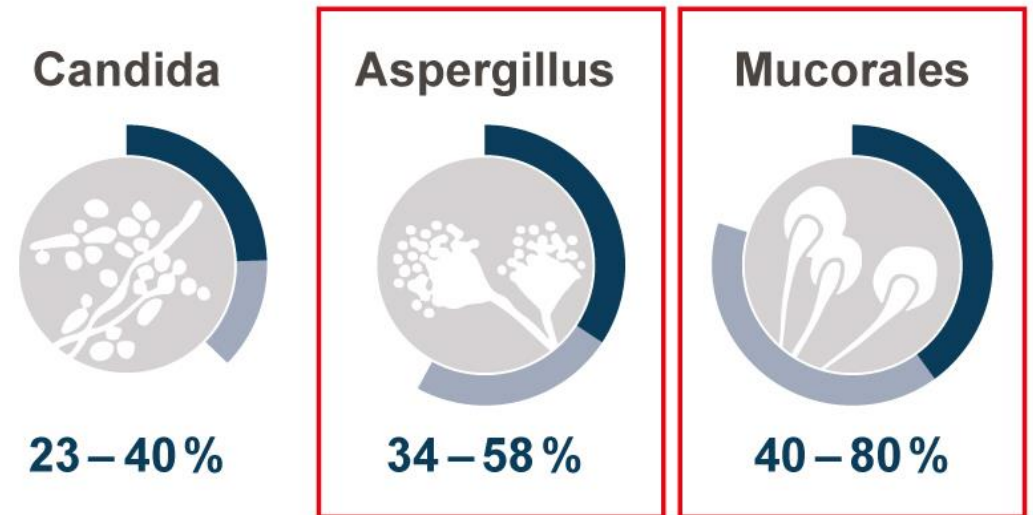
Invasive mold infections



The market — Invasive fungal infections

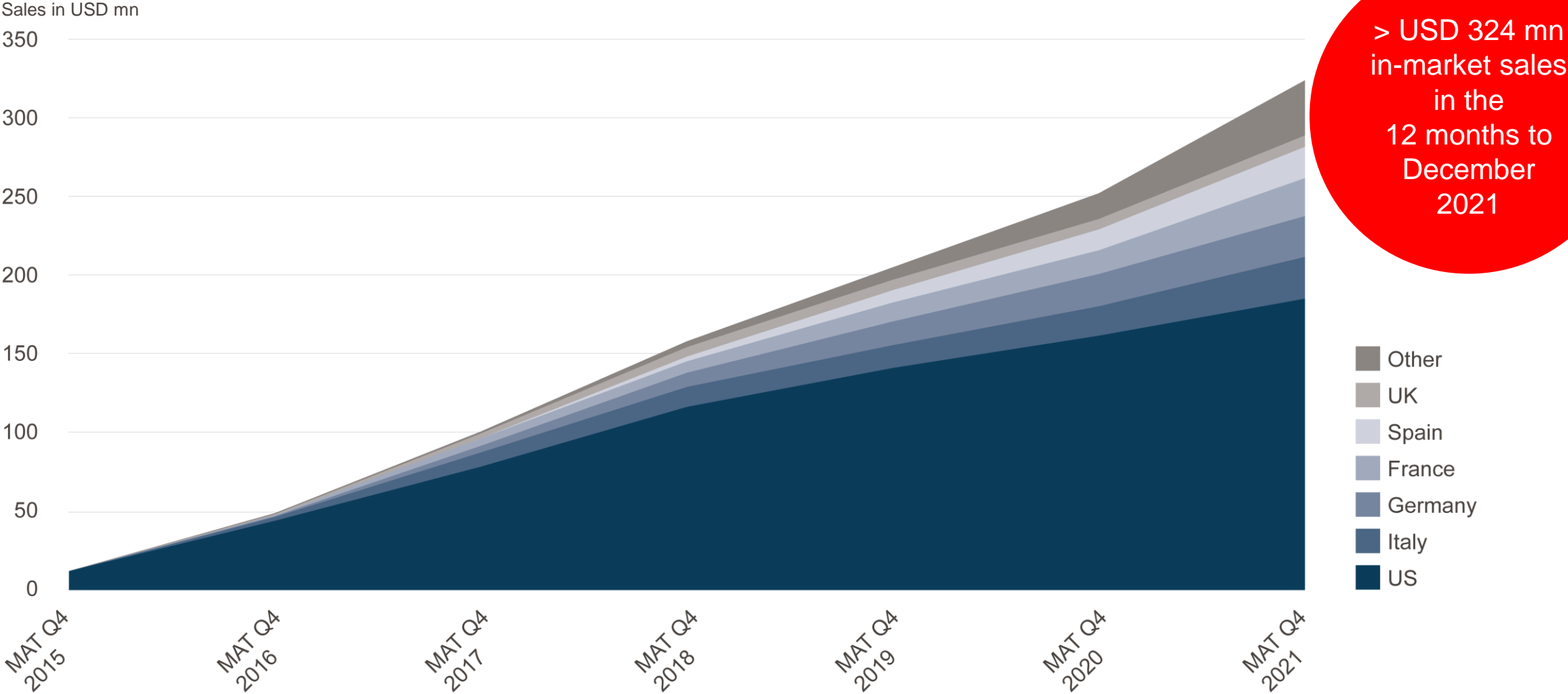
- Severe, potentially life-threatening infections mainly affecting immunocompromised patients
- An important cause of morbidity and mortality in cancer patients undergoing intensive chemotherapy regimens
- Rising number of immunocompromised patients (cancer and transplantations) driving therapeutic demand
- 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, December 2021

Sales of best-in-class antifungals* by product

USD 3.2 bn sales (MAT Q4 2021)

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: isavuconazole, posaconazole, voriconazole, AmBisome, anidulafungin, caspofungin, micafungin



MAT: Moving annual total; Source: IQVIA, December 2021, rounding consistently applied

Confidential/proprietary information of Basilea Pharmaceutica International Ltd, Allschwil – not for distribution

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

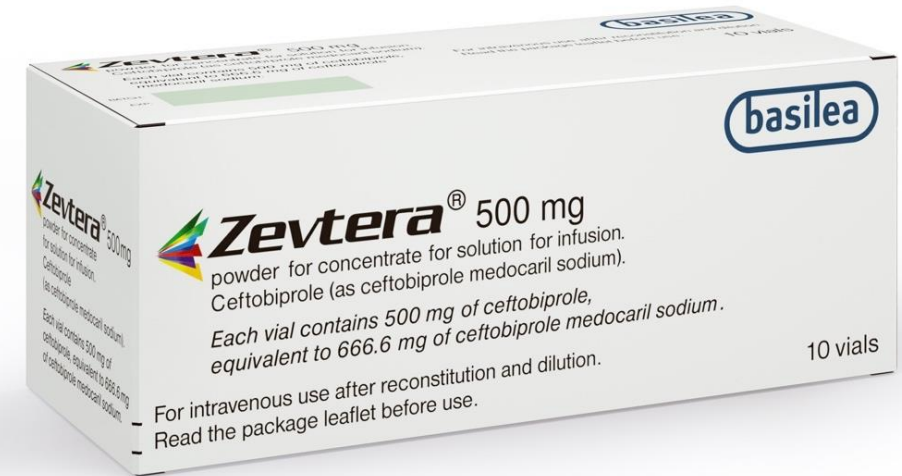
- Broad spectrum hospital anti-MRSA cephalosporin (including Gram-negative bacteria)
 - Rapid bactericidal activity
 - Potential to replace antibiotic combinations
 - Cephalosporin class safety profile
 - Early improvement in HABP, particularly in patients with MRSA, and CABP, including high-risk patients
- 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 filed 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

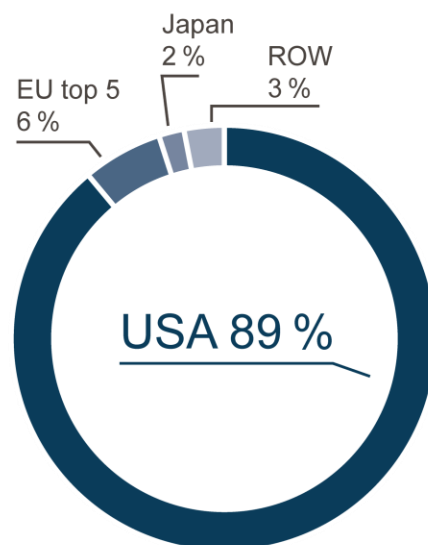


Focused on Growth and Innovation

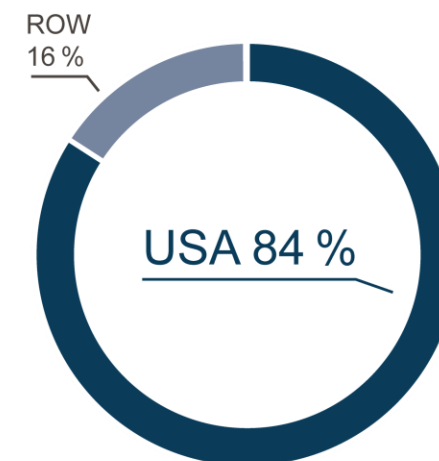


The hospital anti-MRSA antibiotic market — A USD 2.8 bn market* with the U.S. being the most important region

Daptomycin sales by region
(2015, before LOE)



Ceftaroline sales by region
(MAT Q4 2021)



* 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, December 2021

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)
- Phase 3 study in community-acquired bacterial pneumonia (CABP) previously completed³
 - 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
- The phase 3 program has been funded in part (~70% of total program costs; up to USD ~134 mn) with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201600002C



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 2021 (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

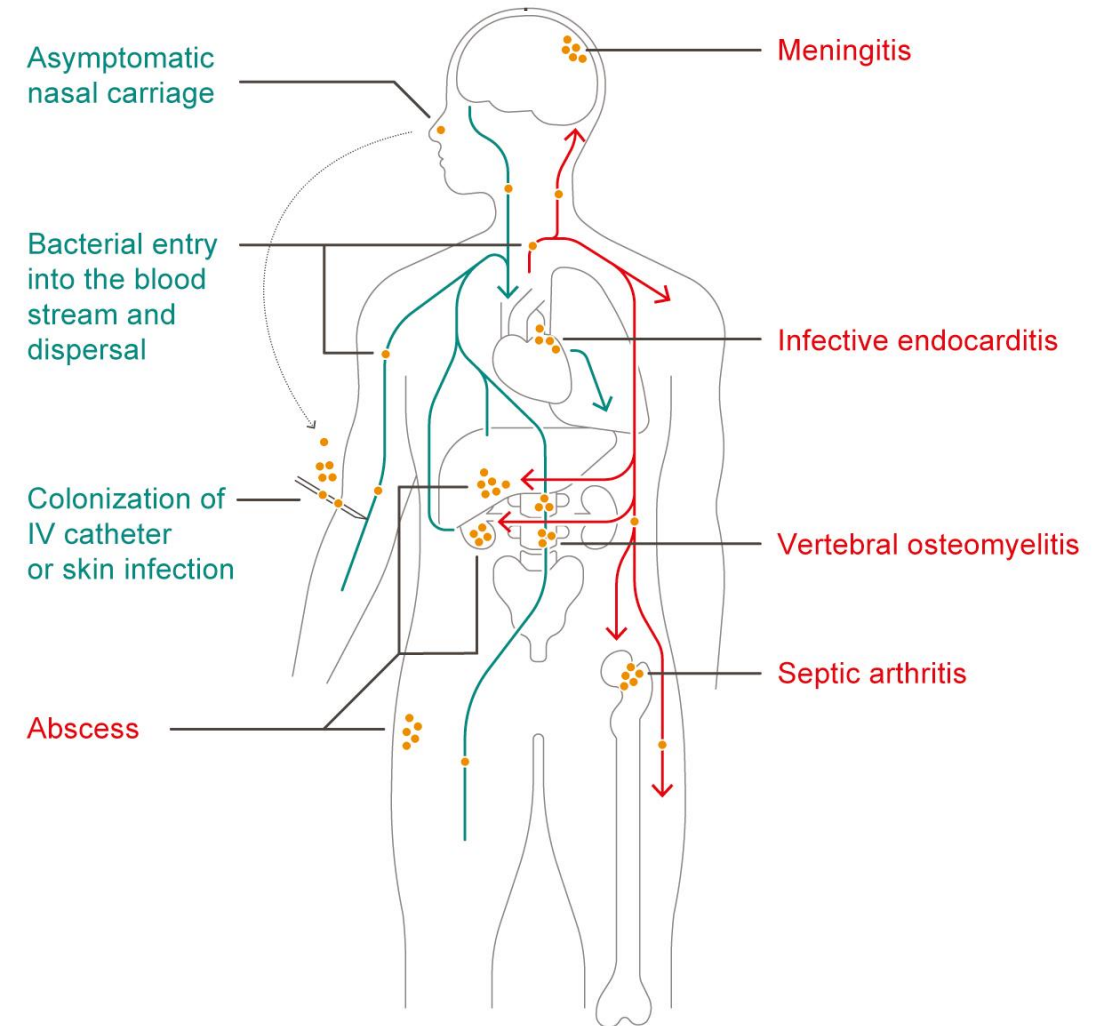
¹ MMWR, 2019;68:214–219.

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

MRSA: methicillin-resistant *Staphylococcus aureus*

MSSA: methicillin-susceptible *Staphylococcus aureus*

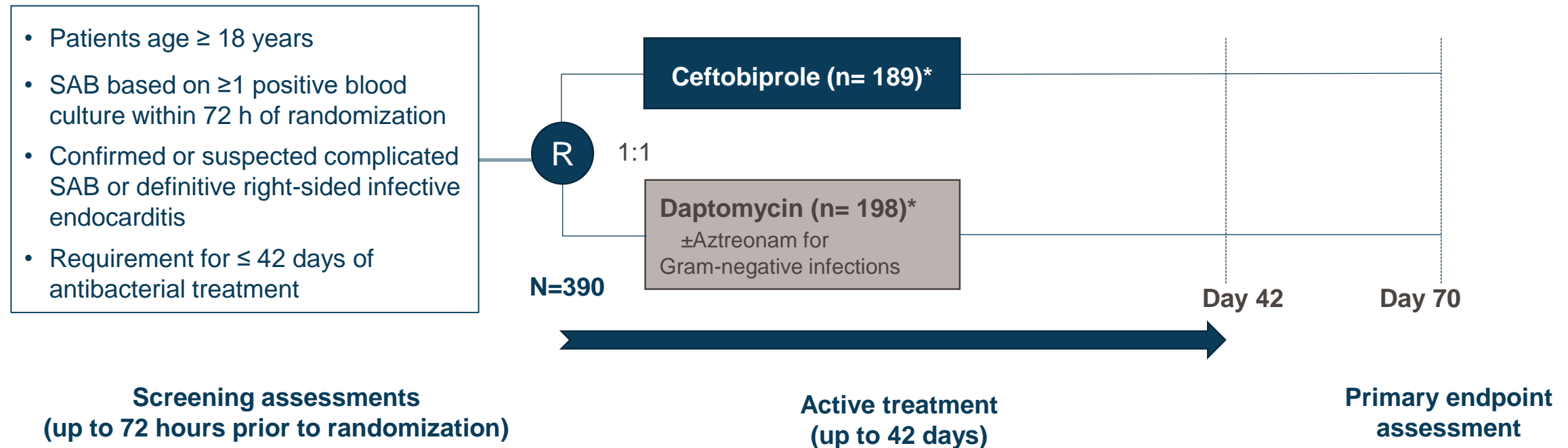
Causes and consequences of SAB



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

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



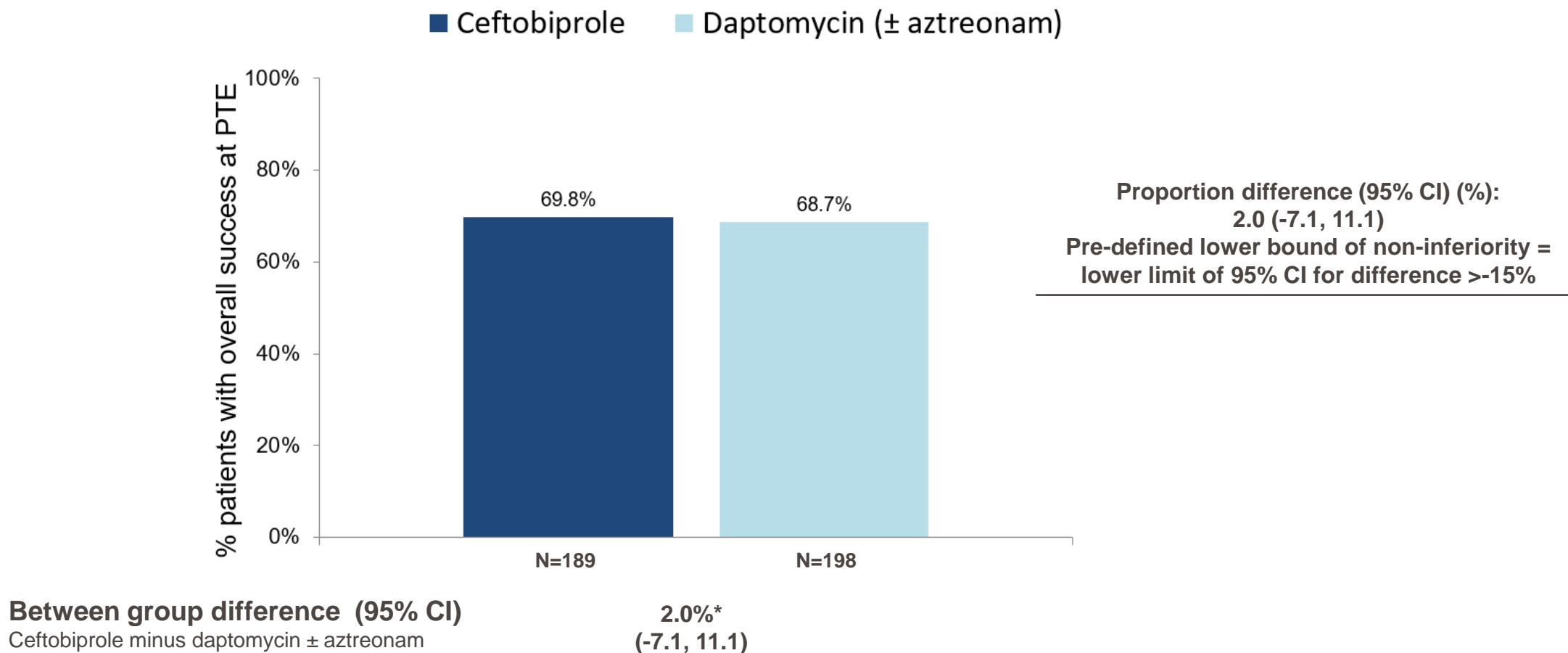
Adapted from Hamed K et al. Future Microbiol. 2020;15:35-48

*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



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: Other results

- Secondary efficacy endpoints including all-cause mortality, new complications of SAB 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

Conclusions

- The ERADICATE study in patients with complicated SAB met the primary and secondary efficacy objectives, supporting the efficacy and safety of ceftobiprole in this indication
- Ceftobiprole was well tolerated and the observed safety profile consistent with previous phase 3 studies and the post-marketing experience with ceftobiprole
- Cross-supportive data package consisting of successful TARGET phase 3 study and successful ERADICATE phase 3 study
 - Special protocol assessment agreement achieved with FDA for both studies
- The study results support an NDA filing, which is planned around year end 2022
- Basilea will seek approval for SAB and ABSSSI
 - In addition, Basilea will explore the possibility for gaining approval for CABP as third indication

Ceftobiprole key attributes

- 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 *Staphylococcus aureus* bacteremia, acute bacterial skin and skin structure infections, and pneumonia^{1, 2}
- Low propensity for resistance development¹
- 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.



Financials & Outlook



Guidance: Sustainable profitability from FY 2023 expected

In CHF mn	FY 2023e (guidance)	FY 2022e* (guidance)	FY 2021 (actual)
Cresamba & Zevtera related revenue	-	98 – 104	131.4
Royalty income	-	~ 59	53.2
Total revenue	-	106 – 112	148.1
Cost of products sold Operating expenses	- -30% vs. 2022	21 – 24 ~ 110	24.1 122.9
Operating (loss)/profit	> 0	(20 – 25)	1.2
Net cash used in operating activities	Cash flow positive	10 – 15	32.0

2022 vs. 2021:
Decrease due to lower
expected milestone payments

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

Outlook 2022

Ceftobiprole

Completed patient enrolment in phase 3 SAB study (ERADICATE) ✓

Isavuconazole

- Marketing approval in Japan ✓
- Marketing approvals in China ✓
- Launched in 70 countries by year-end

Ceftobiprole

Published topline results of phase 3 SAB study (ERADICATE) ✓

Ceftobiprole

File U.S. NDA for SAB and ABSSSI; explore CABP as additional indication

Increasing Cresemba (isavuconazole) & Zevtera (ceftobiprole) revenue

Advancement of preclinical anti-infective assets

In-licensing of anti-infectives

Strategic transactions in order to maximize the value of oncology portfolio

H1 22

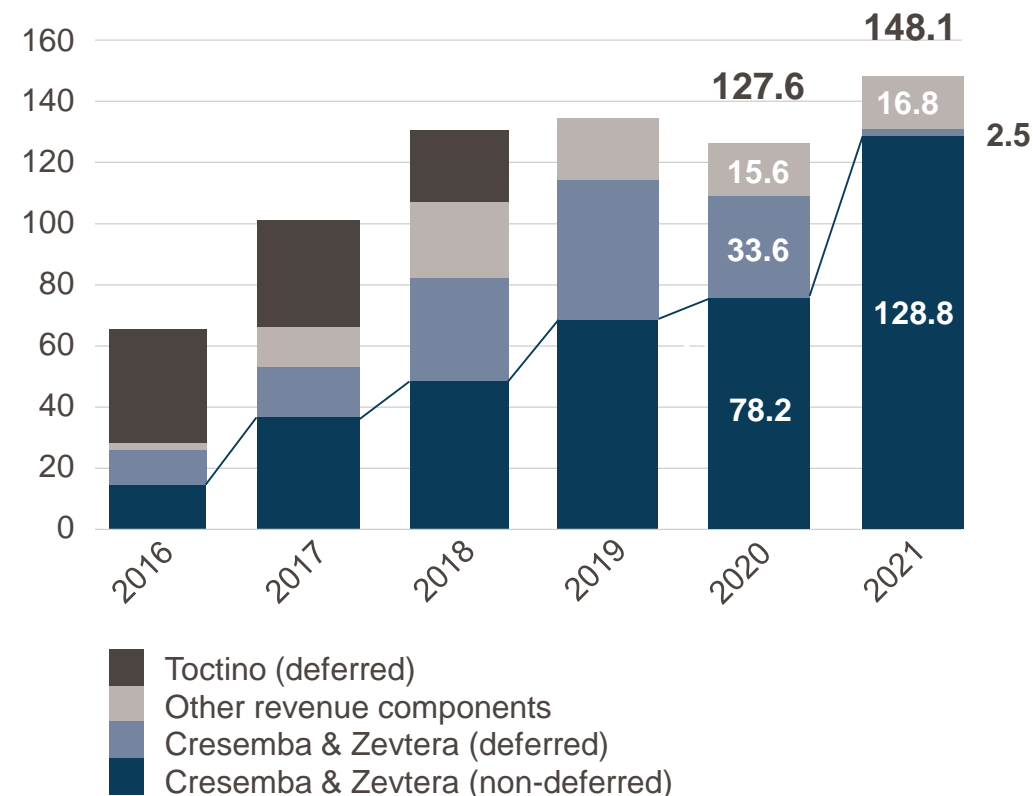
H2 22

Appendix

2021 revenue and year-end cash-position exceed financial guidance

In CHF mn	FY 2021 (actual)	FY 2021e (guidance)	FY 2020 (actual)
Total revenue	148.1	134 – 144	127.6
thereof: Contributions Cresemba & Zevtera			
non-deferred	128.8	115 – 125	78.2
deferred	2.5	2.5	33.6
Operating profit/(loss)	1.2	(7 – 17)	(8.2)*
Cash and investments [#]	150 [173 ^{##}]	142 - 147 [165 – 170 ^{##}]	167.3

Continued strong double-digit growth in Cresemba & Zevtera non-deferred revenue contributions Y-o-Y, CHF mn



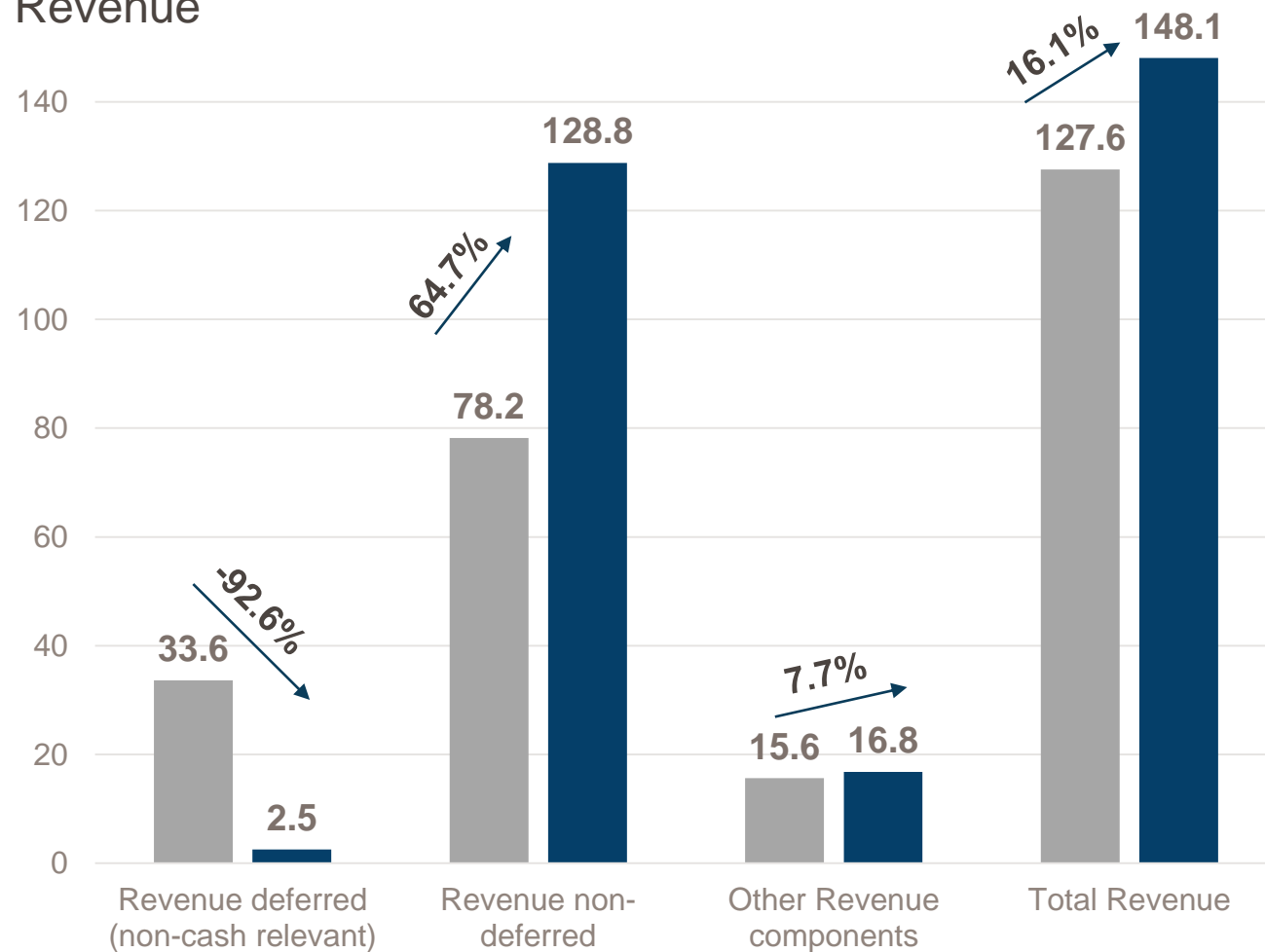
* Including CHF 15mn one-off gain from sale and lease back transaction

Cash, restricted cash and investments

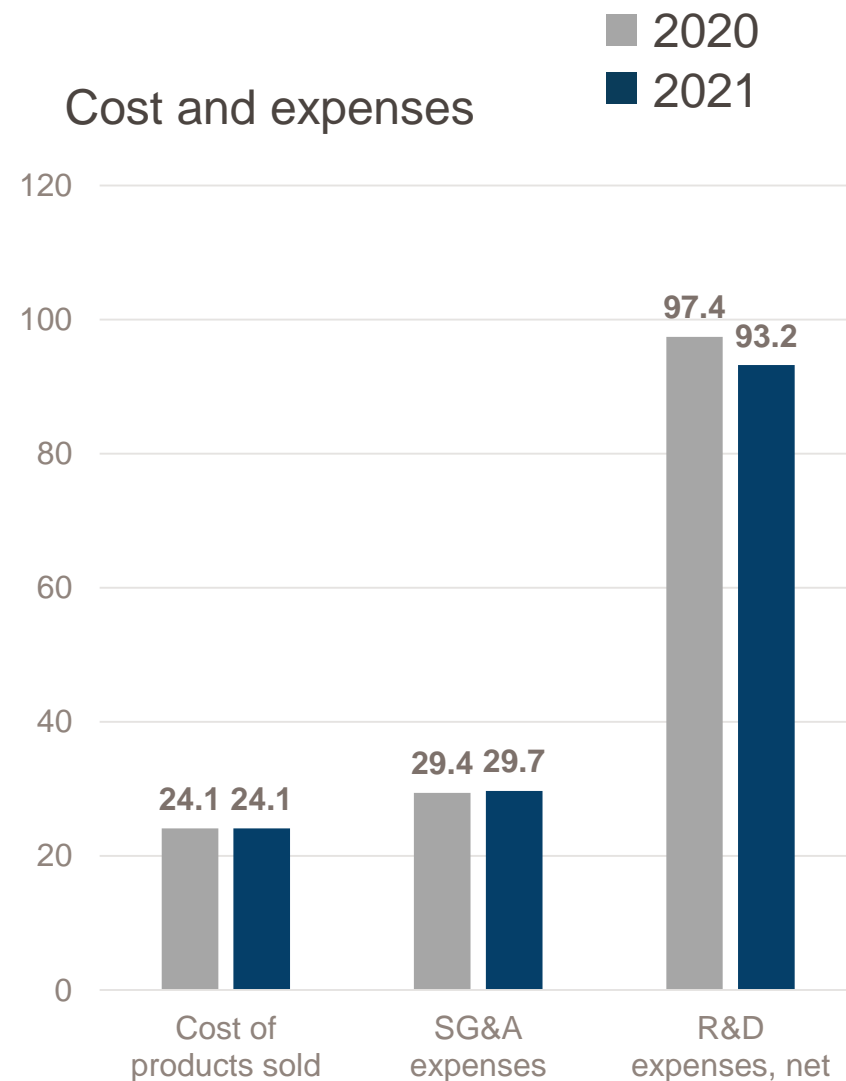
##Excluding impact from reduction of the outstanding convertible bonds in 2021

Financial summary, in CHF mn (1/2)

Revenue



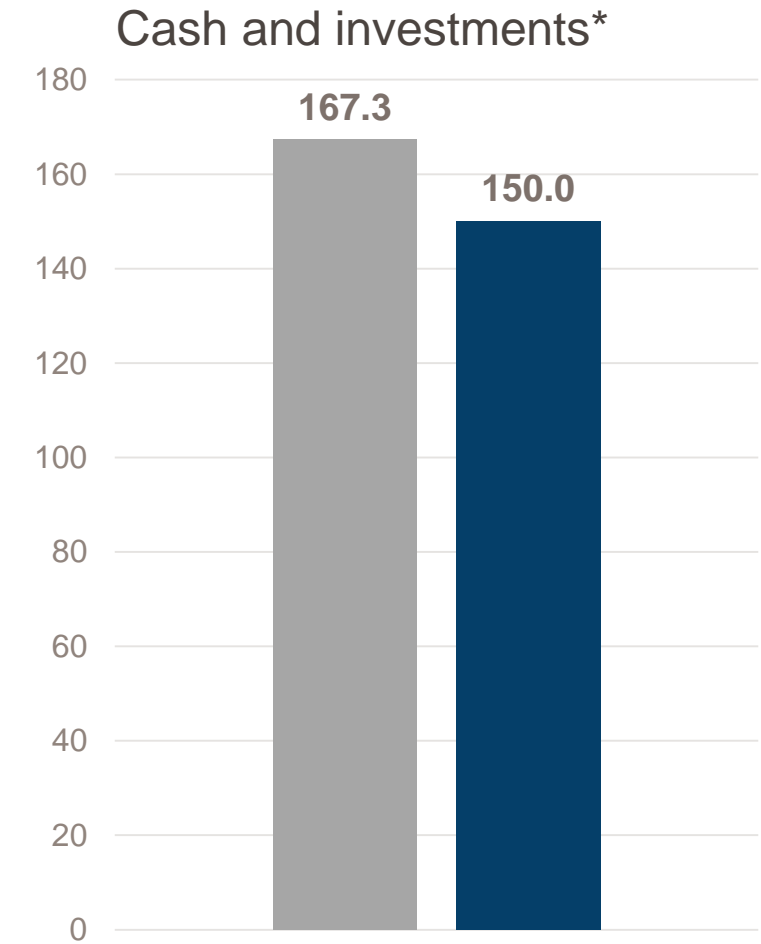
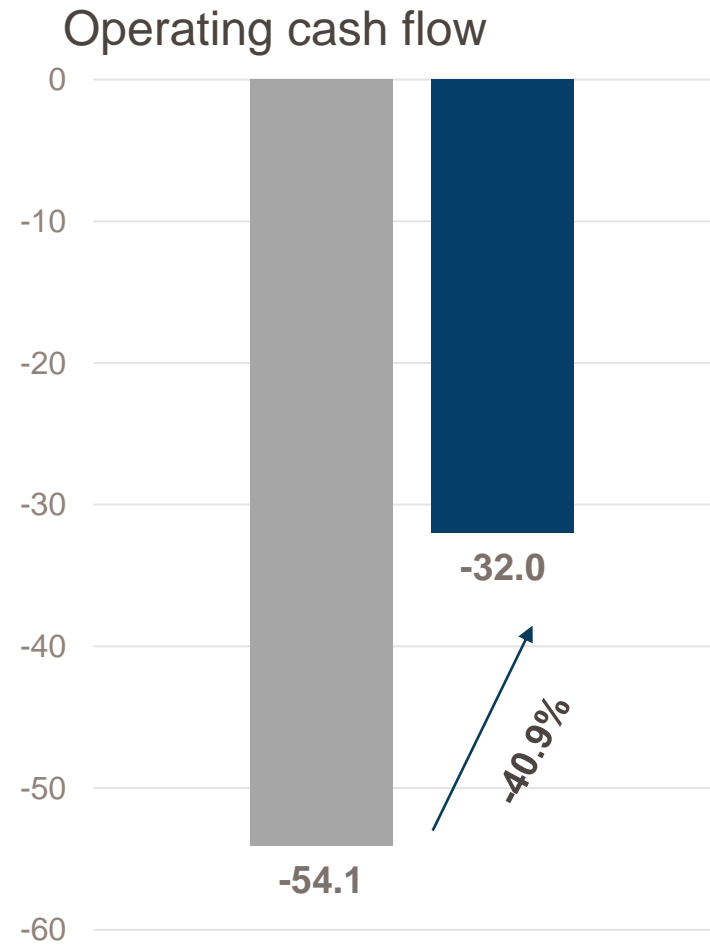
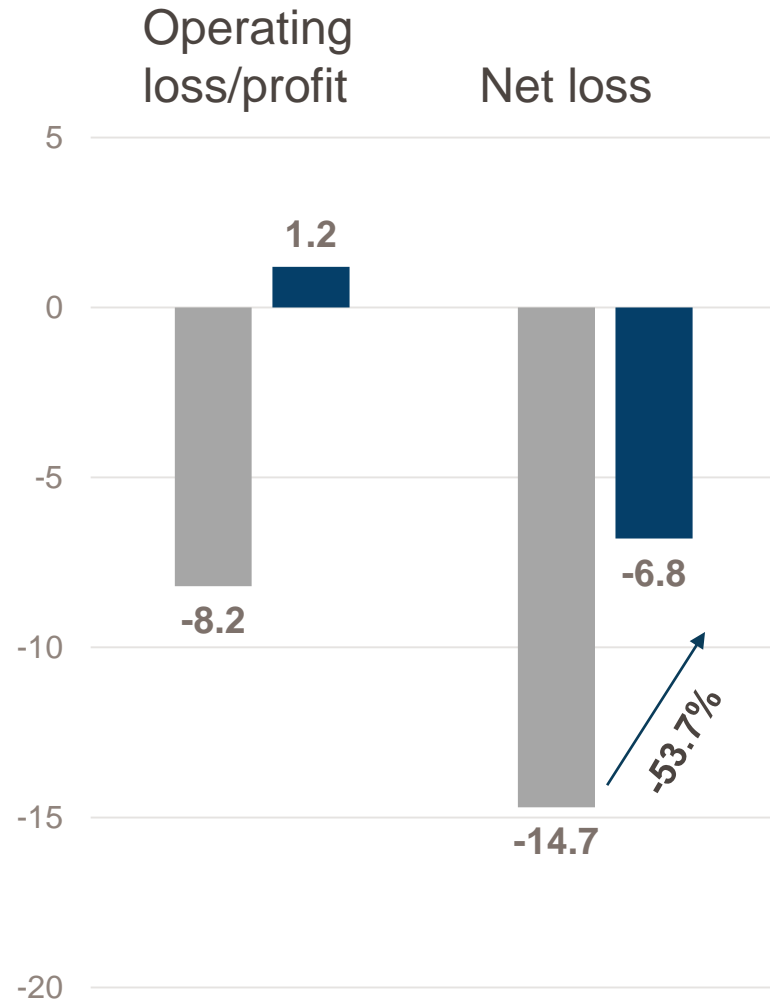
Cost and expenses



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

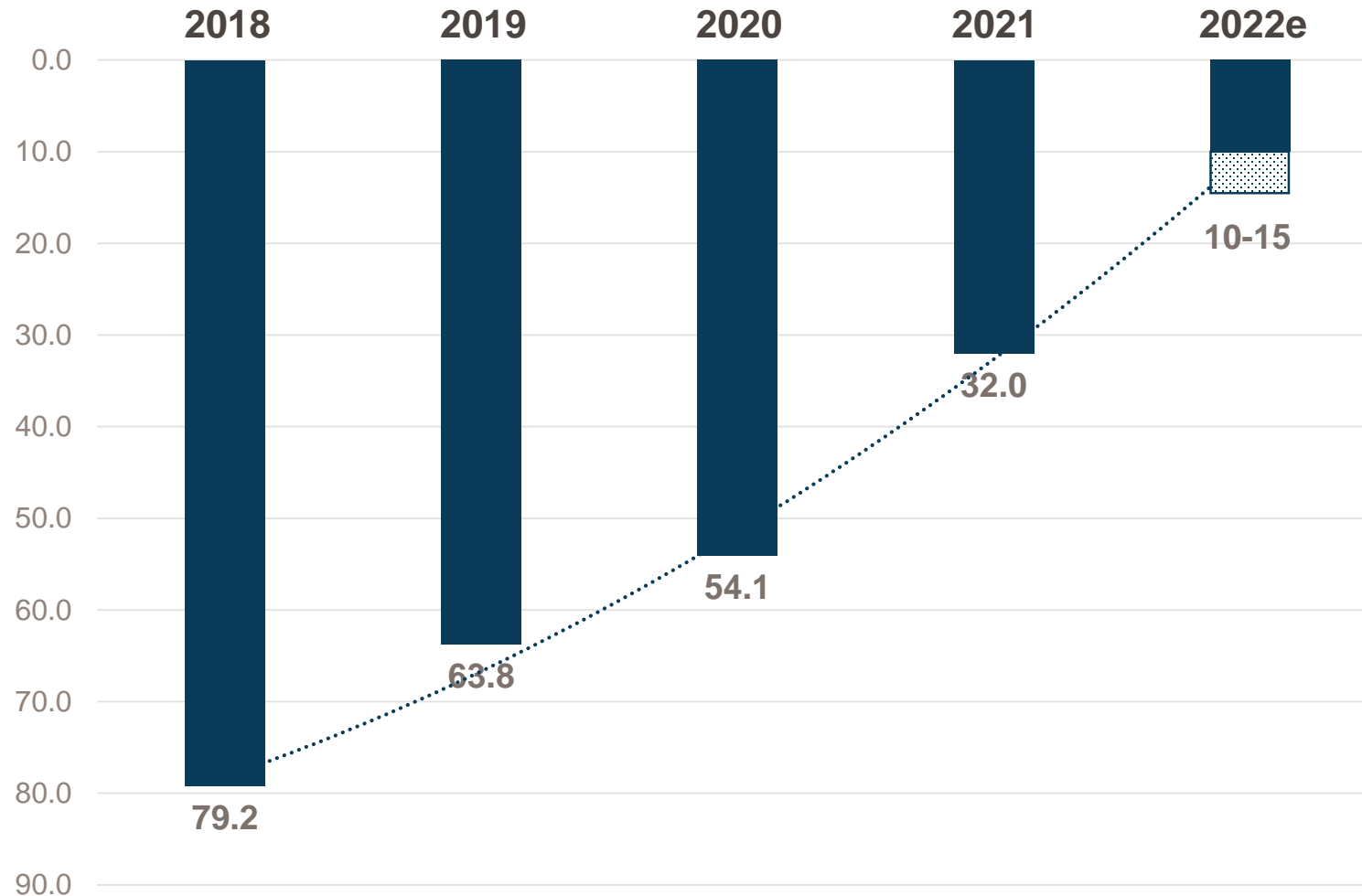
Financial summary, in CHF mn (2/2)

■ FY 2020
■ FY 2021



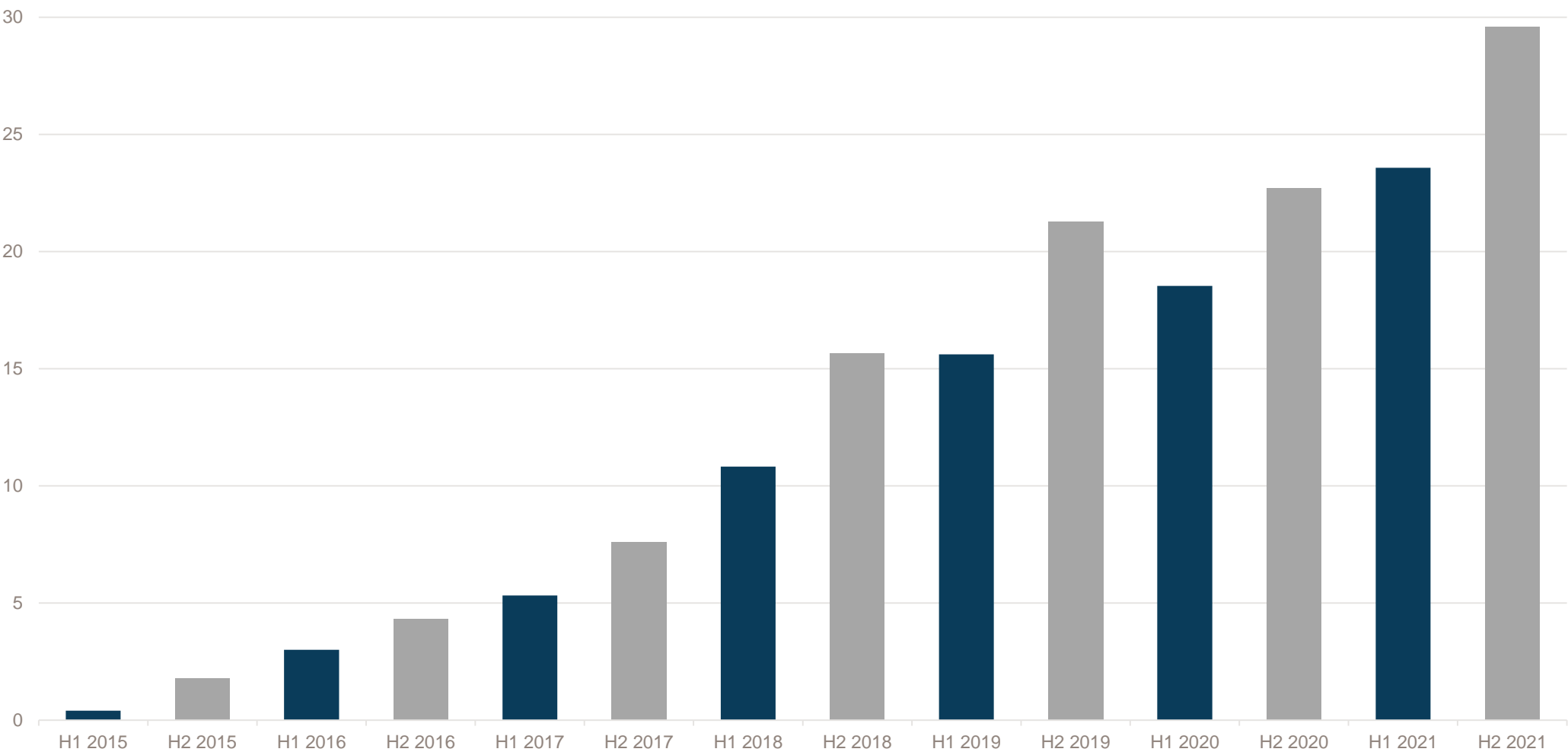
Note: Consolidated figures in conformity with U.S. GAAP; rounding applied consistently, *Cash, cash equivalents, restricted cash and investments

Net cash used in operating activities



**Sustainable
profitability from 2023
onwards**

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

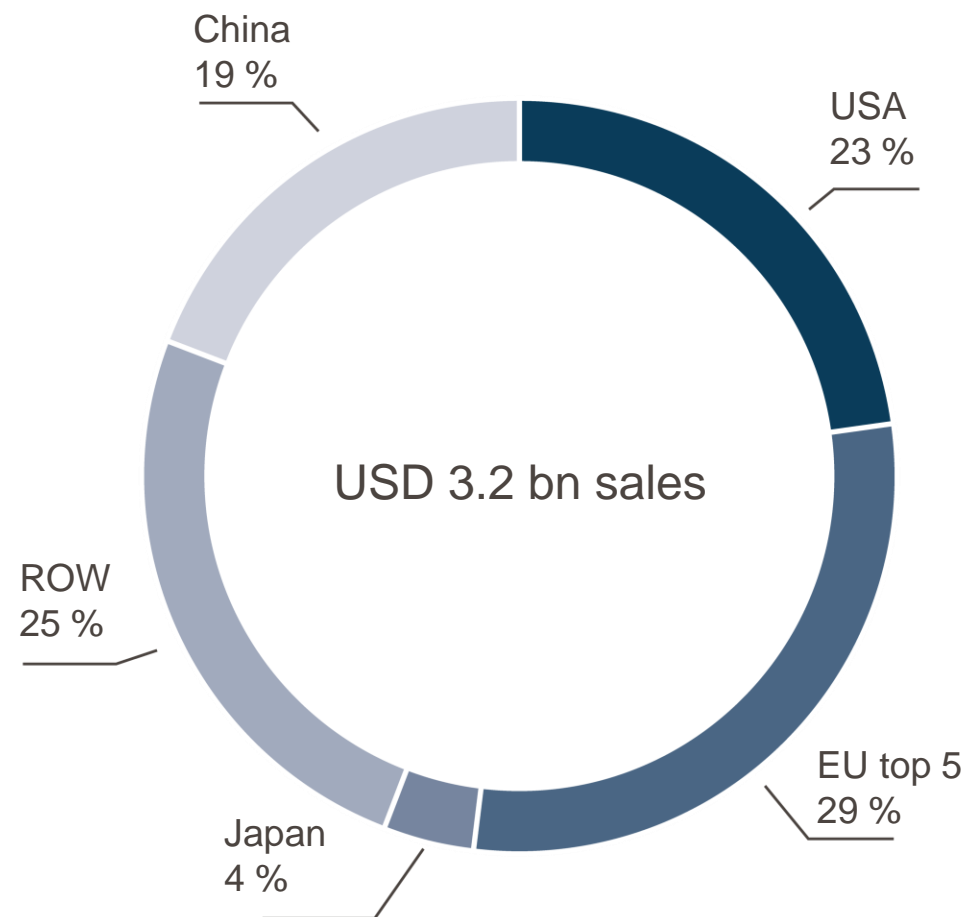


Note: Consolidated figures in conformity with U.S. GAAP; rounding applied consistently

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 Q4 2021)

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



MAT: Moving annual total; Source: IQVIA, December 2021

Confidential/proprietary information of Basilea Pharmaceutica International Ltd, Allschwil – not for distribution

Ceftobiprole — Positive topline phase 3 results reported in ABSSSI

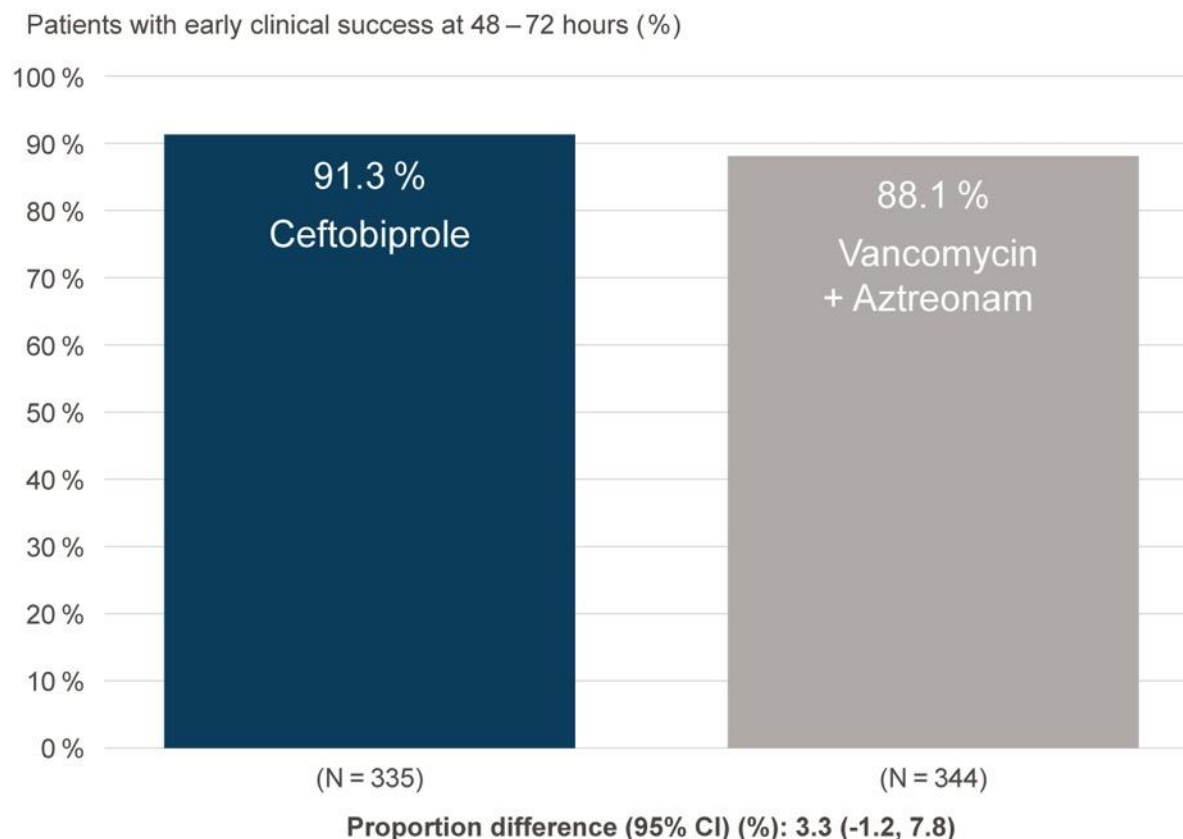
Key topline study¹ results showing non-inferiority of ceftobiprole to vancomycin plus aztreonam for the primary and secondary endpoints



¹ NCT03137173

ABSSSI: Acute bacterial skin and skin structure infections

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 topline 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

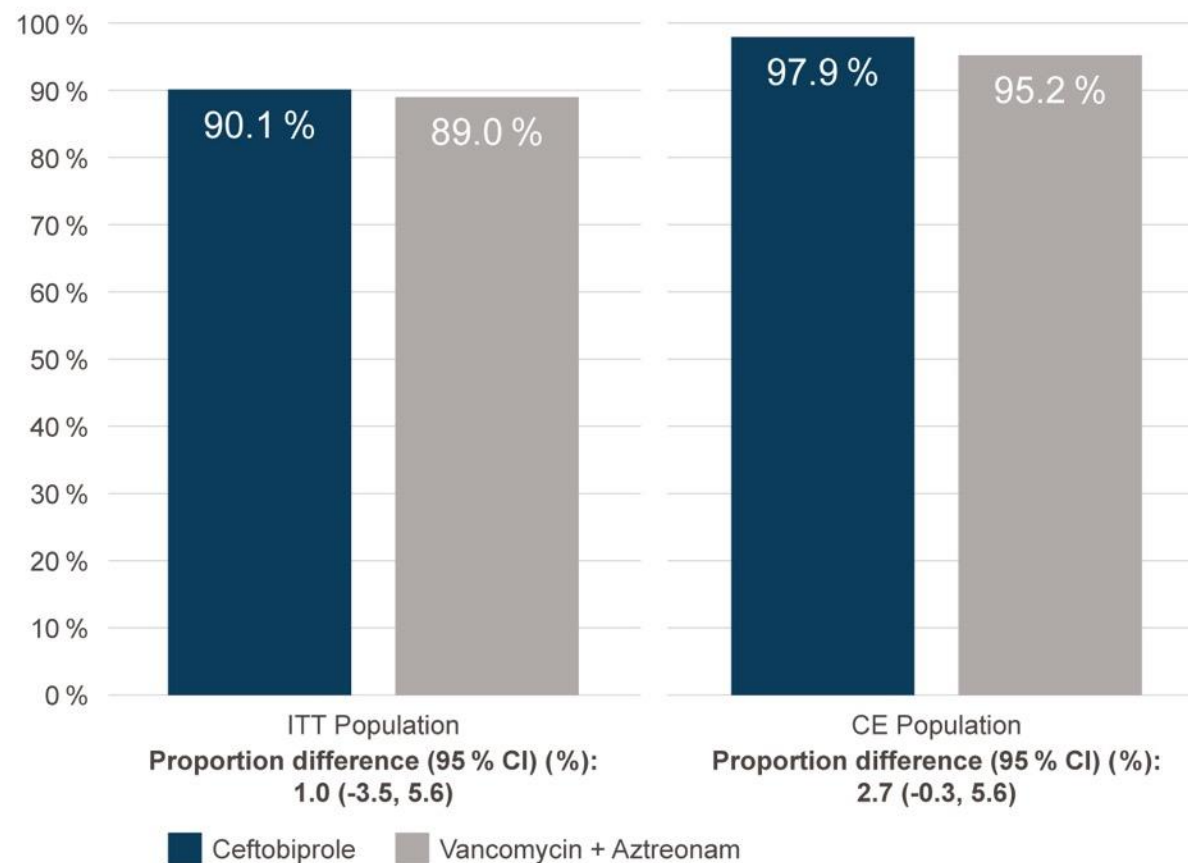


¹ NCT03137173

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}

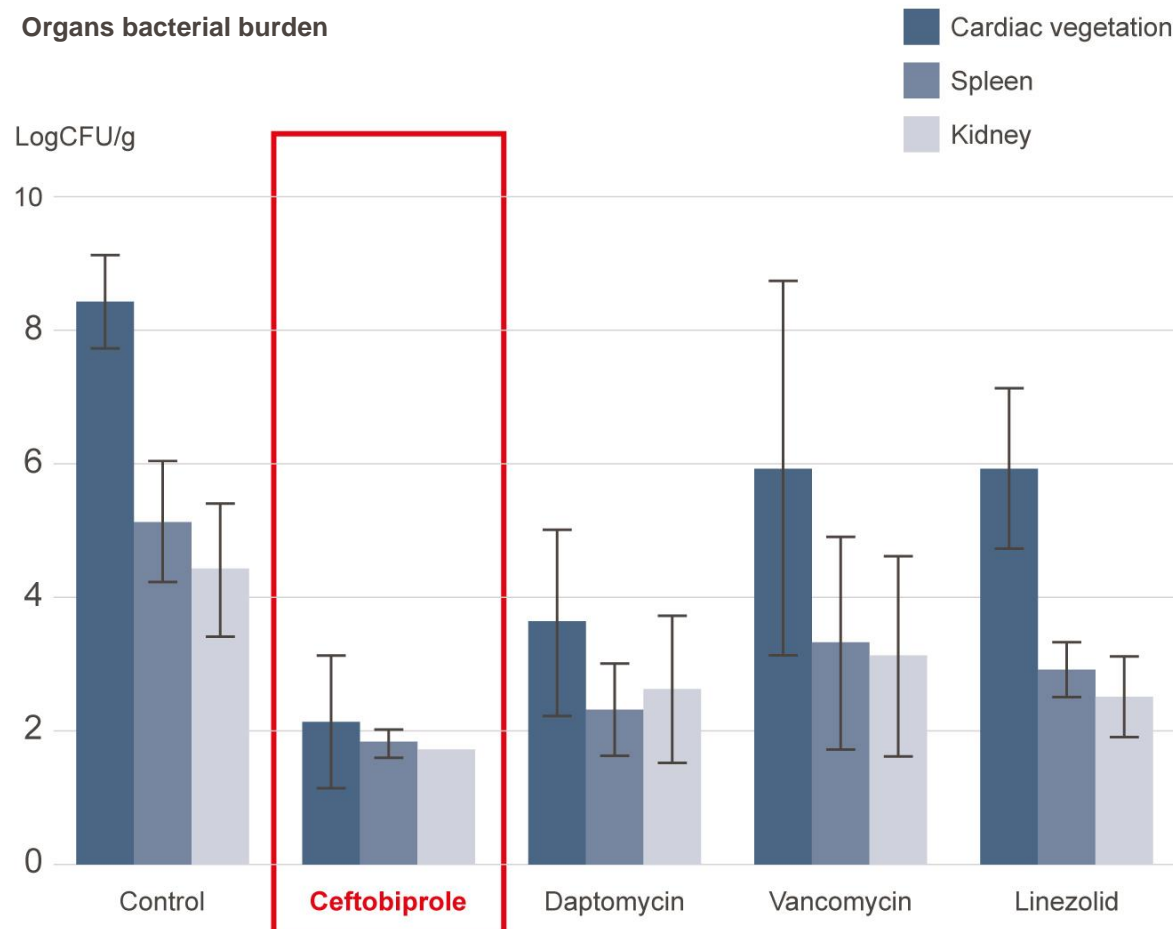
¹Syed YY. Drugs. 2014;74:1523-1542.

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.

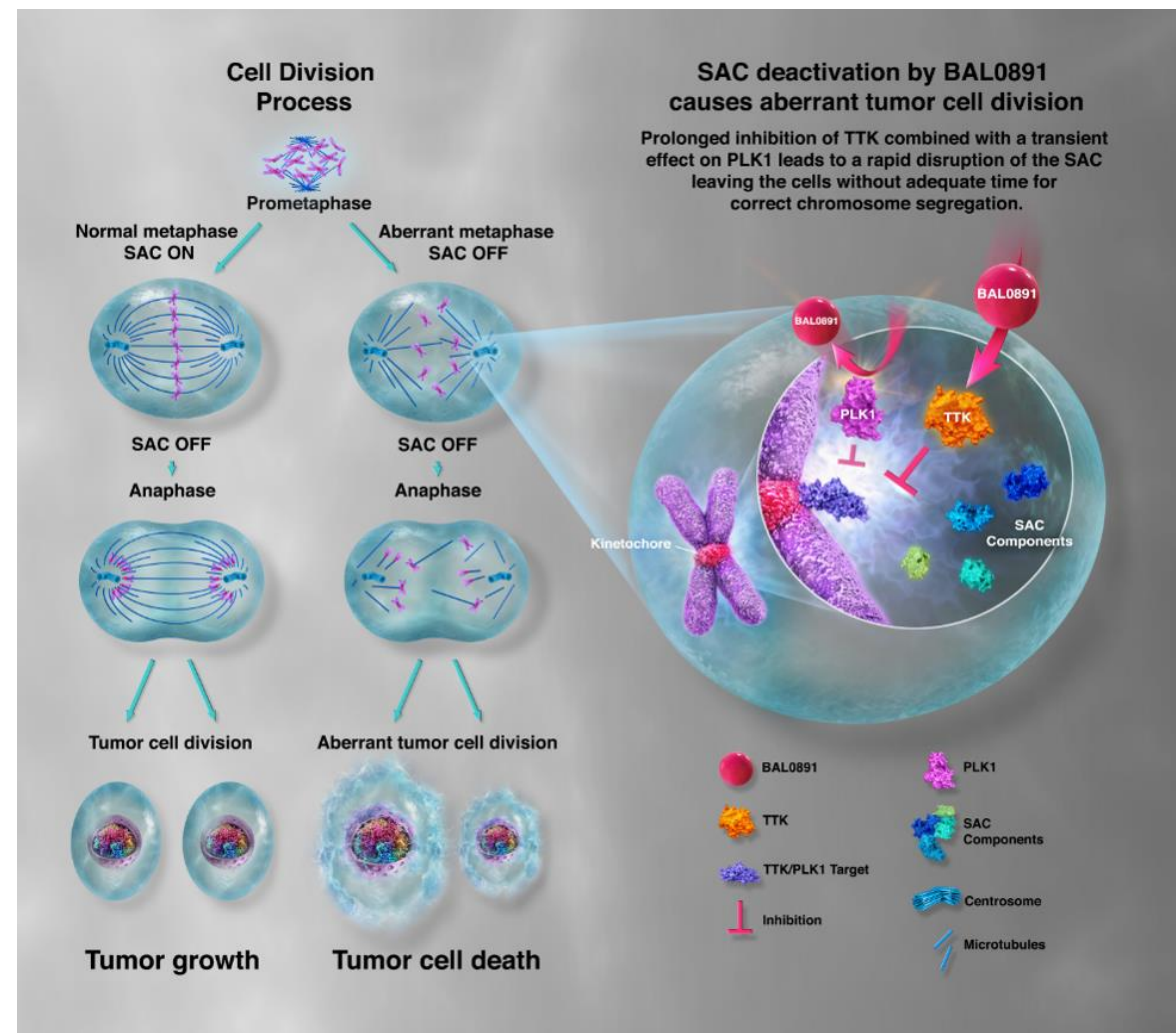
Comparative efficacy in a rabbit model of endocarditis



Organism titers in cardiac vegetations, spleens and kidneys of untreated and antibiotic treated rabbits infected with MRSA³

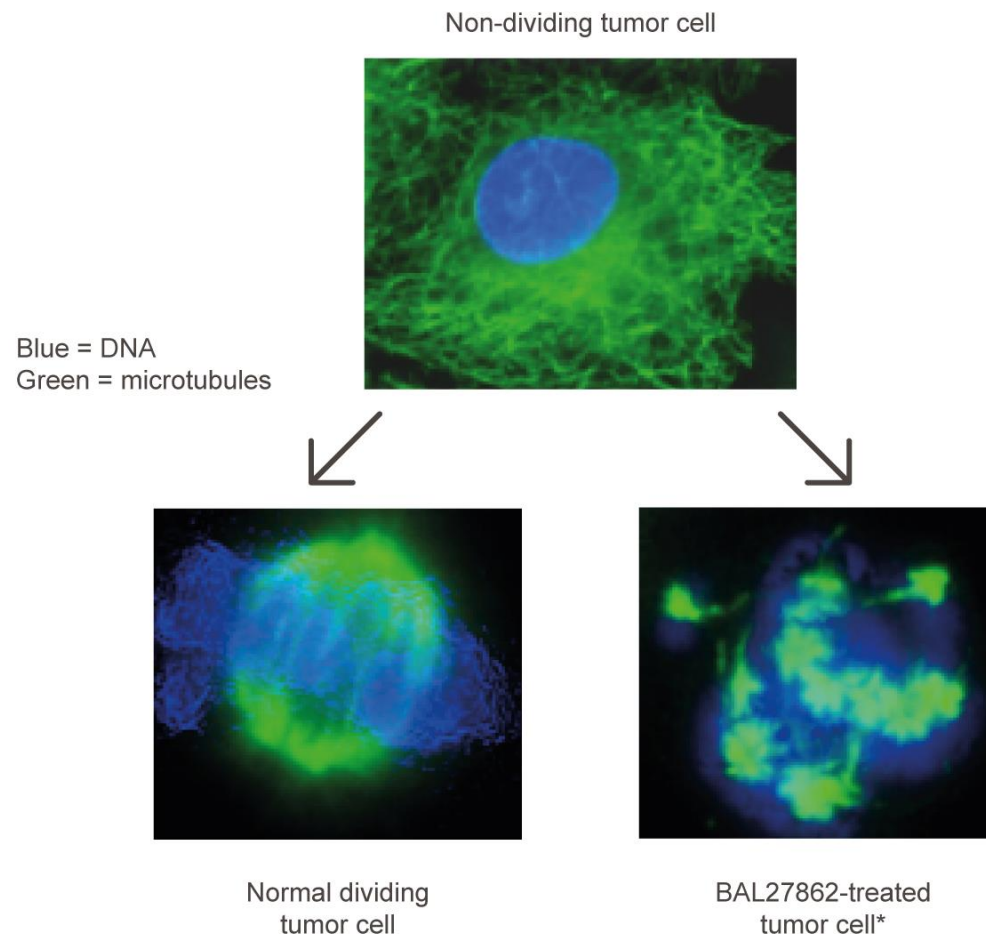
A first-in-class mitotic checkpoint inhibitor

- Unique dual inhibitor of threonine tyrosine kinase (TTK) and polo-like kinase 1 (PLK1)
 - Dual action of BAL0891, with prolonged TTK and transient PLK1 inhibition, leads to a rapid disruption of the spindle assembly checkpoint (SAC)
- Cells are pushed through mitosis without adequate time for correct chromosome alignment and segregation
- Activity results in aberrant tumor cell division leading to tumor cell death
- Potent single-agent anti-cancer activity in preclinical models of human cancer
- FDA approved IND in December 2021
- Preparing to enable start of phase 1 study in patients with solid tumors



Novel tumor checkpoint controller crossing the blood-brain barrier

- Novel compound inducing tumor cell death through spindle assembly checkpoint activation
- Targeting diverse tumor types resistant to standard therapeutic approaches
- Flexible dosing potential, including daily oral dosing
- Crosses the blood-brain barrier with potent activity in brain tumor models alone and in combination
- Comprehensive biomarker program to optimize patient selection, e.g. EB1 (end-binding protein 1)
- Orphan drug designation granted for the treatment of malignant glioma



* Lisavanbulin (BAL101553) is a prodrug of BAL27862

Glossary

–	ABSSSI:	Acute b acterial s kin and s kin s tructure i nfections
–	CABP:	C ommunity- a cquired b acterial p neumonia
–	CARB-X:	C ombating A ntibiotic- R esistant B acteria Biopharmaceutical A ccelerator
–	DRC:	D ata r eview c ommittee
–	HABP:	H ospital- a cquired b acterial p neumonia
–	IND:	I nvestigational n ew d rug
–	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
–	ORR:	O bjective r esponse r ate
–	PLK1:	P olo- l ike k inase 1
–	PTE:	P ost- t reatment e valuation
–	SAB:	S taphylococcus a ureus b acteremia
–	SAC:	S pindle a ssembly c heckpoint
–	TTK:	T hreonine t yrosine k inase
–	VAP:	V entilator- a ssociated p neumonia

Disclaimer and forward-looking statements

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.



Focused on Growth and Innovation

**Hegenheimermattweg 167b
4123 Allschwil
Switzerland**

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

All rights reserved.
© 2022 Basilea Pharmaceutica International Ltd, Allschwil