A leading anti-infectives company

The acquisition of fosmanogepix

Webcast presentation

November 13, 2023

David Veitch

Chief Executive Officer

Introduction

Disclaimer and forward-looking statements

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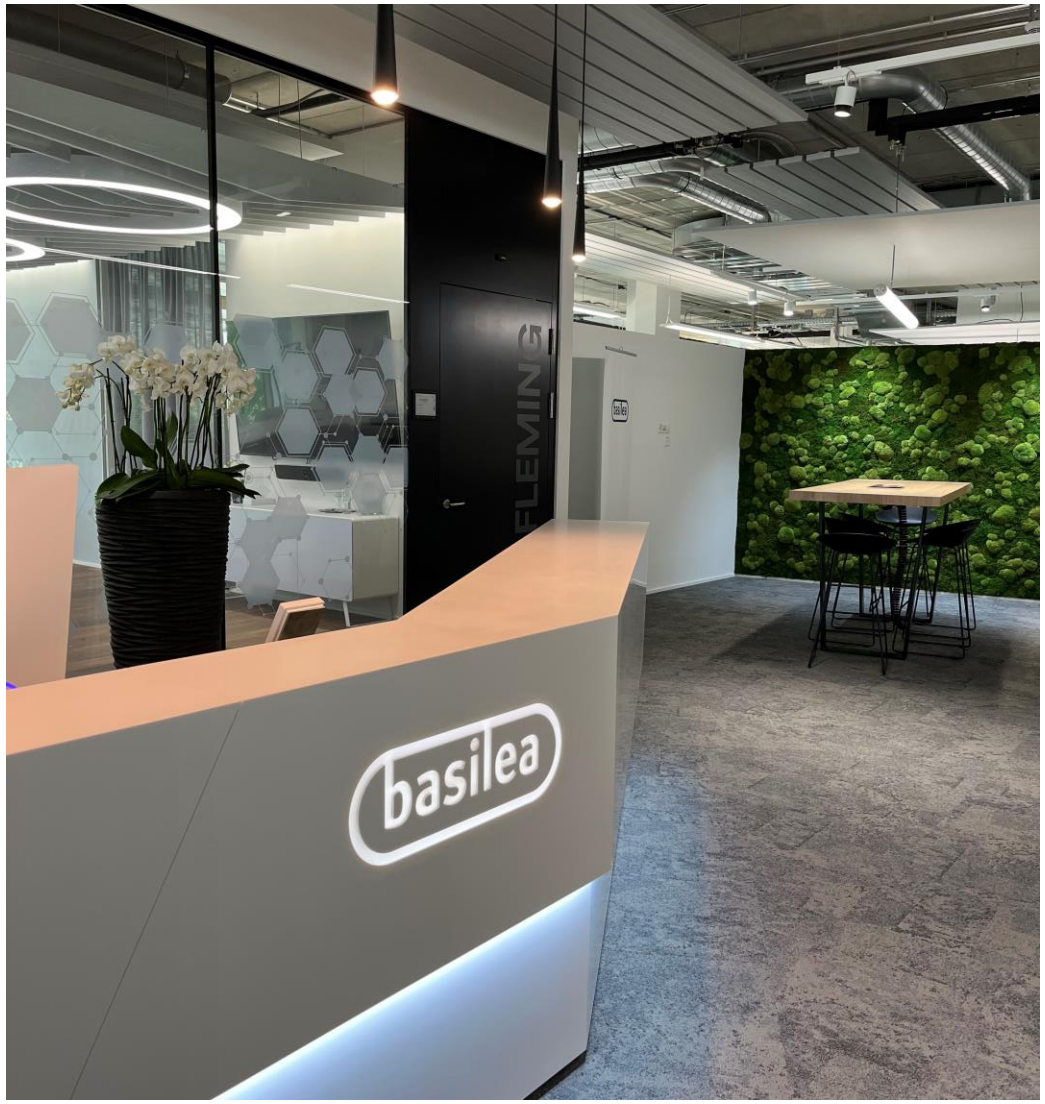
Business update

- Basilea is a leading anti-infectives company in the treatment of severe bacterial and fungal infections
- We have two marketed hospital anti-infective brands, **Cresemba®** and **Zevtera®**, and are working towards approval and launch of Zevtera in the US
- We have entered into 3 transactions of clinical stage assets within a few weeks
  - **Fosmanogepix**, a phase-3-ready broad-spectrum antifungal
  - **BAL2062**, an antifungal for the potential treatment of invasive aspergillosis
  - **Tonabacase**, an endolysin antibacterial for the potential treatment of severe staphylococcal infections
- We have established ourselves as a partner of choice for late preclinical to phase 2 assets and see further attractive opportunities for future transactions



Fosmanogepix – A highly attractive antifungal asset

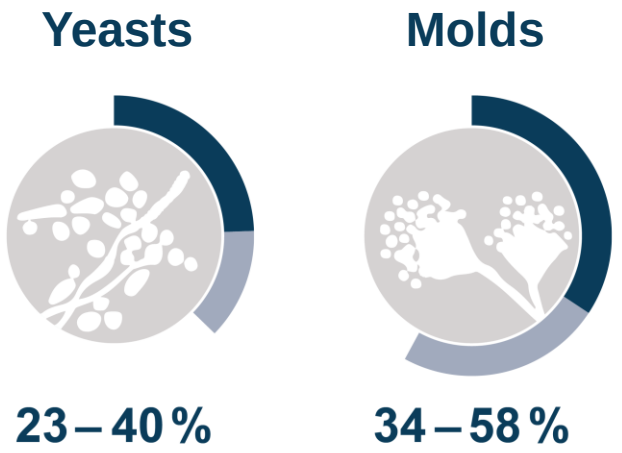
- First-in-class, intravenous and oral antifungal with a novel mechanism of action
- Broad spectrum antifungal activity against yeasts, molds and dimorphic fungi, including *Candida auris*, azole-resistant *Aspergillus* spp. and *Fusarium* spp.
- Three successfully completed phase 2 studies for the treatment of
  - Candidemia, including *Candida auris*
  - Mold infections
- Phase-3-ready for yeast and mold infections with first phase 3 study in candidemia / invasive candidiasis expected to start mid-2024
- Potential to become our next lead commercial product and mid-term value driver
- Asset purchase agreement with Amplyx Pharmaceuticals, an affiliate of Pfizer; Pfizer maintains the right of first negotiation for commercialization

Unmet medical needs in invasive fungal disease

- Invasive fungal infections are severe, potentially life-threatening infections mainly affecting immunocompromised patients
- Rising number of immunocompromised patients including cancer and transplantations driving therapeutic demand
- Limitations of current therapies including spectrum of activity, side effects, tissue distribution and drug-drug-interactions drive the need for new agents
- Fosmanogepix provides activity against all WHO fungal pathogens in the “critical priority group”:
  - *Candida albicans*
  - *Candida auris*
  - *Aspergillus fumigatus*
  - *Cryptococcus neoformans*

WHO fungal priority pathogens list to guide research, development and public health action (2022) https://www.who.int/publications/i/item/9789240060241

Mortality rates for invasive fungal infections



Kullberg BJ, Arendrup MC. Invasive Candidiasis. N Engl J Med. 2016;374:794-5.
Baddley JW, Andes DR, Marr KA, et al. Clin Infect Dis. 2010;50:1559-67.
Roden MM, Zaoutis TE, Buchanan WL, et al. Clin Infect Dis. 2005;41:634-53.
Greenberg RN, Scott LJ, Vaughn HH, Ribes JA. Curr Opin Infect Dis. 2004;17:517-25.

Fosmanogepix fits perfectly with our in-licensing priorities

Partner of choice in the anti-infectives space

- ✓ Strong and proven R&D capabilities to bring drugs from research to market
- ✓ Cost-effective business model
- ✓ Experience in accessing non-dilutive funding incentives
- ✓ Financial strength and strong cash flow generation from commercialized brands

Antifungals

- Novel mechanisms of action ✓
- Addressing areas of highest unmet medical needs ✓
- Gaining benefits through orphan drug pathways ✓
- Novel formulations

Commonalities

- Addressing serious hospital infections with increasing medical need ✓
- Innovative & differentiated assets with potential for successful commercialization ✓
- In-licensing assets from late stage research through to end of phase 2 ✓

Antibacterials

- Traditional and non-traditional approaches
- Potential for demonstrating superiority
- Balance development risks to optimize market access/label

Potential for sustainable growth and value creation

1 The registration status and approved indications may vary from country to country.
2 Formerly GR-2397
3 Phase 3 program was funded in part with federal funds from the US Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA).
4 The Prescription Drug User Fee Act (PDUFA) goal date indicates the date for the FDA to complete its review of the NDA.
5 Exclusive option to in-license upon completion of preclinical profiling

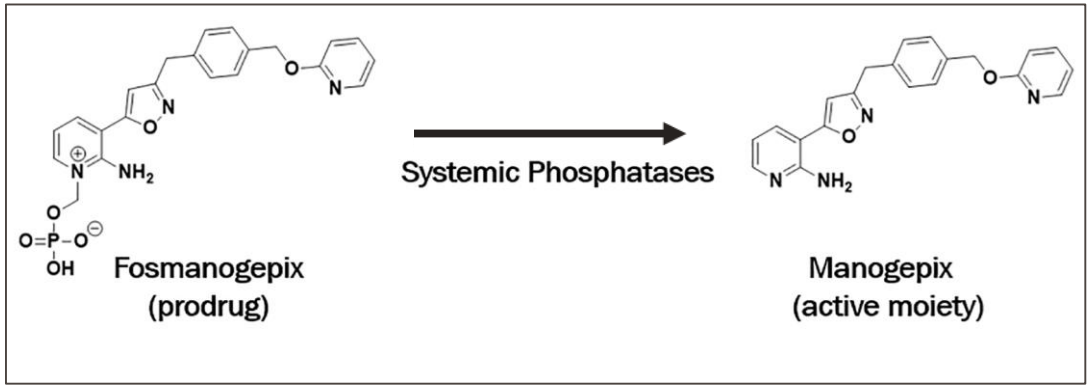
Marc Engelhardt

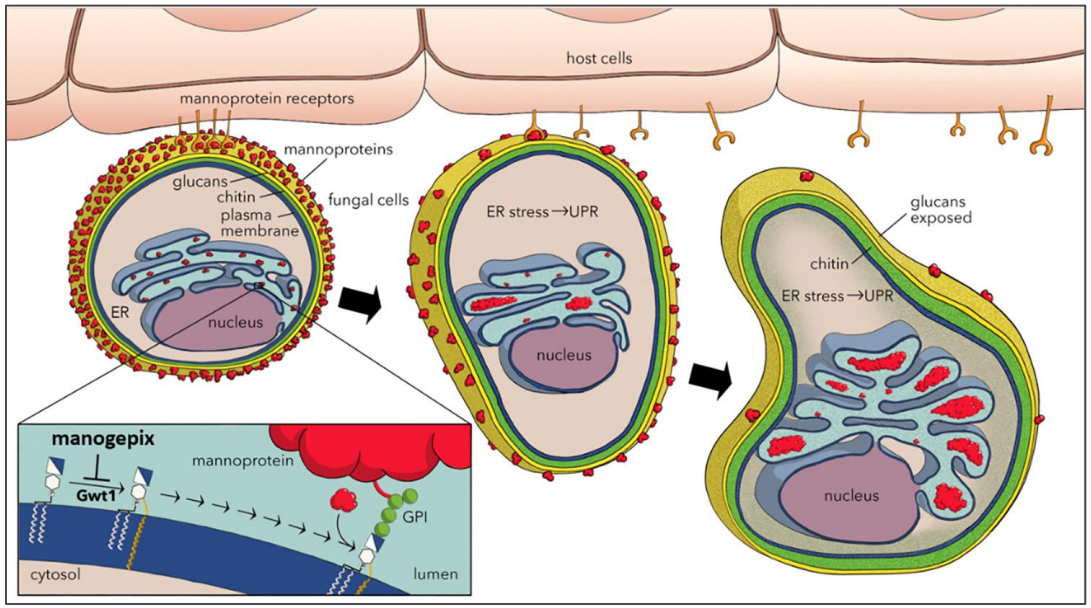
Chief Medical Officer

Fosmanogepix – first-in-class broad-spectrum antifungal

Overview

- Fosmanogepix is the prodrug of manogepix
- Novel mechanism of action
- Inhibition of the protein Gwt1 impedes the production of cell wall mannoproteins, causing cell wall fragility, fungal cell death and decreased potential for biofilm formation
- Potent broad-spectrum activity against resistant yeasts, molds and dimorphic fungi, including azole-resistant phenotypes
- IV and oral availability enables treatment in both inpatient and outpatient settings
- US FDA fast track status, QIDP and orphan drug designations





Friedman DZP, Schwartz IS. Infect Dis Clin North Am. 2023;37:593-616.

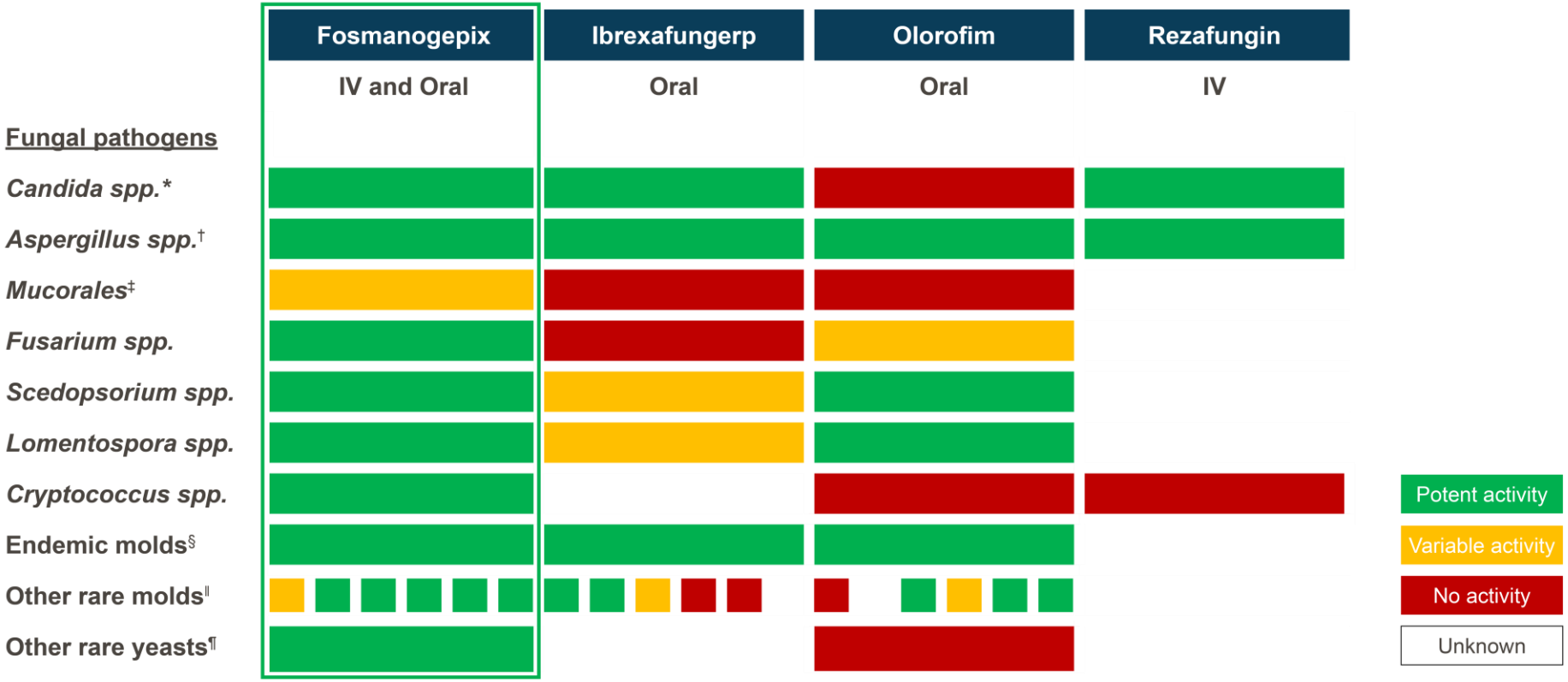
Shaw KJ, Ibrahim AS. J Fungi (Basel). 2020; 6:239

Addressing high unmet medical needs

- Fast track status by the US FDA for invasive candidiasis, invasive aspergillosis, scedosporiosis, fusariosis, mucormycosis, cryptococcosis, and coccidioidomycosis
- Addressing emerging resistance issues in yeast infections including *Candida auris* and azole resistant *Aspergillus* spp.
- Potent activity against mold infections including difficult-to-treat *Fusarium* and *Scedosporium spp*.
- Wide tissue distribution enabling treatment of disseminated infections including CNS
- Favorable drug-drug interaction profile
- *In-vivo* synergism with liposomal amphotericin B and echinocandins may provide utility for the most difficult-to-treat infections

Hoenigl M, Sprute R, Egger M, at al. Drugs. 2021;81:1703-1729.
Winston DJ, Young PA, Schlamm HT, Schiller GJ. Clin Infect Dis. 2023:ciad309.
Gebremariam T, Gu Y, Alkhazraji S, et al. Antimicrob Agents Chemother. 2022;66:e0038022.

Addressing high unmet medical needs (cont)



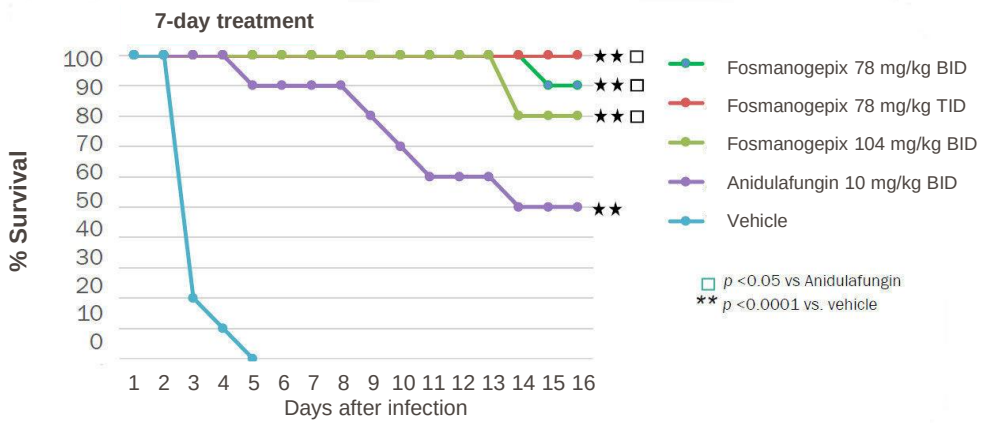
* including *C. albicans*, *C. auris*, *C. dubliniensis*, *C. glabrata*, *C. krusei*, *C. lusitaniae*, *C.parapsilosis*, *C. tropicalis*. Fosmanogepix not active against *C. krusei*.
† including *A. calidoustus*, *A. fumigatus* (including azole-resistant), *A. flavus*, *A. lentulus*, *A. nidulans*, *A. niger, A. terreus*, *A. tubingensis*.
‡ including *Cunninghamella spp.*, *Lichtheimia spp.*, *Mucor spp.*, *Rhizopus spp*.
§ including *Blastomyces dermatitidis*, *Coccidioides immitis*, *Histoplasma capsulatum*.
‖ including *Alternaria alternata*, *Cladosporium spp*. *Paecilomyces variotii*, *Purpureocillium lilacinum*, *Scopulariosis spp.*, *Rasamsonia spp*.
¶ including *Trichosporon asahii*, *Exophiala dermatitidis*, *Malassezia furfur*.

Adapted from Hoenigl M, Sprute R, Egger M, at al. Drugs. 2021;81:1703-1729.

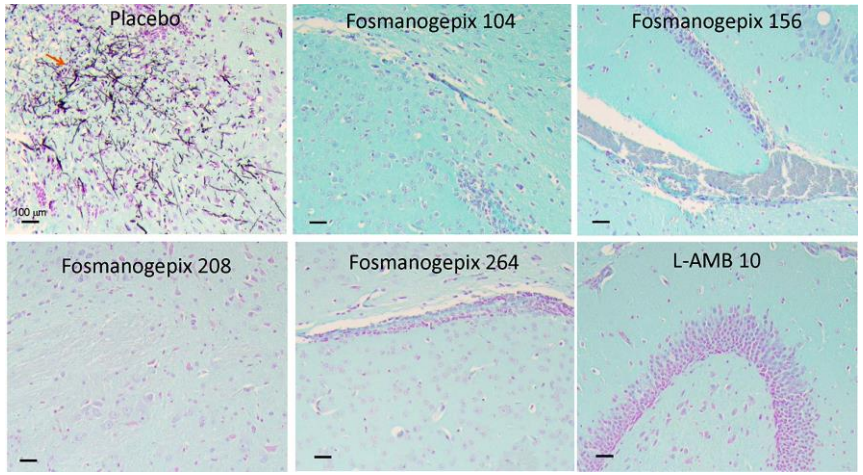
Efficacy demonstrated in preclinical models

- Efficacy demonstrated in numerous *in-vivo* fungal infection models including azole/echinocandin-resistant isolates:
  - Disseminated and/or CNS infection models with various *Candida spp.* including *C. auris, Crytococcus neoformans and Fusarium solani*
  - Pulmonary infection models with *Aspergillus fumigatus, Aspergillus flavus, Coccidioides immitis, Lomentospora prolificans, Rhizopus spp.,* and *Scedosporium apiospermum*
- In addition to increased survival, reduction of fungal burden in lung, kidney, spleen, eye and brain was demonstrated in several animal models

Efficacy of fosmanogepix in an immunocompromised murine model of disseminated *C. auris* infection



Efficacy of fosmanogepix in clearing CNS tissues in an immunocompromised murine model of disseminated *Scedosporium apiospermum* infection



Shaw KJ, Ibrahim AS. J Fungi (Basel). 2020; 6:239.
Hager CL, Larkin EL, Long L, et al. Antimicrob Agents Chemother. 2018;62:e02319-17
Alkhazraji S, Gebremariam T, Alqarihi A, et al. Antimicrob Agents Chemother. 2020;64:e01735-19

Completed clinical phase 1/2 program

Seven phase 1 studies in healthy subjects • Established dose range and safety/tolerability profile • >90% oral bioavailability • No significant food effect • Broad tissue distribution to relevant target organs (mass balance study) • Low propensity for CYP3A4 inhibition	**Fosmanogepix treatment up to 6 weeks**
One phase 1 B study in neutropenic patients with AML • Consistent safety and tolerability profile	**Fosmanogepix treatment up to 2 weeks**
Three phase 2 studies in patients with candidemia, candidemia with *C. auris*, and invasive mold infections • Proof of concept achieved based on survival and clinical success rates adjudicated by an independent review committee • Safety and tolerability characterized by drug-related adverse events of headache, dizziness, fatigue, nausea and vomiting	**Fosmanogepix treatment up to 6 weeks**
More than 300 subjects treated with fosmanogepix	

Shaw KJ, Ibrahim AS. J Fungi (Basel). 2020; 6:239.

Hodges MR, Ople E, Wedel P, et al. Antimicrob Agents Chemother. 2023;67:e0162322.

Vazquez JA, Pappas PG, Boffard K, et al. Antimicrob Agents Chemother. 2023;67(5):e0141922.

Pappas PG, Vazquez JA, Oren I, et al. J Antimicrob Chemother. 2023:dkad256

Planned global phase 3 program

Candidemia / Invasive candidiasis

- Randomized, double-blind, non-inferiority study
  - Approximately 450 patients
- Fosmanogepix IV (oral step-down fosmanogepix) vs caspofungin IV (oral step-down to fluconazole)
- Primary endpoints
  - FDA: Survival at 30 days
  - EMA: Overall response at end-of-study treatment
- Protocol and initial Health Authority approvals obtained
- Expected study start mid-2024

Invasive mold infections (IMI)

- Randomized, open-label study with non-controlled salvage treatment arm
  - Approximately 200 patients
- Cohorts of invasive mold disease including IMI caused by:
  - *Aspergillus* spp.
  - *Fusarium* spp.
  - *Scedosporium* spp.
  - *Lomentospora prolificans*
  - Mucorales fungi, or
  - Other multi-drug resistant molds
- Fosmanogepix IV or oral vs best available therapy
- Endpoints include survival and overall response
- Expected study start end-2024

Adesh Kaul

Chief Financial Officer

Financial implications

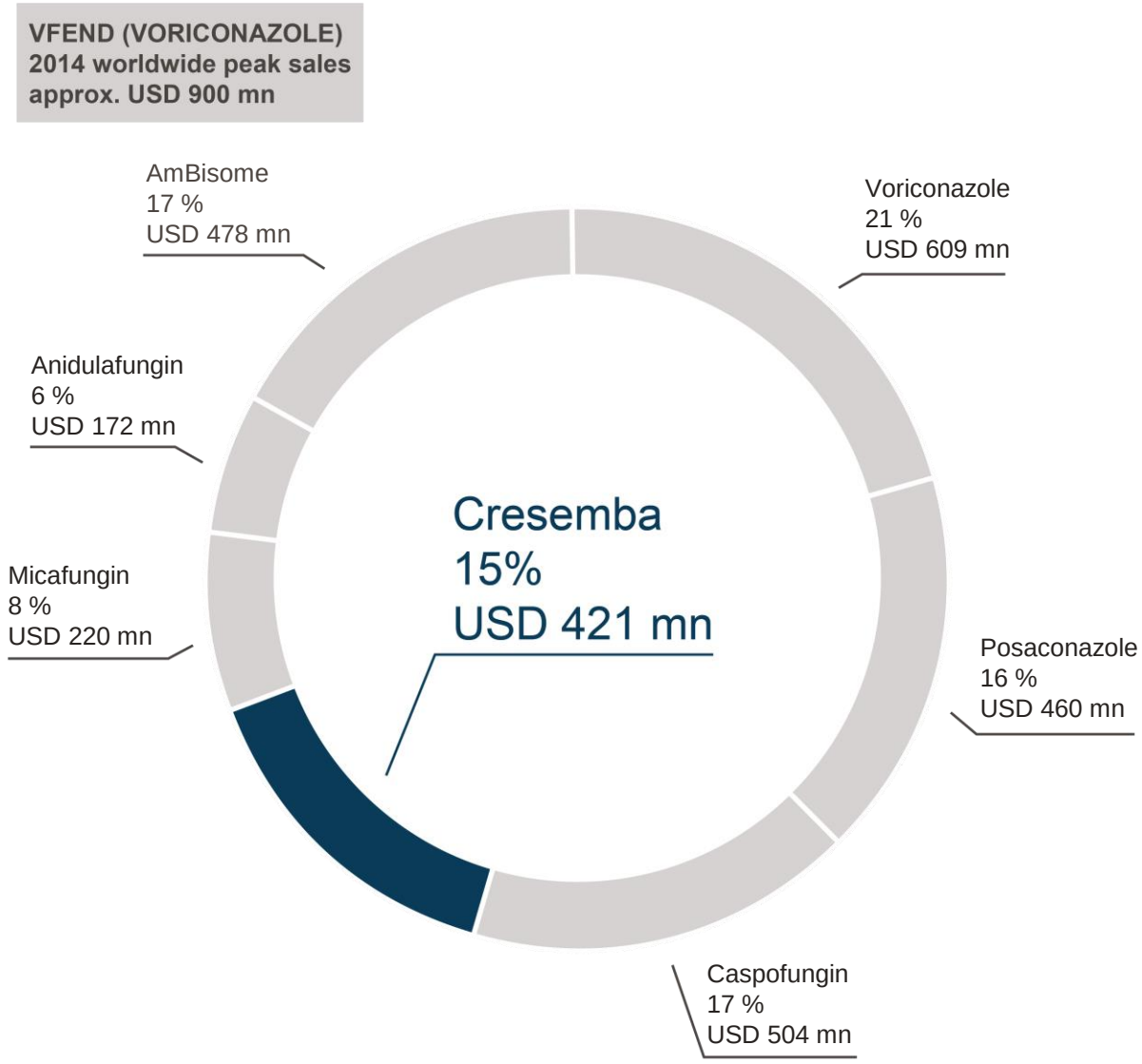
Financial terms

- Fosmanogepix initially developed by Eisai Co, Ltd. and licensed to Amplyx Pharmaceuticals Inc., which was acquired by Pfizer in 2021
- Asset purchase agreement with Pfizer (IP, data, regulatory files), license agreement with Eisai assigned
- Upfront payment: USD 37 mn
- Up to USD 110 mn commercial milestone payments
- Pfizer granted right of first-negotiation for commercialization after publication of phase 3 results

- Basilea assumes future potential payment obligations from previous agreements
  - Up to USD 396 mn potential milestone payments, of which most relate to regulatory and commercial milestone events; total of mid-single digit million payments expected in the coming years
  - Tiered single-digit royalty payments

Business opportunity

- Extended spectrum, covering invasive aspergillosis and invasive candidiasis (IA and IC), opens up significant market
  - Expanding the treatment armamentarium in a therapeutic area with limited treatment options available
  - Addressing emerging resistance issues in yeast infections including *Candida auris* and azole-resistant *Aspergillus* spp.
  - Oral stepdown from echinocandins (and other classes) for the treatment of candidemia / invasive candidiasis
  - Treatment option for difficult-to-treat mold infections, e.g. scedosporiosis, fusariosis, mucormycosis, cryptococcosis, and coccidioidomycosis
- Expecting at least 10-12 years of market exclusivity in major markets based on Orphan Drug and QIDP designations
- Potential key revenue growth driver beyond Cresemba



MAT: Moving annual total; Source: IQVIA Analytics Link, June 2023, rounding consistently applied

Updated FY 2023 guidance

In CHF mn	FY 2023 (new guidance)	FY 2023* (previous guidance)	FY 2022
Cresemba & Zevtera related revenue	**147 – 150**	147 – 150	122.3
of which royalty income	***~76***	*~76*	65.0
Total revenue	**154 – 157**	157 – 160	147.8
Cost of products sold	**~27**	25 – 27	24.6
Operating expenses	**~115**	~80	104.6
Operating profit	**11 – 15**	50 – 55	18.5
Net profit	**2 – 6**	41 – 46	12.1

*Excluding the impact of in-licensing activities

Note: Consistent rounding was applied.

David Veitch

Chief Executive Officer

Outlook

Key milestones

Anti-infective space	Product	H2 2023	H1 2024	H2 2024
Antibacterials	**Ceftobiprole (Zevtera)**	US NDA submission ✓	Regulatory decision in the US (PDUFA date April 3)	
		US NDA accepted for review ✓	Executing US partnership (prior to PDUFA date)	
	Tonabacase	Evaluation license & exclusive option to license ✓		Decide on definitive licensing option
Antifungals	**Isavuconazole (Cresemba)**	Pediatric submissions ✓ Decision on US pediatric extension	Decision on EU pediatric extension	
	Fosmanogepix	Acquisition of rights ✓	Initiate phase 3 study in candidemia / invasive candidiasis (mid-2024)	Initiate phase 3 study in mold infections (around year-end)
	BAL2062	Acquisition of rights ✓		

Increasing Cresemba & Zevtera revenue

In-licensing and acquisition of anti-infectives

Advancement of preclinical anti-infective assets

Q & A

Thank you

Focused on Growth and Innovation

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