

Ad hoc announcement pursuant to Art. 53 LR

## Basilea announces acquisition of fosmanogepix, a phase-3-ready broad-spectrum antifungal

Allschwil, Switzerland, November 13, 2023

Basilea Pharmaceutica Ltd, Allschwil (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial and fungal infections, announced today that it has entered into an asset purchase agreement with Amplyx Pharmaceuticals, Inc., an affiliate of Pfizer Inc., to acquire the rights to fosmanogepix, a clinical-stage broad-spectrum antifungal candidate. In addition, Basilea has acquired the rights to a preclinical antifungal compound.

Fosmanogepix is a potential first-in-class antifungal treatment candidate with a novel mechanism of action. It is available in intravenous and oral formulations and has been evaluated for efficacy and safety in a phase 1 / phase 2 program, including three open-label phase 2 studies for the treatment of Candidemia, including *Candida auris*, and invasive mold infections.<sup>1, 2, 3, 4</sup>

David Veitch, Chief Executive Officer of Basilea, said: "With fosmanogepix, we are adding a very promising drug candidate to our late-stage clinical antifungal pipeline. It has the potential to become an important treatment option for difficult-to-treat, invasive fungal infections. We plan to initiate the first phase 3 study with fosmanogepix mid-2024. This is a transformative transaction for us, as it provides a strong commercial near-term opportunity beyond our currently marketed anti-infectives Cresemba and Zevtera. We have now executed three transactions over the course of the last few weeks that have significantly strengthened our clinical-stage portfolio, and we continue to see interesting opportunities for further transactions in the future."

He continued: "Basilea has a successful track record of bringing novel hospital anti-infectives through clinical development to the market and a proven business model of collaborating with other pharmaceutical companies for the commercialization phase of our assets. We are currently in collaboration with Pfizer for the commercialization of our antifungal Cresemba in most of Europe, as well as in China and the Asia-Pacific region, and they now retain the right of first negotiation for commercial rights for fosmanogepix, once phase 3 development is successfully completed."

Under the terms of the agreement, Basilea will make an upfront payment of USD 37 million and potential commercial milestone payments of up to USD 110 million based on future product sales.

Basilea assumes all rights and obligations from previous agreements, comprising potential development, regulatory, and commercial milestone payments of up to USD 396 million, as well as tiered single-digit royalty payments.

## Updated full-year 2023 financial guidance

Reflecting the transaction, the company updates its financial guidance for the full-year (FY), confirming that it expects operating and net profits for both FY 2023 and FY 2024. The transaction has no impact on the guidance for Cresemba and Zevtera-related revenue. However, the guidance on total revenue is reduced by CHF 3 million. The reason for this is that the US Food and Drug Administration (FDA) has waived the application fee for Basilea's new drug application (NDA) for its antibiotic ceftobiprole in the United States as part of a program to support small businesses. Correspondingly, the BARDA reimbursements, as well as operating expenses, will be reduced by the amount of such application fee.

(in CHF million)	<b>FY 2023e (new)</b>	<b>FY 2023e (previous)</b>	<b>FY 2022</b>
Cresemba & Zevtera related revenue <i>of which royalty income</i>	147 to 150 ~76	147 to 150 ~76	122.3 65.0
Total revenue	154 to 157	157 to 160	147.8
Cost of products sold	~27	25 to 27	24.6
Operating expenses	~115	~80	104.6
Operating profit	11 to 15	50 to 55	18.5
Net profit	2 to 6	41 to 46	12.1

## Conference call and webcast

Basilea Pharmaceutica Ltd, Allschwil will host a conference call and webcast today, Monday, November 13, 2023, at 4 p.m. (CET), to discuss the fosmanogepix transaction and updated guidance.

### [Via audio webcast with presentation](#)

The live audio webcast of the results presentation can be followed here:

<https://media.choruscall.eu/mediaframe/webcast.html?webcastid=eyl6vgk3>. Please note that there is no function to ask questions via webcast. For questions, please additionally dial-in via phone (see below).

### [Via phone](#)

To listen by phone and ask questions, please use the dial-in details below. To ensure prompt access, please call approximately five minutes prior to the scheduled start of the call.

+41 (0) 58 310 5000 (Europe and RoW)

+1 (1) 866 291 4166 (USA)

+44 (0) 207 107 0613 (U.K.)



### Replay

The webcast, along with the presentation will be available [online](#) (same link as live audio webcast above) shortly after the event and accessible for three months.

### **About fosmanogepix**

Fosmanogepix is a clinical-stage broad-spectrum antifungal. It has a novel mechanism of action and its active moiety has shown activity against common species of *Candida* and *Aspergillus*, including multi-drug-resistant strains, such as *Candida auris* and *Candida glabrata*, as well as rare difficult-to-treat molds including *Fusarium* spp., *Scedosporium* spp., and some fungi from the Mucorales order.<sup>1</sup> Fosmanogepix' intravenous and oral formulations have been evaluated in clinical phase 2 studies for the treatment of patients with Candidemia, including *Candida auris*, and invasive mold infections.<sup>1</sup>

Fosmanogepix has received Fast Track and Orphan Drug designations from the US Food and Drug Administration for seven separate indications, and is designated as a Qualified Infectious Disease Product (QIDP) for the treatment of four indications.

### **About invasive mold infections**

Invasive aspergillosis and invasive infections with rare molds (e.g., *Fusarium* spp., *Scedosporium* spp., and Mucorales fungi) are life-threatening infections that predominantly affect immunocompromised patients, including patients with hematologic malignancies (blood cancer), transplant patients, or patients with other immunodeficiency disorders. These infections are associated with high morbidity and mortality.<sup>5,6</sup>

### **About invasive candidiasis**

Invasive candidiasis, including deep-seated tissue candidiasis and candidemia, is an increasingly important nosocomial infection, especially in patients hospitalized in intensive care units. *Candida* species are ranked as the fourth main cause of bloodstream infections in hospitals in the US.<sup>7</sup> The prognosis of invasive candidiasis remains difficult, with a reported mortality rate for invasive candidiasis as high as 40%, even when patients receive antifungal therapy.<sup>8</sup>

### **About Basilea**

Basilea is a commercial-stage biopharmaceutical company founded in 2000 and headquartered in Switzerland. We are committed to discovering, developing and commercializing innovative drugs to meet the needs of patients with severe bacterial and fungal infections. We have successfully launched two hospital brands, Cresemba for the treatment of invasive fungal infections and Zevtera for the treatment of bacterial infections. In addition, we have preclinical and clinical anti-infective assets in our portfolio. Basilea is listed on the SIX Swiss Exchange (SIX: BSLN). Please visit [basilea.com](http://basilea.com).



## Disclaimer

This communication expressly or implicitly contains certain forward-looking statements, such as "believe", "assume", "expect", "forecast", "project", "may", "could", "might", "will" or similar expressions concerning Basilea Pharmaceutica Ltd, Allschwil and its business, including with respect to the progress, timing and completion of research, development and clinical studies for product candidates. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd, Allschwil to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd, Allschwil is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

For further information, please contact:

### Peer Nils Schröder, PhD

Head of Corporate Communications & Investor Relations  
Basilea Pharmaceutica International Ltd, Allschwil  
Hegenheimermattweg 167b  
4123 Allschwil  
Switzerland

Phone +41 61 606 1102

E-mail [media\\_relations@basilea.com](mailto:media_relations@basilea.com)  
[investor\\_relations@basilea.com](mailto:investor_relations@basilea.com)

This ad hoc announcement can be downloaded from [www.basilea.com](http://www.basilea.com).

## References

1. K. J. Shaw, A. S. Ibrahim. Fosmanogepix: A Review of the First-in-Class Broad Spectrum Agent for the Treatment of Invasive Fungal Infections. *Journal of Fungi (Basel)* 2020 (6), 239
2. M. R. Hodges, E. Ople, P. Wedel et al. Safety and Pharmacokinetics of Intravenous and Oral Fosmanogepix, a First-in-Class Antifungal Agent, in Healthy Volunteers. *Antimicrobial Agents and Chemotherapy* 2023 (67), e01623-22
3. J. A. Vazquez, P. G. Pappas, K. Boffard et al. Clinical Efficacy and Safety of a Novel Antifungal, Fosmanogepix, in Patients with Candidemia Caused by *Candida auris*: Results from a Phase 2 Trial. *Antimicrobial Agents and Chemotherapy* 2023 (67), e01419-22
4. P. G. Pappas, J. A. Vazquez, I. Oren et al. Clinical safety and efficacy of novel antifungal, fosmanogepix, for the treatment of candidaemia: results from a Phase 2 trial. *Journal of Antimicrobial Chemotherapy* 2023 (78), 2471-2480
5. J. Cadena, G. R. Thompson 3rd, T. F. Patterson. Aspergillosis: Epidemiology, Diagnosis, and Treatment. *Infectious Disease Clinics of North America* 2021 (35), 415-434
6. M. Slavin, S. van Hal, T. C. Sorrell et al. Invasive infections due to filamentous fungi other than *Aspergillus*: epidemiology and determinants of mortality. *Clinical Microbiology and Infection* 2015 (21), 490.e1-490.e10
7. Candidemia (Blood Infection) and Other *Candida* Infections. 2019 Factsheet by the American Thoracic Society: <https://www.thoracic.org/patients/patient-resources/resources/candidemia.pdf> (Accessed: November 12, 2023)
8. B. J. Kullberg, M. C. Arendrup. Invasive Candidiasis. *The New England Journal of Medicine* 2015 (373), 1445-1456