

## **COMPANY PRESENTATION**

Biofrontera AG

Prof. Dr. Hermann Lübbert, CEO Ludwig Lutter, CFO November 2021

## FORWARD-LOOKING STATEMENTS AND RISKS



Certain statements in this presentation are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 regarding the public offering and the intended use of proceeds from the offering.

These statements may be identified by the use of forward-looking words such as "anticipate", "believe", "forecast", "estimate" and "intend" among others. Such forward-looking statements are based on the currently held beliefs and assumptions of the management of Biofrontera AG, which are expressed in good faith and, in their opinion, reasonable. Forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results, financial condition, performance, or achievements of the Company, or industry results, to differ materially from the results, financial condition, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and other factors are set forth in the annual report on Form 20-F filed with the SEC, including Item 3.D. "Key Information - Risk Factors", and in future reports filed with the SEC. Given these risks, uncertainties and other factors, prospective investors are cautioned not to place undue reliance on these forward-looking statements. The Company does not undertake an obligation to update or revise any forward-looking statement.

## **BIOFRONTERA AT-A-GLANCE**



We are an international biopharmaceutical company focusing on the development and commercialization of pharmaceutical products for the treatment of sun-induced skin diseases, particularily actinic keratosis. In the U.S., we also market a topical antibiotic for the treatment of bacterial skin infections.

#### **HEADQUARTERS**

Headquartered in Leverkusen, Germany

U.S.-headquarters in Woburn, MA

#### **PRODUCTS**

Biofrontera's
Photodynamic Therapy
(PDT) drug Ameluz® is
approved in the U.S., EU
and Switzerland

Exclusive license for U.S. marketing of topical antibiotic Xepi<sup>®</sup>

#### SALES FORCE

Dedicated sales teams in the U.S., Germany, Spain and the UK

#### FINANCIAL PERFORMANCE

Revenue growth from €4.1 million in 2015 to €31.3 million in 2019

Revenue of €30.3 million in 2020

#### R&D

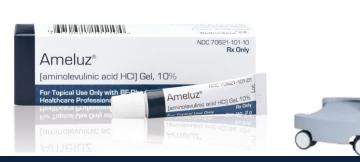
Improve market
positioning of existing
products through label
extensions

#### STOCK MARKET

Listed on the Frankfurt Exchange (B8F) and on Nasdaq (BFRA)

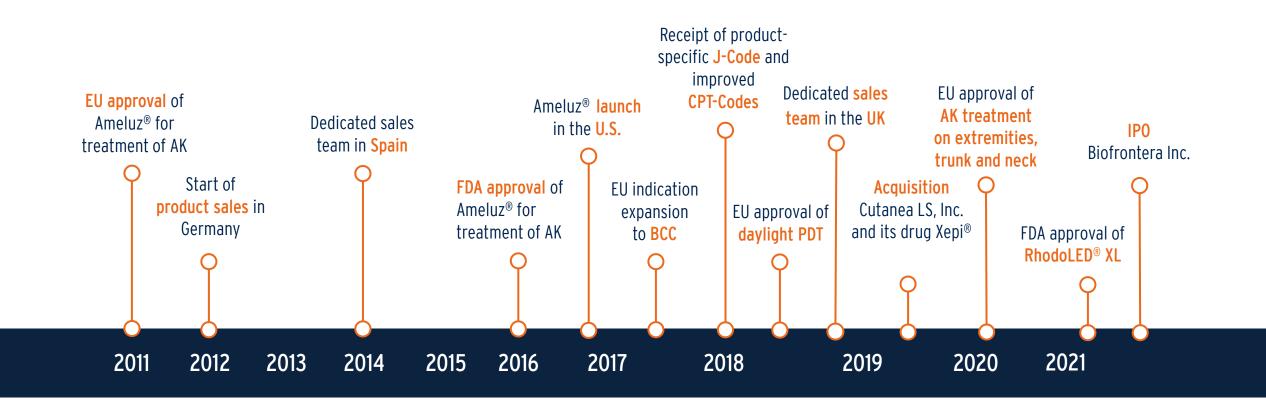






## **OUR MILESTONES**

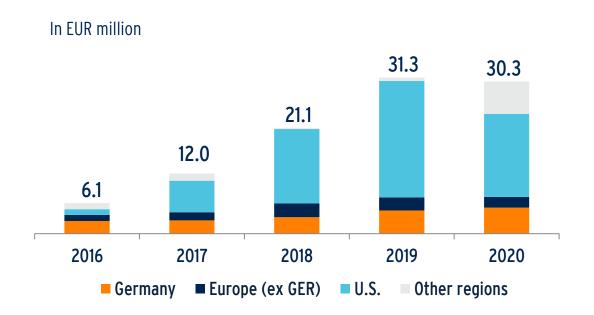




## REVENUE DEVELOPMENT



## 5-year total revenue development



## Revenue from product sales by quarter since 2018

#### In EUR million



## BIOFRONTERA GROUP FINANCIAL RESULTS



#### In EUR million

	2016	2017	2018	2019	2020	9M 2020	9M 2021
Total revenue	6.1	12.0	21.1	31.3	30.3	20.8	18.5
thereof product sales	5.0	10.6	21.0	30.6	24.0	14.3	18.5
thereof US revenues	1.2	6.3	14.9	23.3	16.6	9.1	12.3
Loss from operations	(11.8)	(13.9)	(18.5)	(23.4)	(7.6)	(8.4)	(12.6)
EBITDA				1.0	(4.7)	(5.4)	(9.7)
EBIT				(2.2)	(10.0)	(10.0)	(12.1)
Cash & cash equivalents	15.1	11.1	19.5	11.1	16.5	16.2	29.5
Financial debt	3.9	12.5	13.6	23.3	23.9	30.4	24.6*

Lower 2020 product sales due to pandemic, compensated by one-time payment of €6.0 million from license agreement

<sup>\*</sup> prematurely repay the loan of the European Investment Bank ("EIB")

## **AMELUZ®**



AMELUZ® gel in combination with photodynamic therapy (PDT) using BF-RhodoLED® lamp or daylight is indicated for the lesion-directed and field-directed treatment of actinic keratoses (AK) of mild-to-moderate severity on the face and scalp¹



<sup>1</sup> For full prescribing information for Ameluz, please see <a href="https://bit.ly/AmeluzPl.">https://bit.ly/AmeluzPl.</a>
<sup>2</sup> Zink, Hautarzt. 2017 Nov;68(11):919-928; <sup>3</sup> www.awmf.org/leitlinien/detail/II/032-0220L.html. <sup>3</sup> Fuchs & Marmur, Dermatol Surg. 2007 Sep; 33(9):1099-101. <sup>4</sup> Fernández-Figueras et al., J Eur Acad Dermatol Venereol. 2015 May;29(5):991-997. Picture source: Gilly S. Munavalli, MD, MHS, FACMS, Wake Forest University, School of Medicine Department of Dermatology, Charlotte, NC, USA

## 1 in 3

## CANCER DIAGNOSES WORLDWIDE CAN BE ATTRIBUTED TO SKIN CANCER<sup>2</sup>



AKs are premalignant
lesions of the skin
caused by excessive UV
light that can
potentially develop into
skin cancer (squamous
cell carcinoma) if left
untreated<sup>3</sup>

Mild or even invisible lesions may progress to skin cancer more frequently than severe lesions<sup>4</sup>

## **AMELUZ®-PDT**



## Conventional PDT: ILLUMINATION WITH BF-RHODOLED®







Daylight PDT: 2H STAY OUTSIDE



PREPARATION
OF TREATMENT
AREA



APPLICATION AMELUZ® GEL



ACTINIC KERATOSIS BEFORE AND AFTER A SINGLE TREATMENT

A second treatment may be required on about 40% of the patients<sup>1</sup>

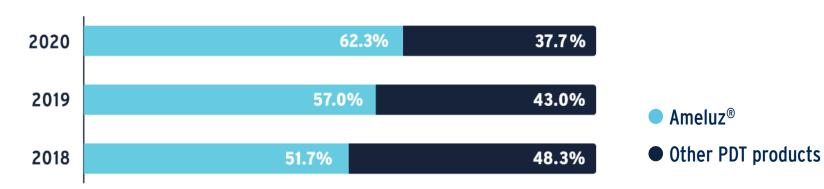
<sup>1</sup> For full prescribing information for Ameluz, please see https://bit.ly/AmeluzPl

## AMELUZ® - GERMAN MARKET<sup>1</sup>

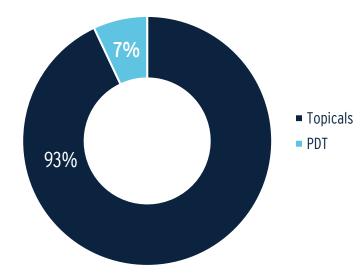


- Our largest EU market with about 800K treatments for AK annually<sup>1</sup>
- Daylight PDT has doubled the German PDT market segment since 2018
- Strategic label expansion has made Ameluz® the leader in PDT in Biofrontera's domestic market Germany

## SHARE OF AMELUZ® IN GERMAN PDT MARKET



Germany: AK market by treatment option (2020)\*



\* data for cryotherapy not available

<sup>1</sup> Insight Health data 2019

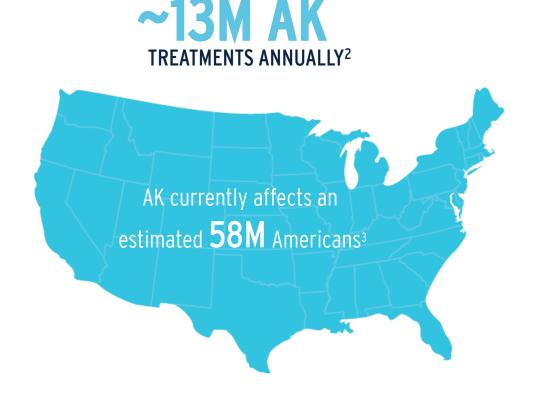
Schäfer et al., J Eur Acad Dermatol Venereol, 20214 Mar: 28(3):309-13

## AMELUZ® - U.S. MARKET



# The U.S. represents a multi-billion dollar addressable market for Ameluz®-PDT

For patients older than 45, AK is the most frequent indication treated by dermatologists<sup>1</sup>

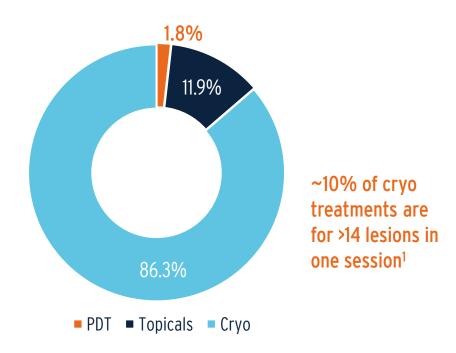


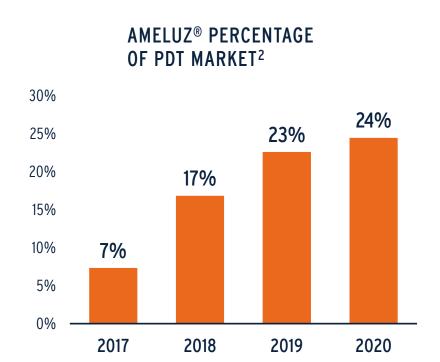
Landis et al., (2014) Derm. Online J. 20(4), Market data accessible from CMS and IQVIA, 2019; www.skincancer.org/skin-cancer-information/actinic-keratosis/

## TOTAL ADDRESSABLE U.S. MARKET OF ~\$4 BILLION



## 2020 U.S. AK MARKET BY TREATMENT OPTION<sup>1</sup>





**Current Ameluz® list price \$3153** 

<sup>&</sup>lt;sup>1</sup>Market data accessible from CMS and IQVIA, 2020

<sup>&</sup>lt;sup>2</sup>Based on company estimates and analysis of market data accessible from CMS and IQVIA

# POTENTIAL AMELUZ® LABEL EXPANSION TO OPTIMIZE U.S. MARKET POTENTIAL



Product	Indication	Study type	Anticipated start of patient recruitment
BF-RhodoLED® XL	PDT lamp for illumination of larger body regions	Not applicable	FDA approval in October 2021
Ameluz®	Actinic keratosis	Pharmacokinetics study	completed
Ameluz <sup>®</sup>	Superficial basal cell carcinoma	Phase III	ongoing
Ameluz <sup>®</sup>	Actinic keratosis	Phase I safety study with 3 tubes of Ameluz®	site initiation ongoing
Ameluz®	Moderate to severe acne	Phase IIb	site initiation ongoing
Ameluz®	Actinic keratosis	Phase III on face and scalp with 3 tubes and pain-reducing illumination protocol	2022
Ameluz®	Actinic keratosis	Phase III on trunk & extremities	2022
Ameluz <sup>®</sup>	Squamous cell carcinoma <i>in situ</i>	Phase III	2023

## **COMPETITIVE ADVANTAGES**



#### FOR THE PATIENT

- Patients may experience up to 91% total clearance<sup>1</sup>
- Field-directed Ameluz®-PDT may provide protection from potentially fatal progression of mild or invisible AKs
- No scarring or lasting skin destruction
- The cosmetic outcome (lasting improvement of sun damage)
- The number and speed of required treatments

#### FOR THE DOCTOR

- Patients may experience up to 91% total clearance<sup>1</sup>
- Ameluz®-PDT uniquely provides both lesion-directed and field-directed treatment
- Ameluz® formulation allows for easy and controlled application
- Total control of treatment compliance
- Favorable economics for U.S. doctors as a result of established reimbursement codes

<sup>&</sup>lt;sup>1</sup> For full prescribing information for Ameluz, please see <a href="https://bit.ly/AmeluzPl.">https://bit.ly/AmeluzPl.</a>

## **XEPI**<sup>®1</sup>



- A topical prescription medicine for impetigo due to *Staphylococcus* aureus or *Streptococcus pyogenes*, approved in the U.S. in adult and pediatric patients two months of age or older<sup>1</sup>
- Bactericidal against S. aureus und S. pyogenes, including MRSA<sup>1</sup>
- Current list price \$297<sup>2</sup>
- Already ~80% of patients with commercial insurance are covered for Xepi<sup>®</sup> without precondition



## 3 million+

CASES OF IMPETIGO PER YEAR IN THE U.S.<sup>3</sup>

In 2019, over 13 million prescriptions were written for drugs (generic mupirocin) in indications where Xepi® can be effective<sup>4</sup>



**Impetigo** 

- A contagious superficial bacterial skin infection
- Impetigo is treated aggressively to avoid community spread and resistance development<sup>5</sup>

<sup>&</sup>lt;sup>1</sup> For full prescribing information for Xepi, please see https://bit.ly/XepiPI;<sup>2</sup> Current company data on file; <sup>3</sup>https://www.fda.gov/consumers/consumer-updates/how-treat-impetigo-and-control-common-skin-infection; <sup>4</sup>Prescription data from IQVIA, 2020; <sup>5</sup>http://www.who.int/mediacentre/factsheets/fs194/en/

## IPO OF BIOFRONTERA INC.



## Proceeds foreseen for market expansion of our flagship product Ameluz®

#### Why the time is now

- Medical need for field therapy of actinic keratosis (AK)
- Attractive remuneration for healthcare providers
- Product with unrivaled efficacy
- Rapid expansion of commercial infrastructure
- Strong investment in label expansion through BF Group

## TO FINANCE THE AMELUZ® MARKET EXPANSION, WE LISTED BIOFRONTERA INC. ON NASDAQ

- U.S.-centric, stand-alone, commercial stage pharmaceutical company poised to capitalize upon the significant U.S. growth opportunities.
- Provides a structure that gives Biofrontera Inc. the financial flexibility to implement its growth plan.
- License and supply agreement within Biofrontera Group allows independent growth of Biofrontera Inc. and Biofrontera AG.
- Biofrontera AG will continue to participate in the value created at Biofrontera Inc. through revenue sharing ruled by LSA and through marketable shares



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