



**Delivering Novel  
Antiviral Therapies to  
Patients with  
Weakened Immune  
System**

JP Morgan Conference, January 2024



# FORWARD LOOKING STATEMENTS

## Disclaimer

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Certain information set forth in this presentation contains “forward-looking information”, including “future oriented financial information” and “financial outlook”, under applicable securities laws (collectively referred to herein as forward-looking statements). Except for statements of historical fact, information contained herein constitutes forward-looking statements and includes, but is not limited to, the (i) projected financial performance of the Company; (ii) completion of, and the use of proceeds from, the sale of the shares being offered hereunder; (iii) the expected development of the Company’s business, projects and joint ventures; (iv) execution of the Company’s vision and growth strategy, including with respect to future M&A activity and global growth; (v) sources and availability of third-party financing for the Company’s projects; (vi) completion of the Company’s projects that are currently underway, in development or otherwise under consideration; (vi) renewal of the Company’s current customer, supplier and other material agreements; and (vii) Future liquidity, working capital, and capital requirements. Forward-looking statements are provided to allow potential investors the opportunity to understand management’s beliefs and opinions in respect of the future so that they may use such beliefs and opinions as one factor in evaluating an investment. These statements are not guarantees of future performance and undue reliance should not be placed on them. Such forward-looking statements necessarily involve known and unknown risks and uncertainties, which may cause actual performance and financial results in future periods to differ materially from any projections of future performance or result expressed or implied by such forward-looking statements.

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The reader is cautioned not to place undue reliance on forward-looking statements.

# AICURIS AT A GLANCE



Privately held, cash-flow positive, late-stage biopharmaceutical company with revenue generating commercial product, PREVYMIS®<sup>1</sup>



Exclusively focused on antiviral therapies for immunocompromised patients with significant unmet need



Phase 3 asset, Pritelivir, with multiple upcoming inflection points and Breakthrough Therapy Designation



Differentiated product candidates, designed to target each virus with the most promising mode-of-action



Executive management with direct experience bringing antivirals to market



Germany-based with recently formed US subsidiary to prepare for expected US commercial launch of Pritelivir

# DRIVING VALUE THROUGH R&D AND COMMERCIALIZATION

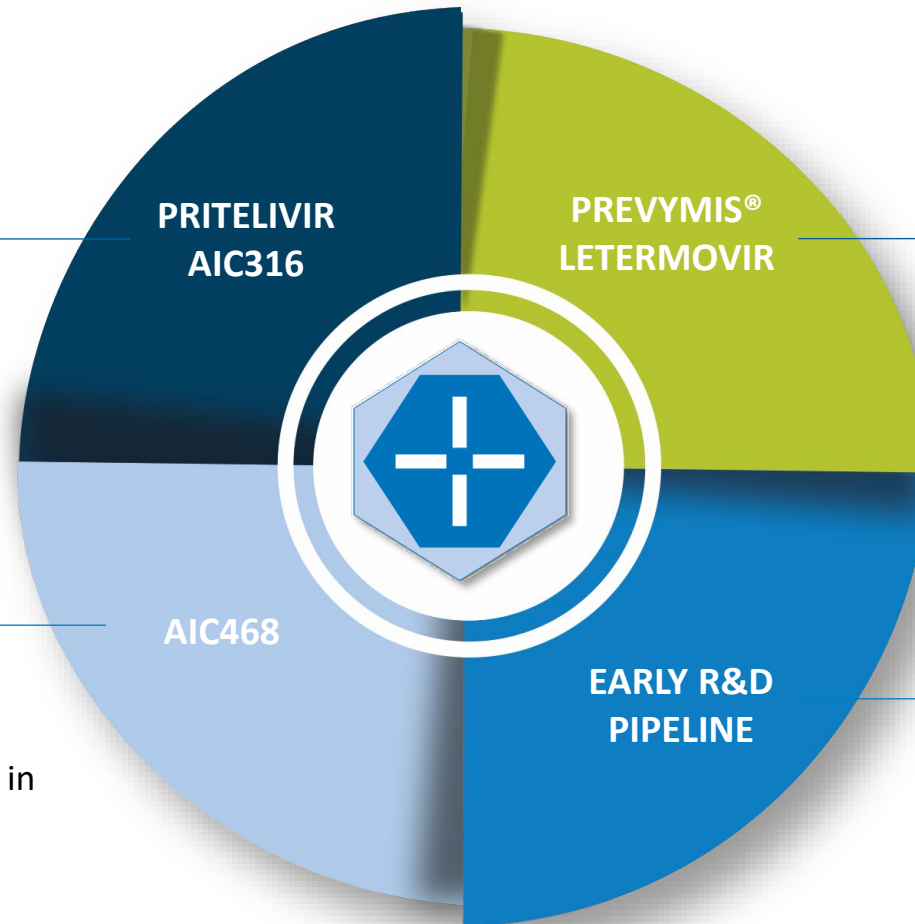
With focus on defined immunocompromised patient population

## DRIVING SHORT TERM VALUE

- Product launch for immunocompromised patients expected 2026
- Commercialization by a focused sales force\*

## SOLID PATH TO LONG TERM VALUE

- Rapid development in indications without approved treatment options
- Expansion of AiCuris commercial portfolio in similar patient populations



## IMMEDIATE, CONTINUING CASH FLOW

- Income from royalties, regulatory and commercial milestones
- Enabling advancing our R&D portfolio

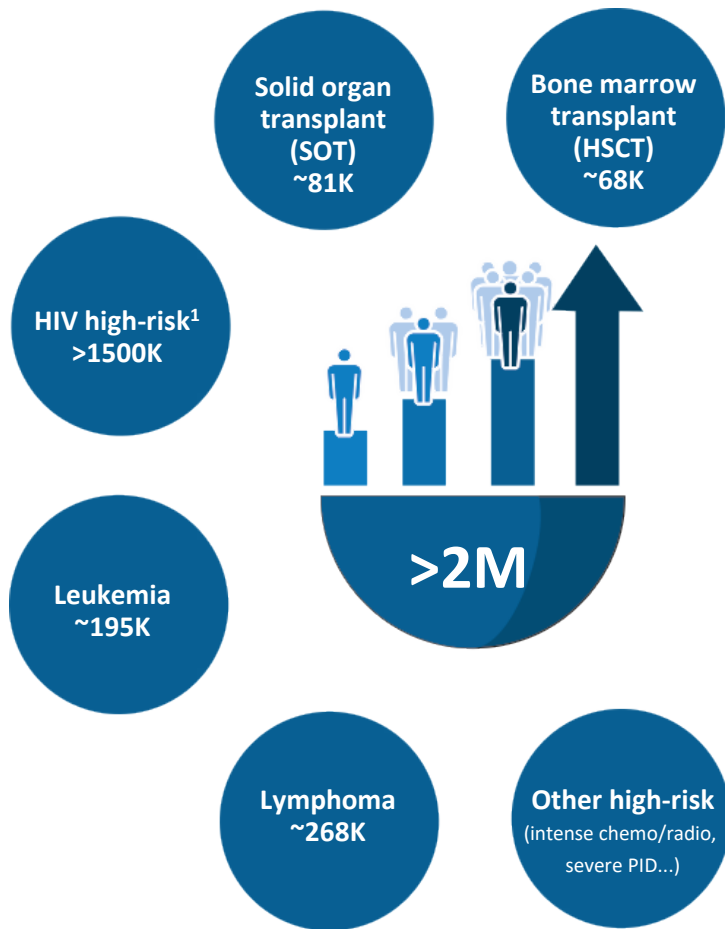
## POTENTIAL BEYOND

- Novel assets with a novel mechanism of action and synergies to Pritelivir/AIC468
- Expanding Pritelivir/AIC468 in broader patient populations

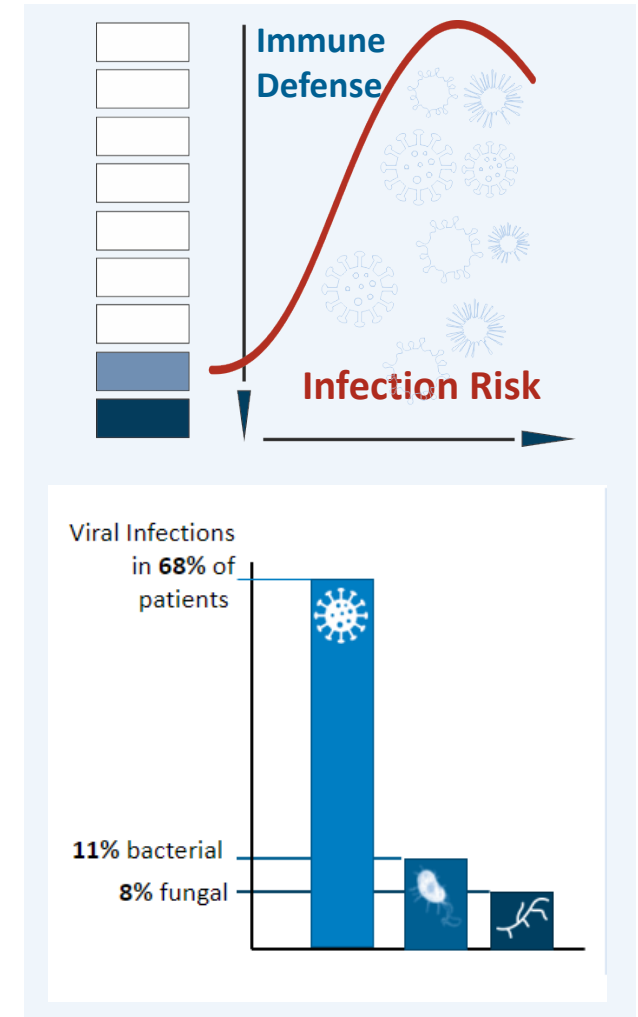
\*in-licensing/acquisition of additional late-stage asset can create commercial synergy for AiCuris

# HIGH MEDICAL NEED FOR ANTIVIRALS

A growing number of patients are severely immunocompromised



- Multiple diseases are directly associated with **severe immune deficiencies** or require immunosuppressive treatments
- Novel and aggressive treatments to prolong life expectancy lead to **prolonged immunosuppression**
- Population of severely immunocompromised patients is **growing rapidly** (e.g., HSCT growing at 11.2% CAGR<sup>2</sup>; SOT at 3.7%<sup>3</sup>)
- In addition, **>1B patients are moderately immunocompromised** (e.g., patients with cancer, chronic or autoimmune diseases)
- Recurrent viral infections lead to severe disease and mortality in many patients



Patient numbers are shown as new cases per year for the 7 major markets (US, China, Japan, Germany, France, Italy, UK; references on file), developing countries not referenced.

# FOCUSED R&D PIPELINE WITH LATE-STAGE LEAD ASSET

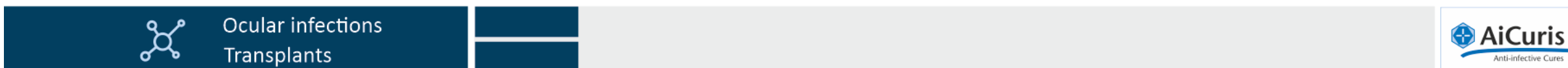
## HSV treatment



## BKV treatment



## AdV treatment



## HCMV prophylaxis



 Small Molecule  Antisense oligonucleotide

Merck & Co., Inc., Rahway, NJ, USA (Hereinafter MSD)



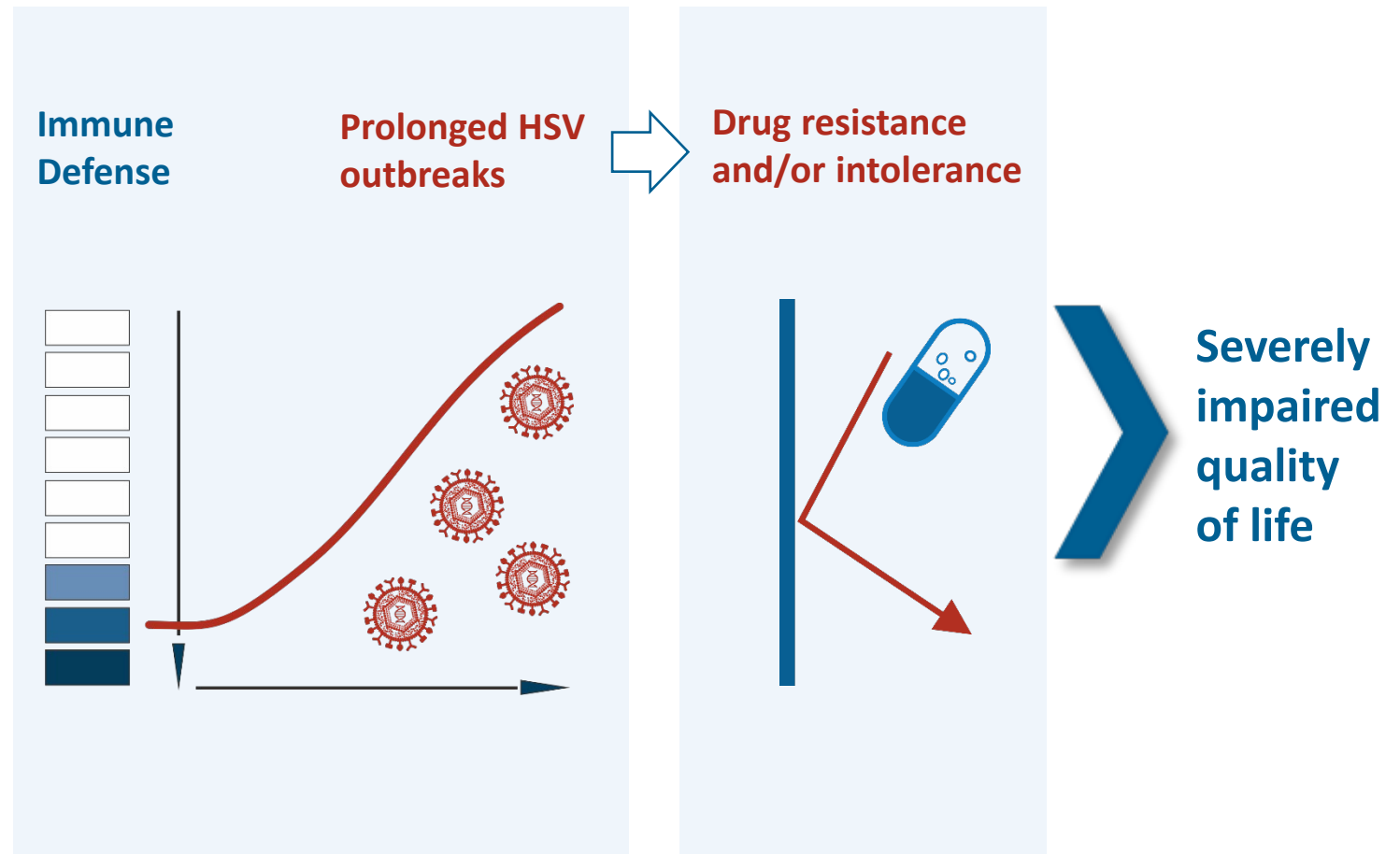
# 01

**Pritelivir  
Phase 3  
Program  
(AIC316)**



# PRITELIVIR AIMS TO SOLVE HIGH MEDICAL NEED IN IMMUNOCOMPROMISED PATIENTS

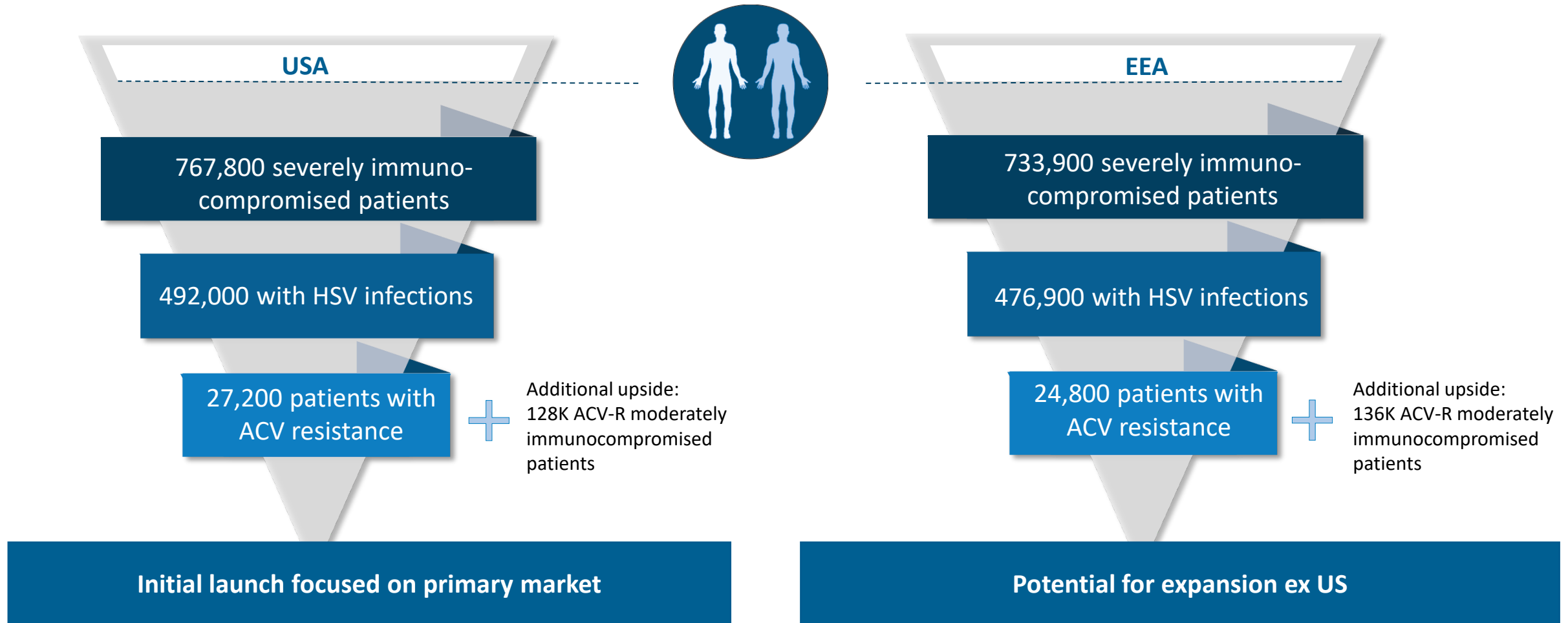
- **3.7B & 0.5B people** latently infected with HSV-1 & HSV-2, respectively<sup>1</sup>
- HSV manifests in genital and labial herpes, keratitis, encephalitis, disseminated disease and neonatal herpes
- **More frequent, prolonged and severe** manifestations in immunocompromised (IC) patients
- **Up to 27%<sup>2</sup>** of IC patients develop drug resistances and are at risk for disseminated disease
- **Increased hospitalization rates** due to painful mucocutaneous lesions





# PRIMARY USE IN IMMUNOCOMPROMISED ACYCLOVIR-RESISTANT PATIENTS

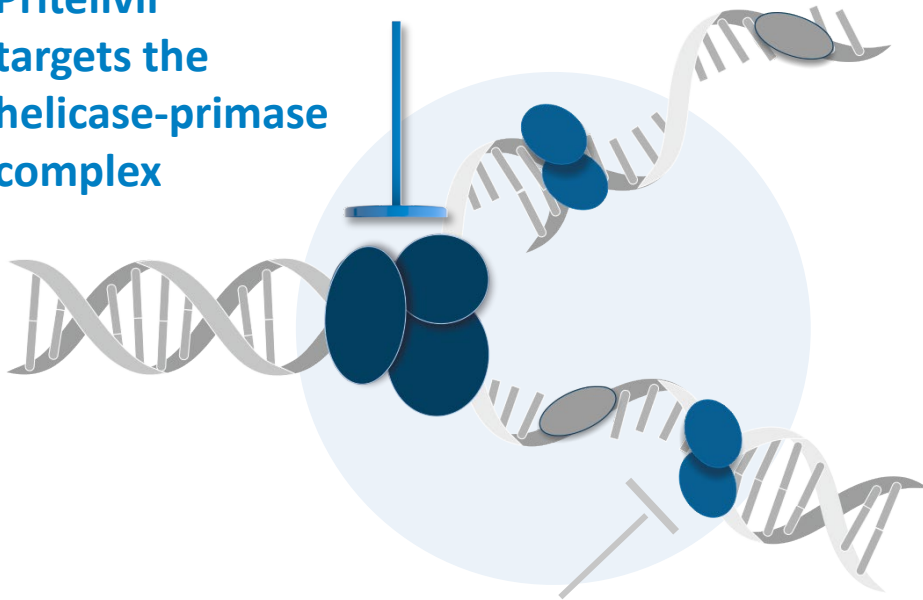
A niche indication with potential for expansion



# PRITELIVIR IS DESIGNED TO TREAT PATIENTS WITH DRUG-RESISTANT INFECTIONS

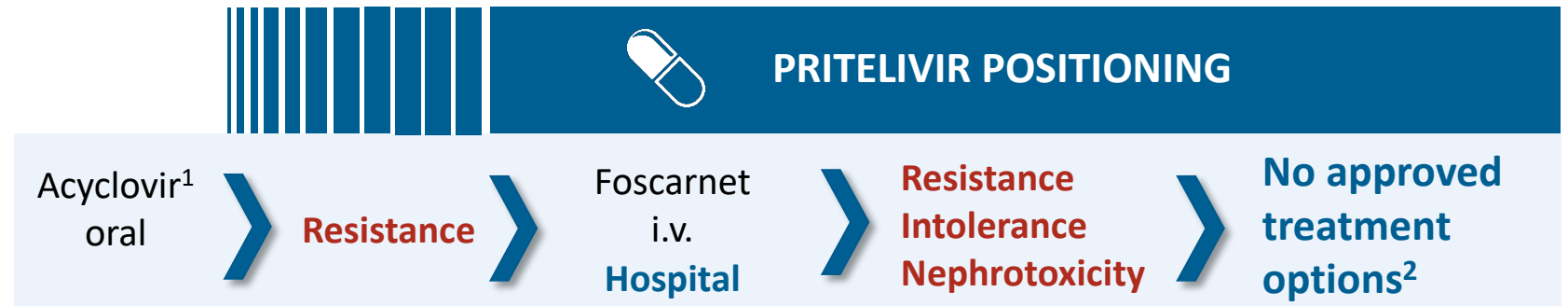
A small molecule inhibiting viral replication of HSV-1 and HSV-2 via a novel mechanism

**Pritelivir targets the helicase-primase complex**



Nucleoside analogs (standard-of-care) inhibit the HSV DNA polymerase

- **Differentiated** from standard-of-care and rescue therapy by:
  - **Favorable bioavailability** and half-life, allowing for once-a-day dosing in an oral application
  - **Superior risk/benefit ratio** and safety profile to Foscarnet
  - **Lower propensity of resistance** compared to Acyclovir



<sup>1</sup>Or prodrugs with increased oral bioavailability (valacyclovir or famciclovir)

<sup>2</sup>Cidofovir or topical Imiquimod as salvage treatments

# PRITELIVIR OBTAINED FDA BREAKTHROUGH THERAPY DESIGNATION (BTD)

Phase 2 data demonstrated a favorable safety profile and lesion healing in majority of patients

- **Higher healing rate observed** vs. Foscarnet in Acyclovir-resistant patients
- **Favorable safety profile:** No drug-related AEs in Acyclovir-resistant patients
- **Healing also demonstrated in dual-resistant patients** with highest unmet need and no approved treatment options



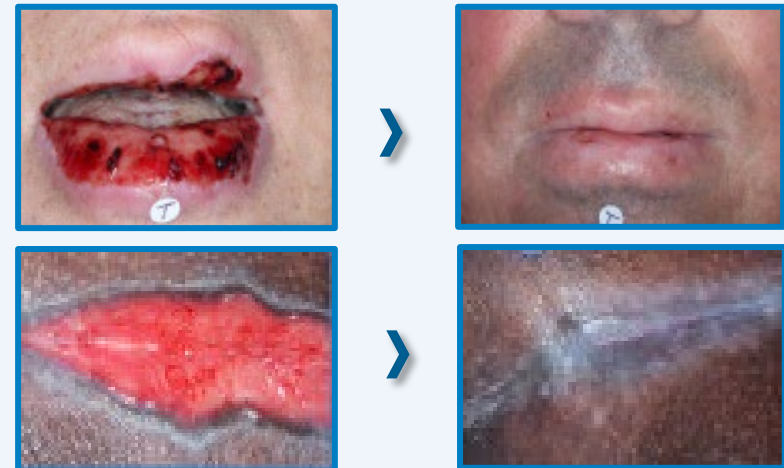
## Healing rates after treatment

Healing Rates	Pritelivir	Foscarnet
Acyclovir-resistant Pts	<b>93%</b> (14/15 pts)	<b>57%</b> (4/7 pts)
Dual-resistant <sup>1</sup> Pts	<b>63%</b> (5/8 pts)	N.A

<sup>1</sup>Acyclovir-resistant and foscarnet-resistant and/or -intolerant

Data on file

## Acyclovir-resistant infection > After Pritelivir treatment



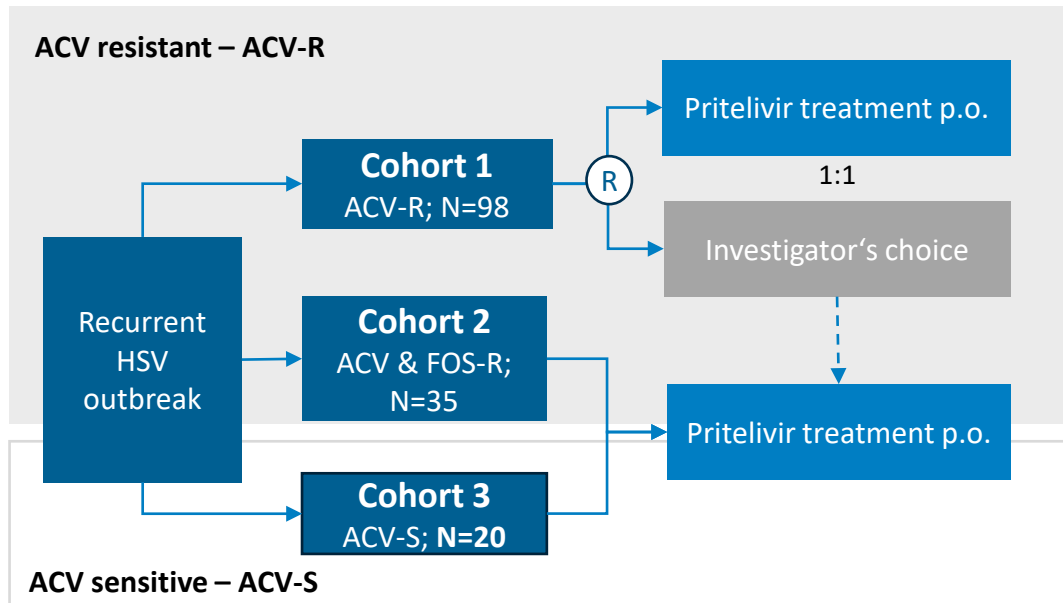
Workowski et al., Poster presentation, ID week 2021

# PRITELIVIR PHASE 3 TRIAL IS ACTIVELY ENROLLING PATIENTS

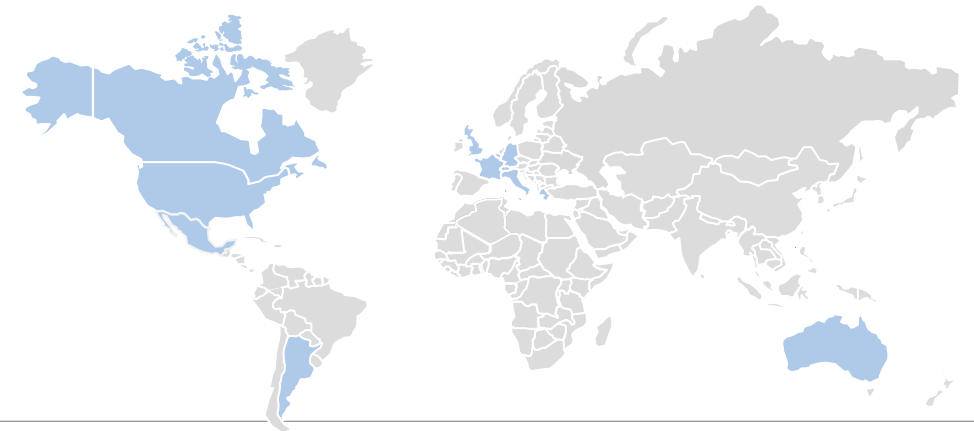
NDA filing planned for 2H2025

- **Randomized, open-label, multi-center trial** enrolling 153, mostly acyclovir-resistant, immunocompromised patients

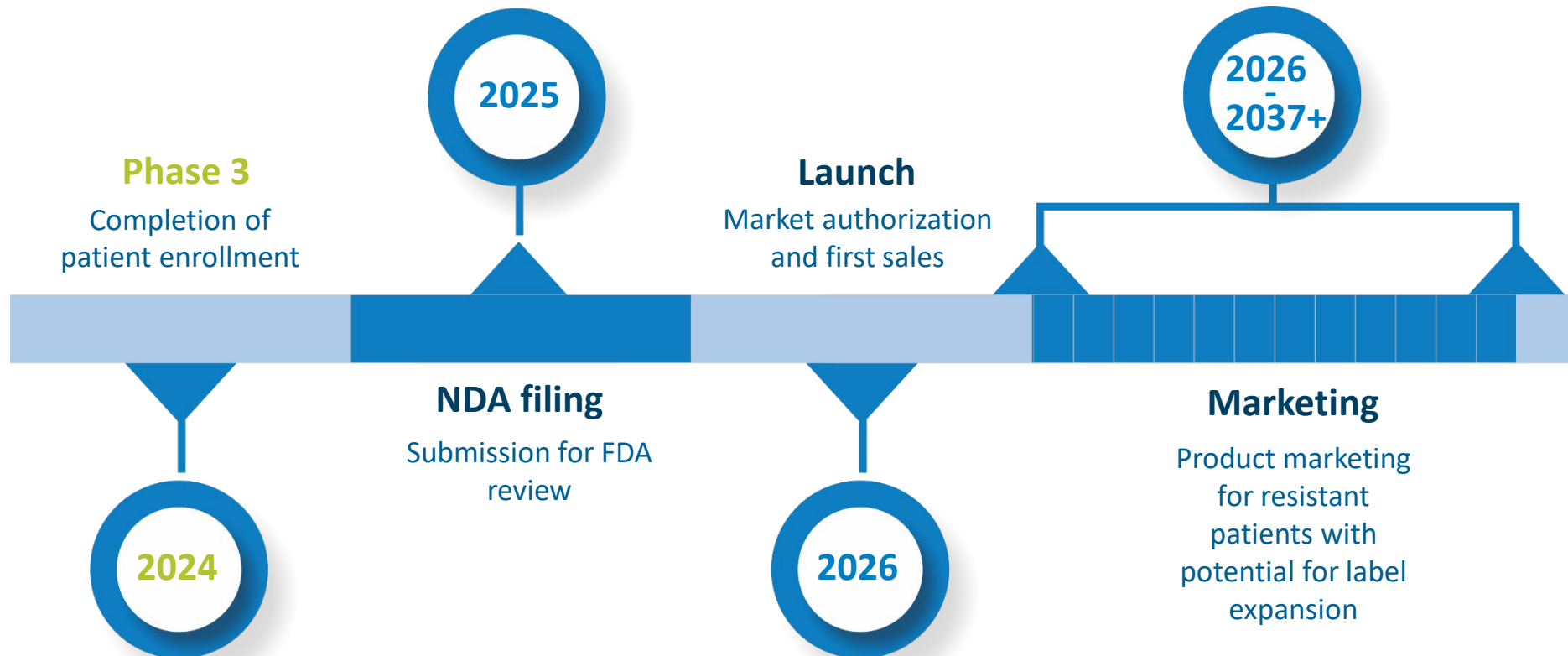
## ▪ Trial design



- **Primary Endpoint:** Healing rate of lesions (day 28)
- **Secondary Endpoints:**
  - Several efficacy endpoints including healing rate of lesions (day 42), time to healing, recurrence & resistance rate
  - Several safety endpoints including rates of chronic kidney disease, renal impairment, other AEs, discontinuation, and resource utilization
- **Global study** with 70 sites in 14 countries



# PRODUCTIVE ONGOING DIALOGUE WITH FDA FOR RAPID PATH TO MARKET



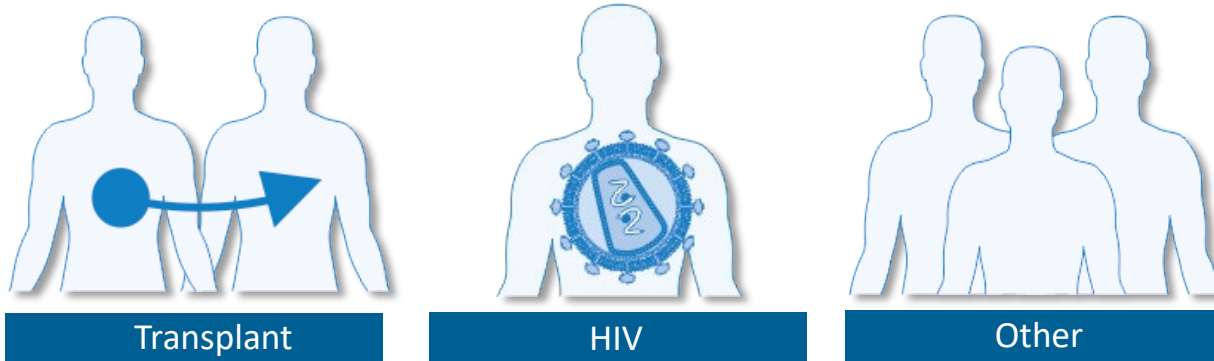
## Launch Preparation ongoing

- Ongoing FDA dialogue facilitated by Breakthrough Designation
- Medical Awareness activities started
- CMC registration/validation batches successfully manufactured
- AiCuris US presence established

# PRITELIVIR IS WELL POSITIONED TO FILL RELEVANT GAPS IN A HIGH-NEED MARKET

## ■ Early Access Program ongoing:

- >65 patients with more than 100 outbreaks treated in 10 countries
- Majority are transplant (57%) or HIV-infected (25%) patients
- Interim analysis: 31 out of 44 evaluable patients with documented healing of lesions (70%)<sup>1</sup>



**Results confirming data from Phase 2 trial,  
de-risking Phase 3 analysis**



**Resistance-breaking**



**Favorable safety and efficacy  
profile**



**Oral administration,  
no hospitalization required**



**Accelerated development path  
(FDA Breakthrough Designation)**



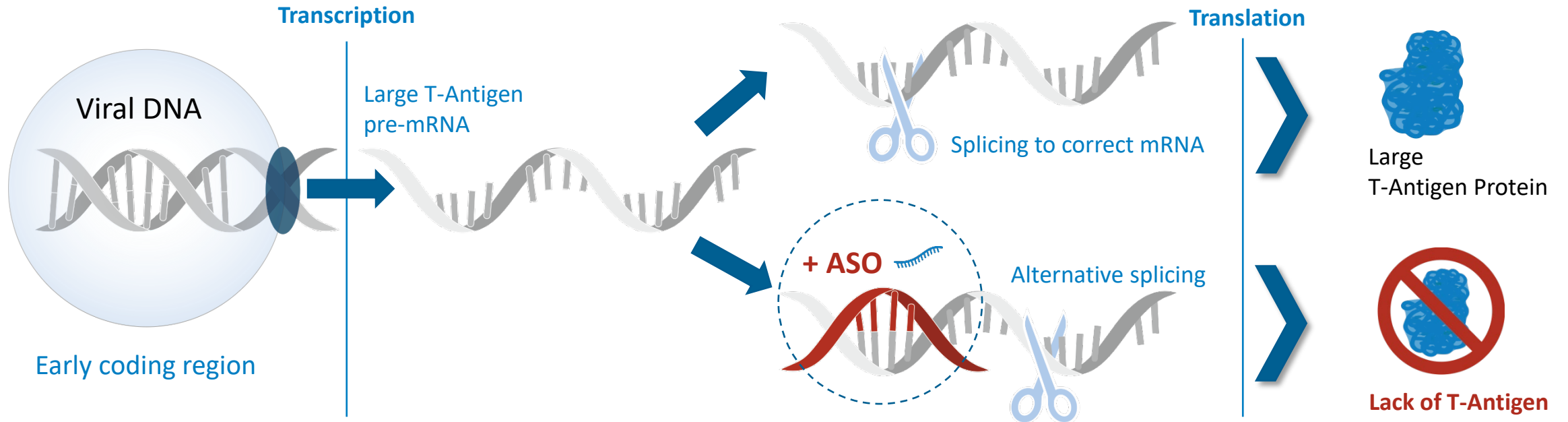
02

AIC468



# AIC468 IS A SECOND-GENERATION ANTISENSE OLIGONUCLEOTIDE TARGETING BK VIRUS

Aiming to protect against severe conditions caused by BKV reactivation in SOT and HSCT patients

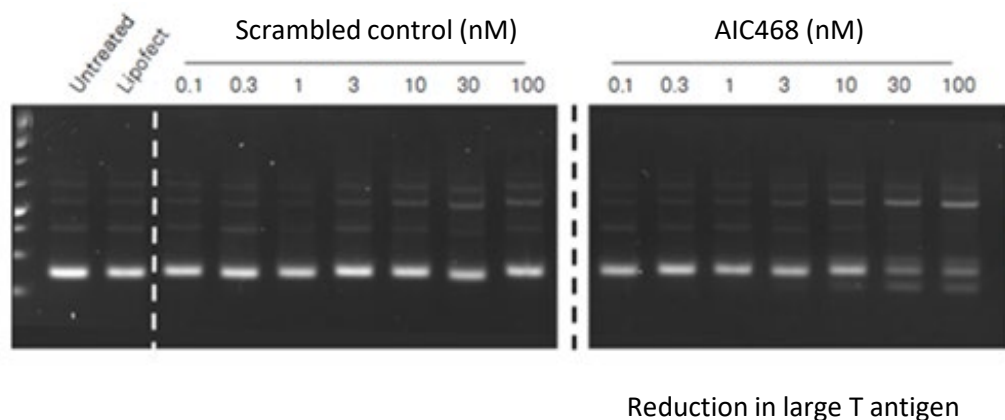


- As a **direct-acting agent**, AIC468 targets the virus intracellularly
- **Inhibition of correct splicing** prevents formation of large T-Antigen
- The large T-Antigen is essential for **BK virus replication**

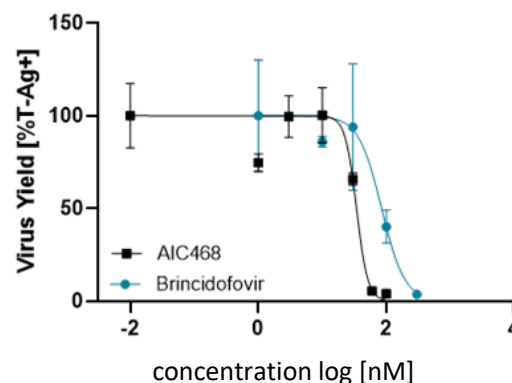
# AIC468 PRECLINICAL DATA WARRANT CLINICAL TRIAL APPLICATION

CTA submitted Q4 2023

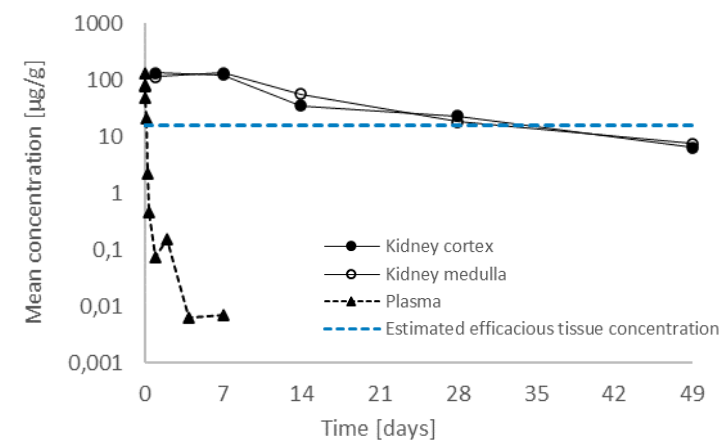
## *In vitro* specificity



## *In vitro* efficacy



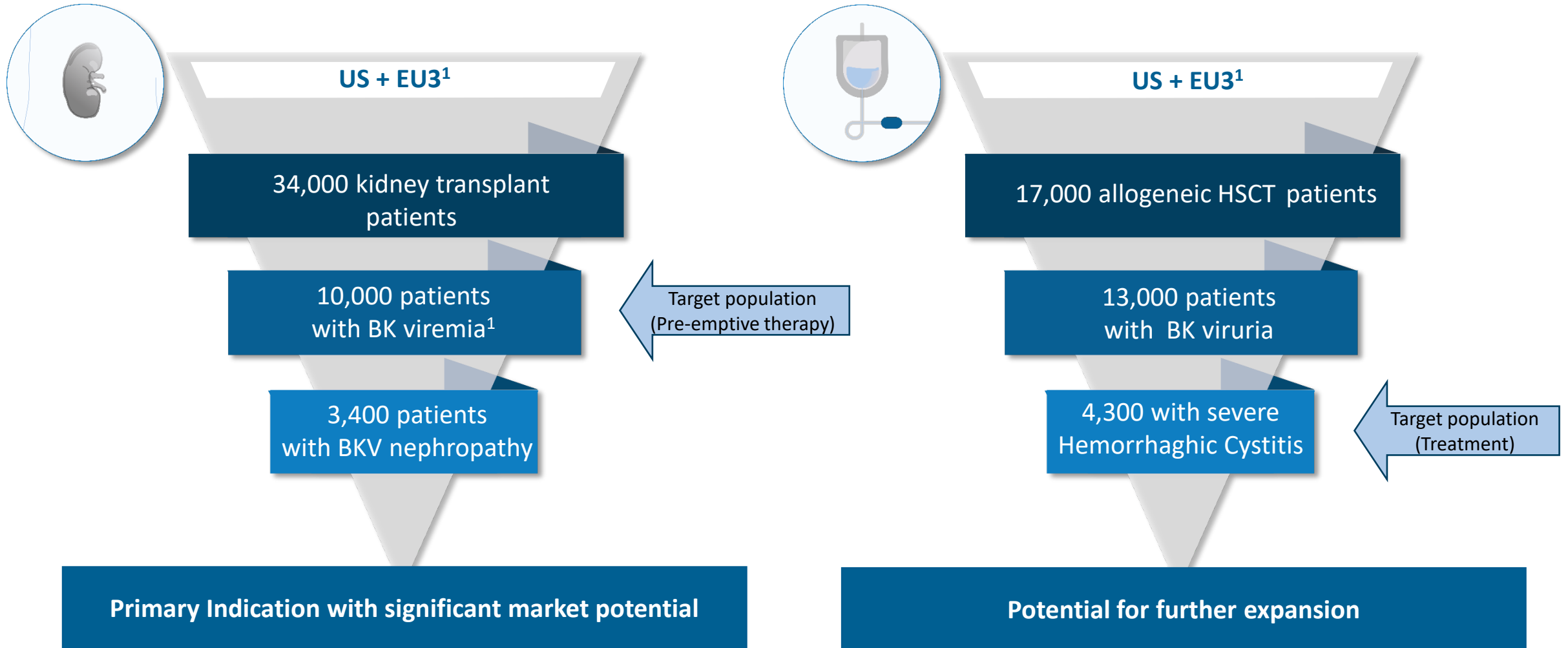
## *In vivo* pharmacokinetics



- **AIC468 significantly reduces large T-Antigen** expression and **inhibits BKV replication *in vitro*** in a dose-dependent manner
- **Pharmacokinetic studies** in mini pig model demonstrated biodistribution to kidney tissue and coverage of estimated effective dose over more than 3 weeks
- **First-in-human trial starts mid 2024**: Adaptive trial design combining a single and a multiple ascending dose escalation to investigate safety and tolerability; enrollment of N≥80 healthy individuals within 12 months planned

# AIC468 INITIAL LAUNCH PLANNED IN KIDNEY TRANSPLANT PATIENTS

With potential to expand to human stem cell transplants (HSCT)



# AIC468 IS IDEALLY POSITIONED TO TACKLE BK VIRUS-RELATED SEVERE CONDITIONS

Intracellular approach with novel mode-of-action

- **Overcomes limitations** of other approaches in development (antibodies, cellular immunotherapies)
- **Significant market potential** in kidney transplant patients, option to expand to bone marrow transplant (HSCT) patients
- **US patent granted** 2Q2023
- **GMP grade drug substance** successfully manufactured
- **Clinical trial application** submitted in Dec 2023 after scientific advice in 1H2023
- **Phase I single and multiple ascending dose study** starts mid 2024



**Novel ASO approach** with direct anti-viral activity



**Preclinical data package** warranted clinical trial application



**Fast development track** in niche indication



AiCuris and Hybridize Therapeutics entered worldwide license agreement for a direct-acting RNA-based therapy against BK Virus in 2022

# 03

PREVYMIS<sup>®</sup>  
(Letermovir)





# PREVYMIS® (LETERMОВIR) PROTECTS IMMUNOCOMPROMISED TRANSPLANT PATIENTS

First-and-only marketed treatment to prevent HCMV reactivation



*Perceived by the medical community as “Game Changer” in acute hospital care.*

- **HCMV reactivation in 60-70%** of seropositive transplant patients can lead to severe conditions and death
- **PREVYMIS® (Letermovir) prevents HCMV reactivation** in transplant patients
- **Approved and marketed** for HSCT patients in 60 countries by MSD
- **Label recently expanded** for kidney transplant patients in the US and EU
- **AiCuris participates in commercial success** by royalty and milestone payments



**>\$429M YTD Net Sales 3Q2023**  
Quarterly royalty stream to AiCuris



**Approved for prophylactic treatment** of immunocompromised patients



**New viral target** with no human counterpart

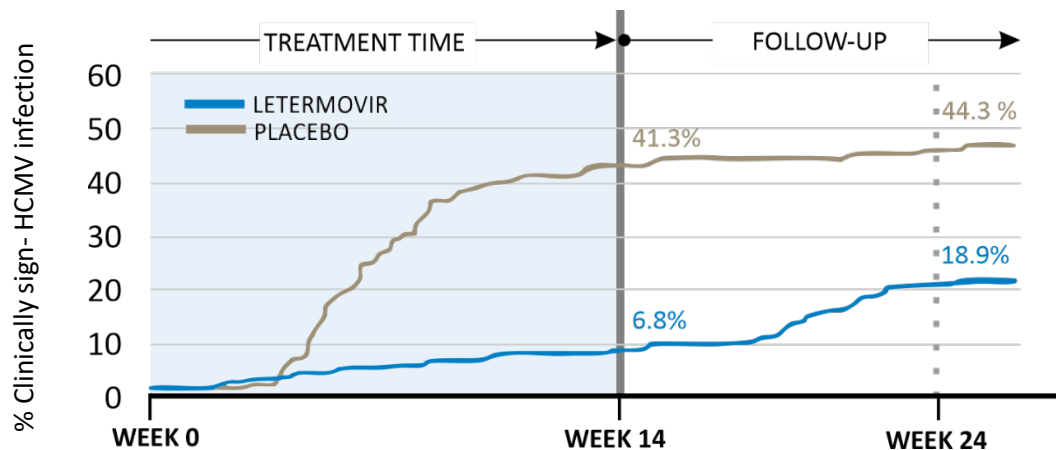
# PREVYMIS® WAS OUT-LICENSED TO MSD AND IS MARKETED FOR HSCT & KT PATIENTS

## Initial Launch in HSCT supported by Safety & Efficacy Data<sup>2</sup>



HSCT

- **Efficacy:** Prevention of symptomatic HCMV infection starting with day 1 of treatment
- **Safety:** Comparable safety profiles in Letermovir and placebo-controlled patients
- **Improvement of all-cause mortality** 24 weeks after start of treatment

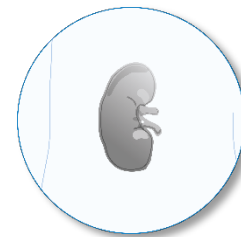


## Two additional Phase 3 trials met Primary Endpoint



HSCT

- **HSCT Phase 3 trial** demonstrated improved outcomes with longer treatment duration (200d)
- **sNDA approved** in August 2023



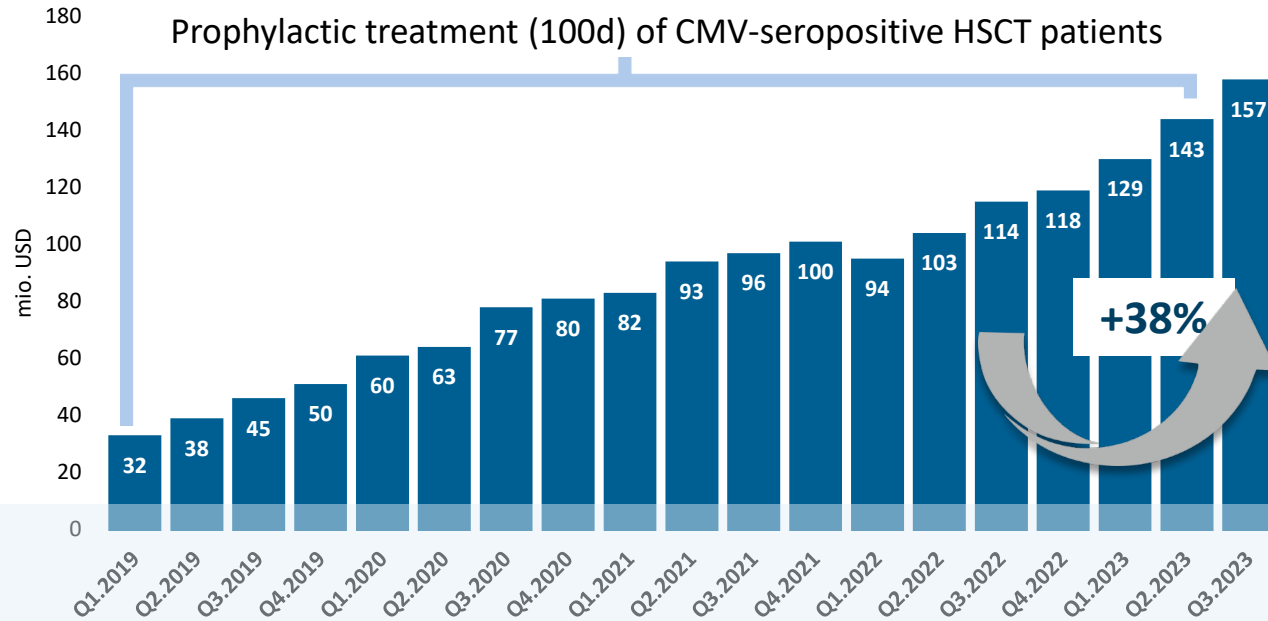
Kidney Transplant

- **Kidney transplant Phase 3 trial** met primary endpoint and showed non-inferiority to valganciclovir with superior tolerability
- **sNDA approved** in June 2023

# PREVYMIS® (LETERMOVIR) GENERATED >\$429M NET SALES YEAR TO DATE 3Q2023

Ongoing label extensions will open additional market opportunities

## Net sales increasing year over year



## Additional market opportunities:

- **HSCT patients** with longer treatment duration (200d), sNDA approved August 2023 in the US; submitted in other countries
- **Kidney transplant patients;** sNDA approved June 2023 in the US; submitted in other countries
- **US and EU pediatric** filing expected in 2024
- **Investigator-initiated trials** in other solid organ transplants (SOT), neonates, HIV and ICU patients might drive additional upside

# 04

Corporate



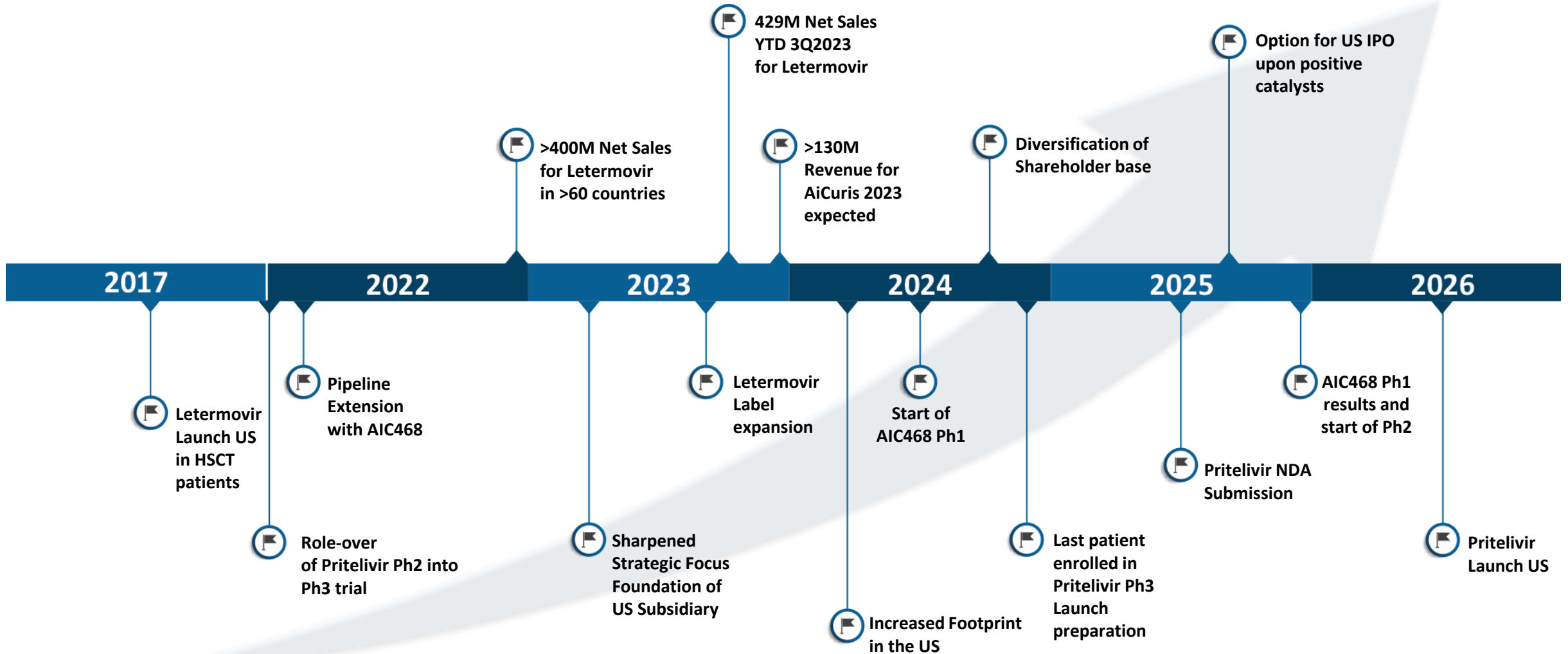
# REVENUES BUILD A STRONG FINANCIAL FOUNDATION FOR FUTURE GROWTH

## Financial Highlights

InM\$ <sup>1</sup>	2023 Year-to-date 30-Sep-2023	2023 31-Dec-2023 (Forecast)
Total Revenues	90.9	133.3
Cost of Sales	(9.2)	(12.9)
R&D Expenses	(37.7)	(50.5)
G&A Expenses	(6.9)	(9.0)
Operating Income (loss)	37.1	60.9
EBT	24.3	44.5
Cash, Cash Equivalents & Marketable Securities	41.1	21.5

# BECOMING A FULLY INTEGRATED BIOPHARMACEUTICAL COMPANY

Delivering Novel Antiviral Therapies to Patients with Weakened Immune System





# ESTABLISHMENT OF US SUBSIDIARY

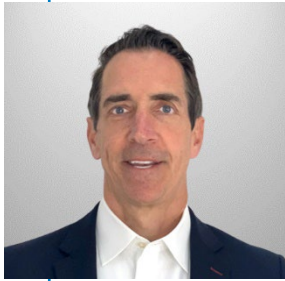
## Experienced and Targeted US Medical and Sales Force



- US subsidiary established in 1H 2023 in Marlborough, MA
- AiCuris current structure allows CEO and CFO to directly manage US Subsidiary and includes access to services (e.g. HR, IT, Finance) from the parental company
- The US buildout will be in an appropriate staggered fashion to maximize growth and minimize cash burn
- A streamlined medical and sales team will be focused on HSCT and SOT centers in the US
- Key HIV centers and HCPs will also be targeted
- Our experienced marketing team will approach non-core patients through effective and measurable non-personal marketing strategies
- For Europe and rest of the world we are aiming to out-license commercialization rights

# AICURIS BENEFITS FROM A STRONG LEADERSHIP TEAM

## Executive Board



Larry Edwards

### Chief Executive Officer

>20 Years of Executive Strategic and Commercial Leadership experience in Biotech & Large Pharma.

Previous CEO of La Jolla, & Tetrphase Pharmaceuticals. Member of several Supervisory Boards for Emerging Biotech Companies



Sabrina Kuttruff-Coqui

### Chief Financial Officer

PhD, Immunology

>10 years experience in the biotech industry

Held various R&D and business leadership positions, latest Head of Business Planning Immatics NV

Joined AiCuris 2022



Holger Zimmermann

### Chief R&D Officer

PhD, Biologist / Virologist

>20 years in pharma and biotech industry

Various scientific and management positions at Bayer & AiCuris, with AiCuris since foundation in 2006

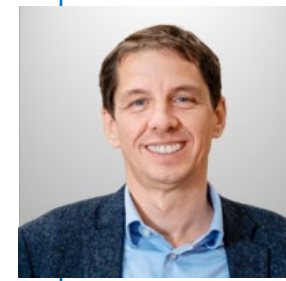
## Supervisory Board



Stefan Oschmann

### Chairman of AiCuris Supervisory Board

Chairman of UCB, Member of the Supervisory Board Springer Nature. Various Management positions, latest as Chairman of the Executive Board & CEO of Merck KGaA



Helmut Jeggle

### Executive Officer Salvia GmbH

Worked in leading positions at ATHOS KG from 2007 until April 2021; Member of numerous Supervisory Boards including BioNTech SE (as Chairman) and 4SC AG



Helga Rübsamen-Schaeff

### Founding CEO of AiCuris

Member of the Board of Partners & Chair of the Research Council of E. Merck KG, Member of the Supervisory Board of Merck KGaA and of the National Academy of Science, Leopoldina



Sean Marett

### CBO and CCO BioNTech SE

Member of BioNTech's Executive Board since 2012, prior positions in global strategic and regional marketing at GlaxoSmithKline (US) and Pfizer (EU), Business Development Executive at Evotec and Loralis

# WELL POSITIONED FOR FUTURE GROWTH

Multiple upcoming inflection points, including Phase 3 asset with Breakthrough Therapy Designation

\$133M Revenue from royalties and milestone payments YTD 4Q2023 (F)

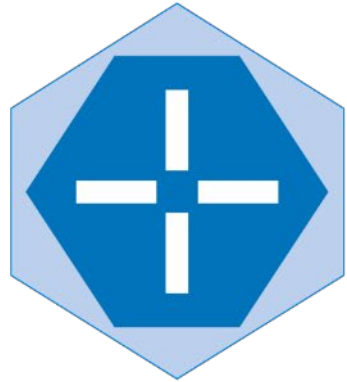
\$21M<sup>1</sup> Cash/Cash equivalents & positive Cash Flow 2023

Strong and committed shareholder base, led by majority Shareholder ATHOS KG

Executive Management and prize-winning R&D team with direct experience bringing antivirals to market

Germany-based R&D hub with recently formed commercial subsidiary in the US





# AiCuris

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Thank you for your attention

