AiCuris

Anti-infective Cures

Delivering Anti-Infectives to Patients in Need

Non-confidential Slide Deck

May 2023

FORWARD LOOKING STATEMENTS

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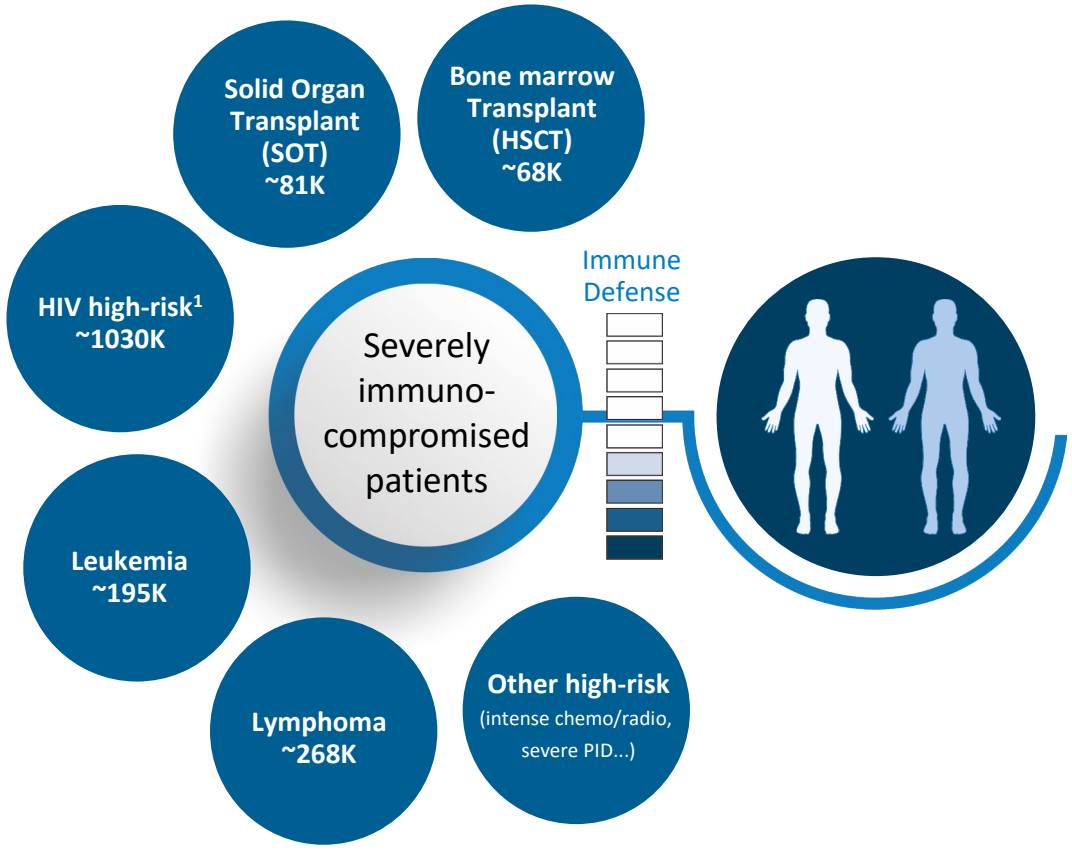
AICURIS AT A GLANCE

Delivering Anti-Infectives to Patients in Need

- Novel anti-infective treatment options for immunocompromised patients
- Comprehensive Research & Development Engine from Discovery to Phase 3
- Proprietary, differentiated candidate with fast track to launch
- R&D Pipeline for value creation with multiple inflection points within 24M
- Solid financial foundation for future growth from commercial partnership
- Experienced Management & Supervisory Board with Extensive Industry Track Record

AiCuris Anti-infective Cures

A SIGNIFICANT NUMBER OF PATIENTS ARE SEVERELY IMMUNOCOMPROMISED

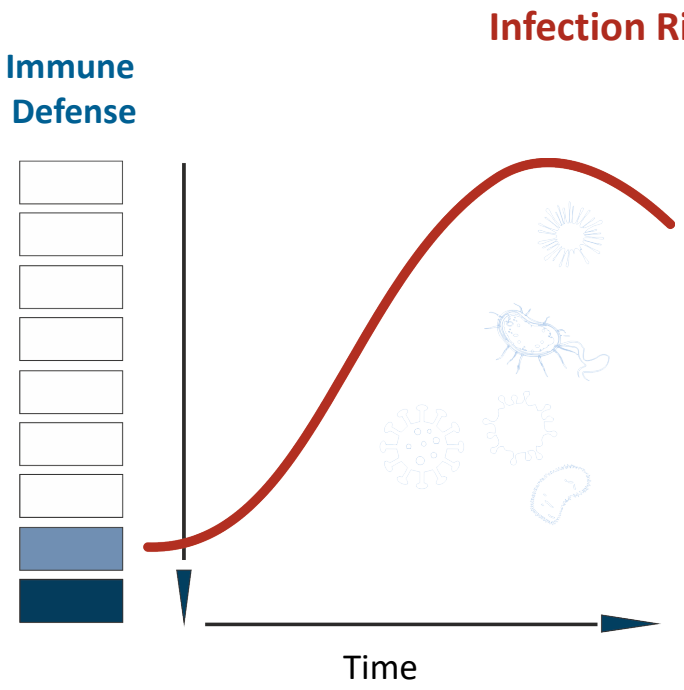


- Several diseases are associated with **severe immune deficiencies** (e.g., hematologic malignancies)
- Other medical conditions require **immune-suppressive treatments** (e.g., HSCT, SOT)
- Aggressive treatments to increase life expectancy lead to **prolonged immune-suppression**
- In addition, **>1B patients are moderately immunocompromised** (e.g., patients with cancer, chronic or autoimmune diseases)

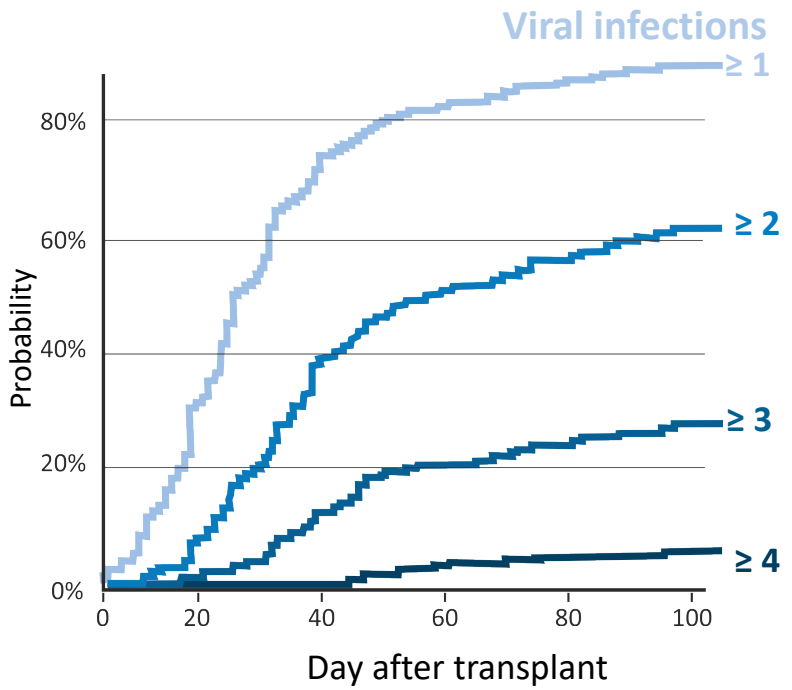
Patient numbers are shown as new cases per year for the 7 major markets (US, China, Japan, Germany, France, Italy, UK; references on file), developing countries not referenced.
[1]Total prevalence of high risk for infection due to suboptimal antiretroviral therapy (https://cfs.hivci.org/ & De Los Rios et al., Preventive Medicine, 2020).

IMMUNOCOMPROMISED PATIENTS HAVE A HIGH MEDICAL NEED FOR ANTI-INFECTIVES

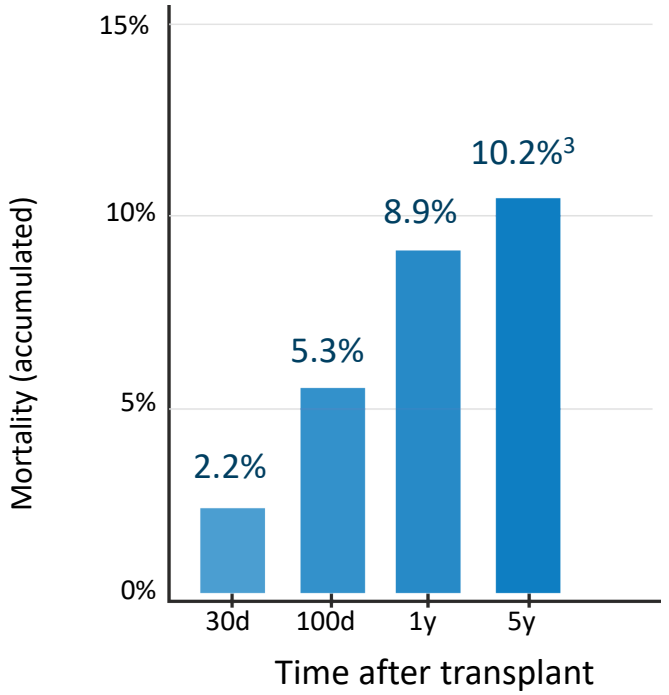
Risks for Infection vs Immune status



Probability of viral infections (after HSCT[1])



Mortality due to infections (after HSCT[2])



Immunocompromised patients are at high risk for infections → **Latent infections reactivate & new infections are contracted** → **Recurrent infections lead to severe disease & mortality**

[1]Adapted from Hill et al., Blood, 2017
[2]Adapted from Styczynski et al., Bone Marrow Transplantation, 2020
[3]Accounting for 22.3% of total deaths during observation period.

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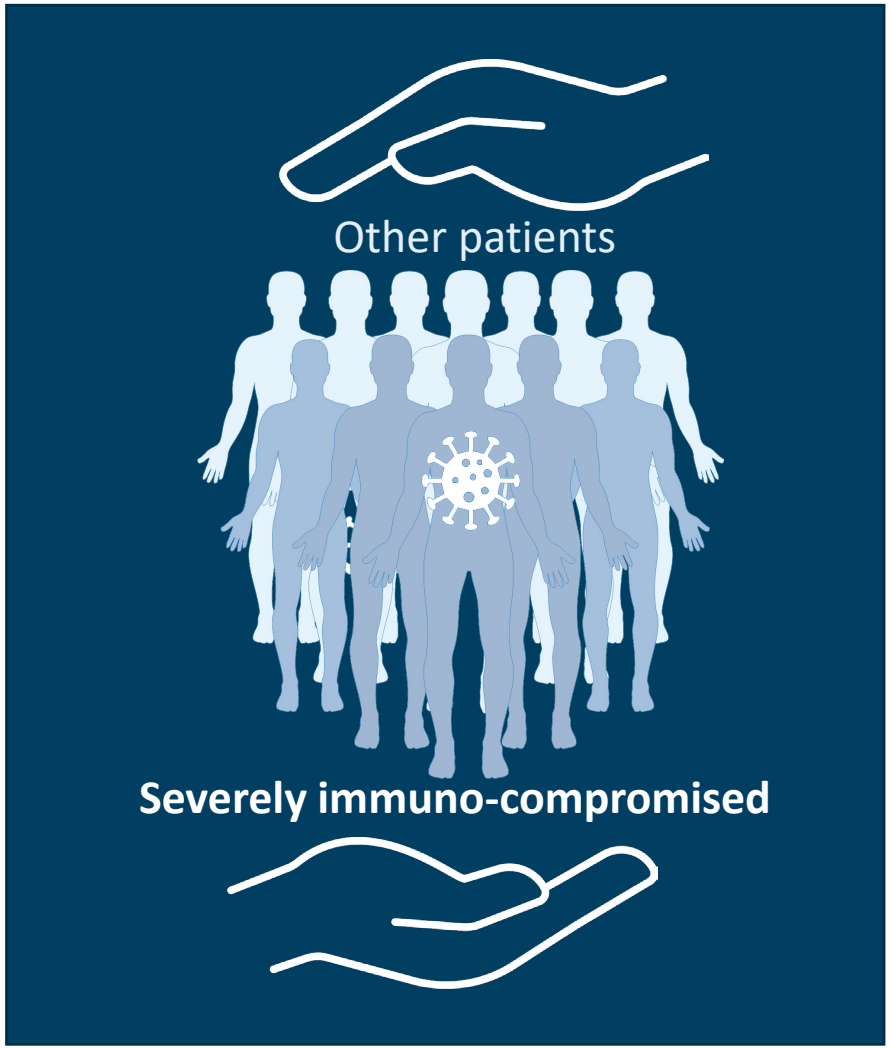
WE ARE DELIVERING ANTI-INFECTIVES TO A GROWING PATIENT POPULATION



- Increasing need for **anti-infective agents**, market growing at 3.19% CAGR from 2022 – 2028[1]
- **Population of immune compromised patients is growing rapidly** (e.g., HSCT growing at 5.9% CAGR[2]; SOT at 3.7%[3])
- Novel and prolonged treatments of underlying conditions are leading to an **increasing need for anti-infectives**
- **Increasing drug resistances** are observed due to increasing spread and occurrence of infectious agents
- **Only few companies are serving patients with anti-viral therapeutics**

[1]Anti-Infective Agents Market Report, The Insight Partners
[2]HSCT Market Size Report, Technavio
[3]United Network for Organ Sharing (www.unos.org)

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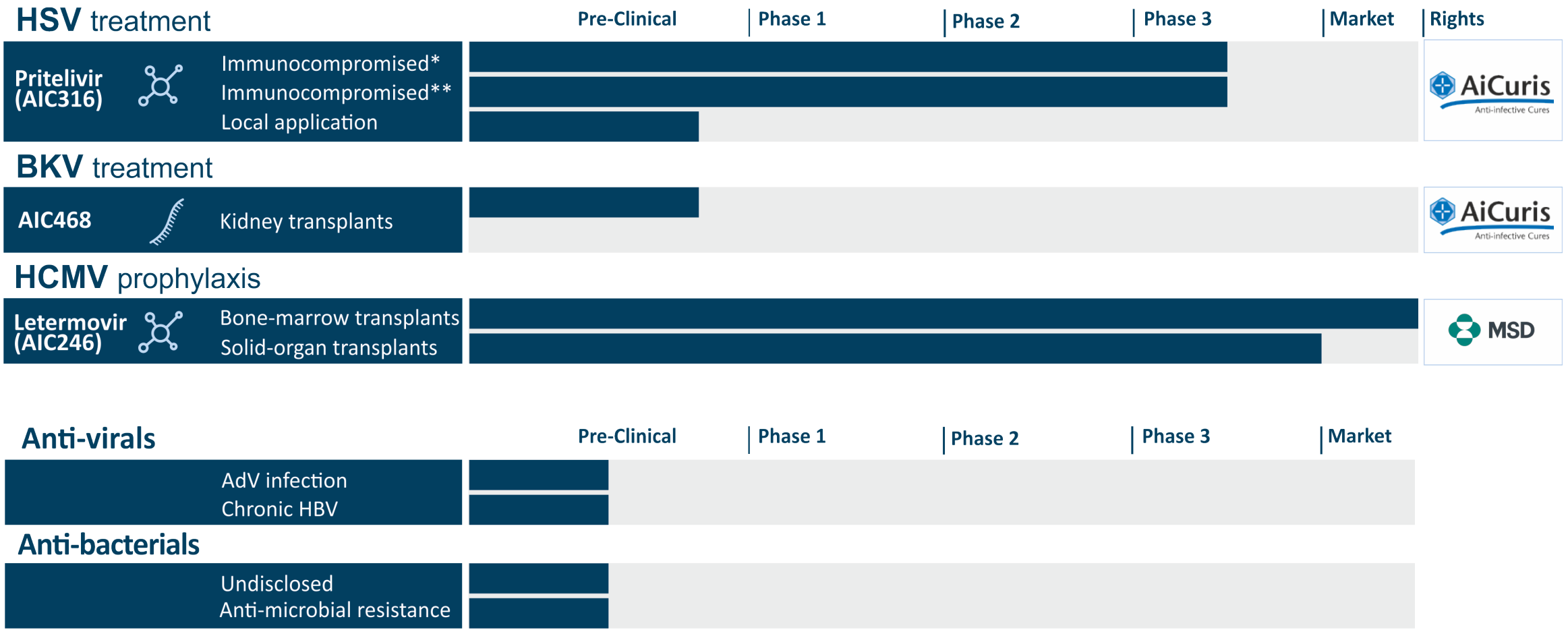
FOCUSED R&D PIPELINE SERVING IMMUNOCOMPROMISED PATIENTS



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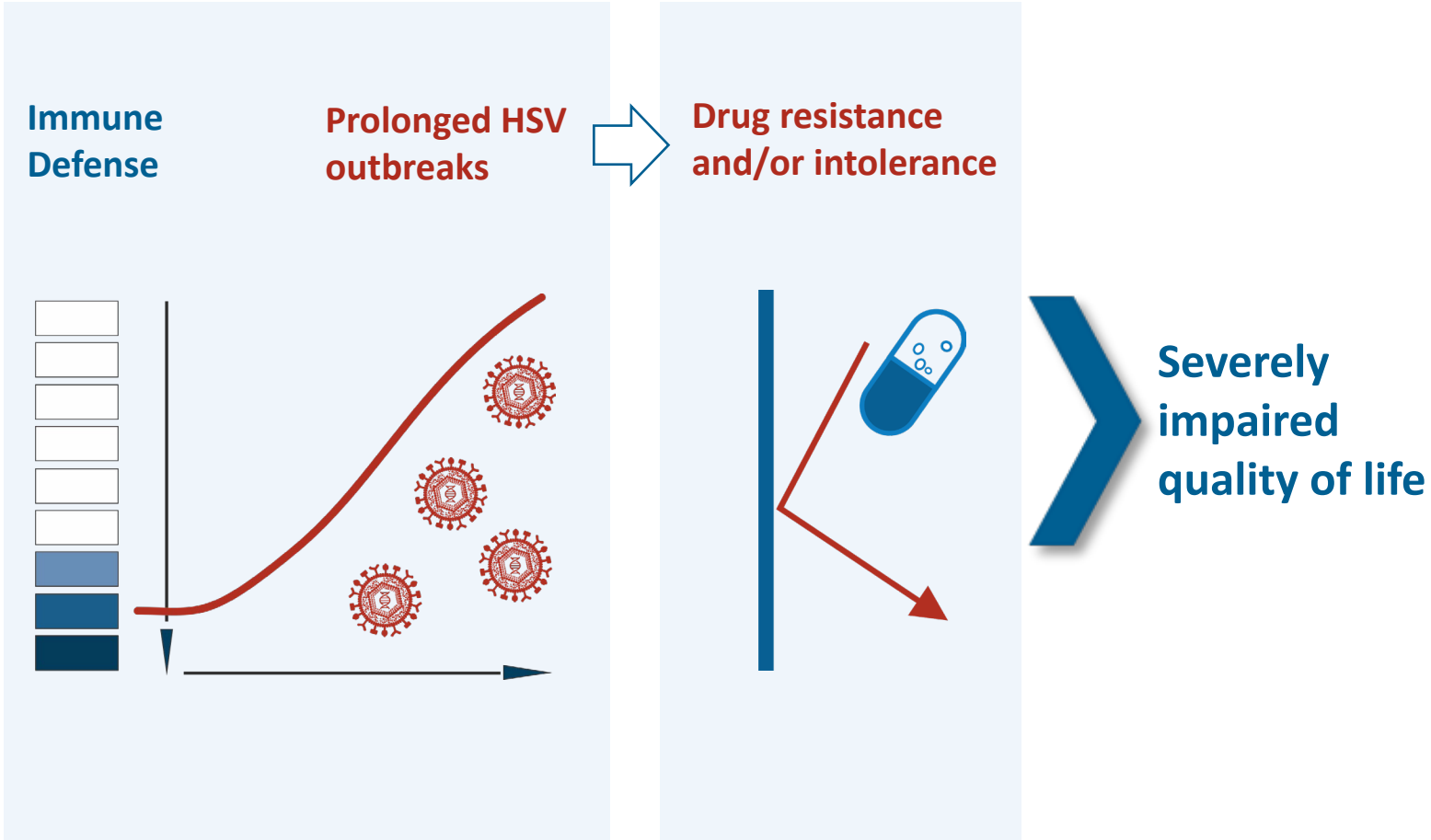
01

Pritelivir (AIC316)

HERPES SIMPLEX VIRUS CAUSES RECURRENT AND PAINFUL LESIONS

High medical need in immunocompromised patients

- **3.7B & 0.5B people** latently infected with **HSV-1 & HSV-2,** respectively[1]
- HSV-2 manifests in **genital herpes, labialis, retinitis, meningitis & sepsis** with **80-90% recurrences**
- **More frequent, prolonged & severe** manifestations in immunocompromised patients (IC)
- **Up to 25%[2]** of IC patients develop **drug resistances** and are at risk for disseminated disease
- **Painful mucocutaneous lesions** lead to increased hospitalization rates



[1]Global prevalence HSV-1: 66%; HSV-2: 16% (www.who.int/news-room/fact-sheets/detail/herpes-simplex-virus)
[2]Morfin et al., Clinical Virology, 2004

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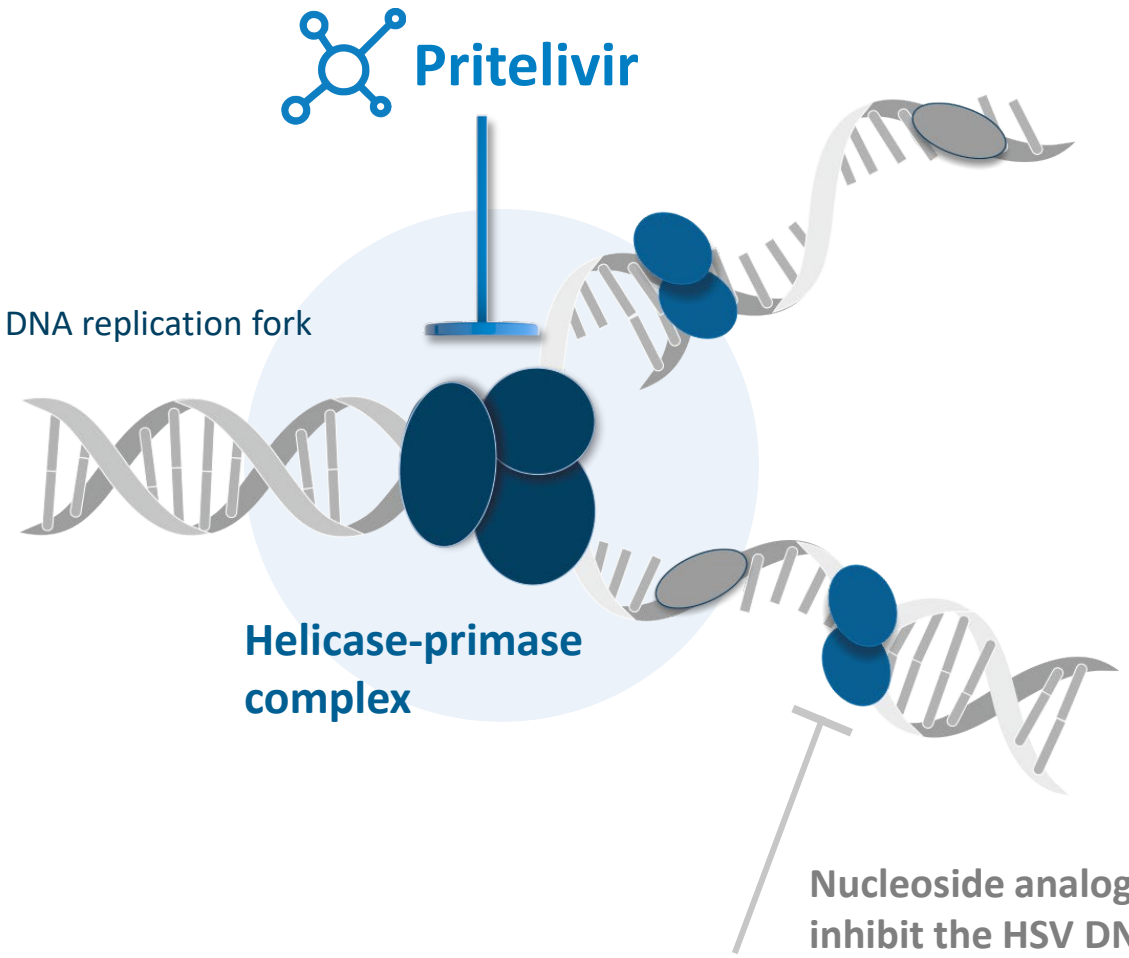
PRITELIVIR IS A SMALL MOLECULE WITH A NOVEL MECHANISM OF ACTION

Pritelivir inhibits viral helicase-primase



- Pritelivir is a small molecule inhibiting **viral replication of HSV-1 and HSV-2**
- In contrast to existing drugs, Pritelivir targets the **viral helicase-primase complex**
- Pritelivir **prevents infection of uninfected cells** as it does not require activation by viral enzymes

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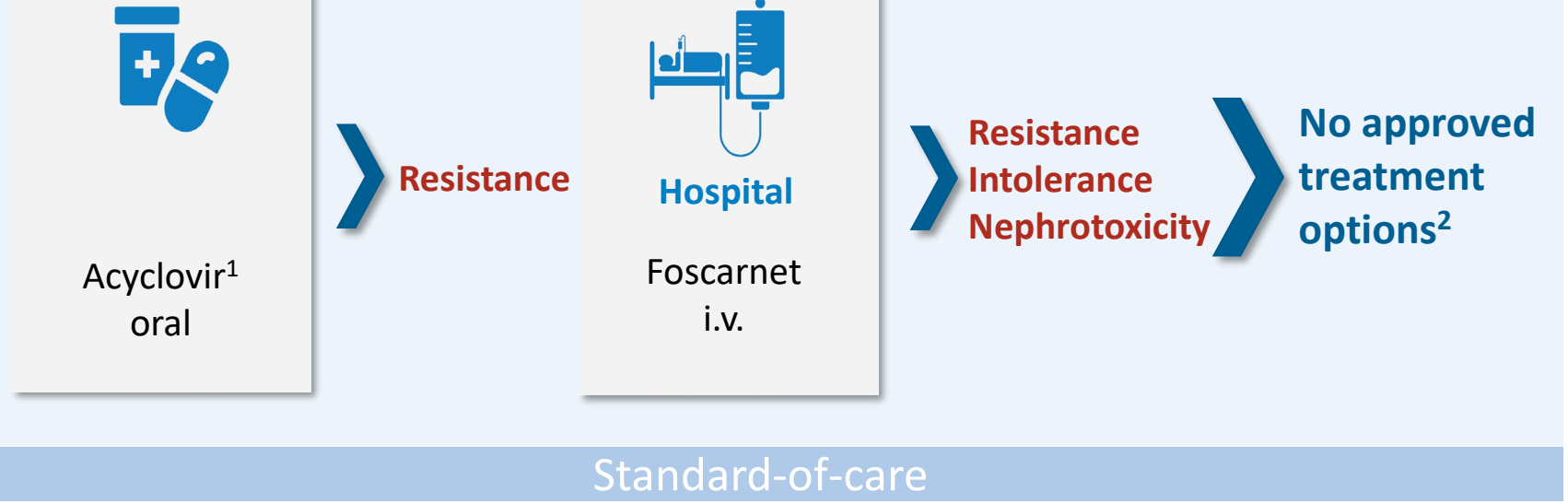
PRITELIVIR IS DESIGNED TO TREAT PATIENTS WITH DRUG-RESISTANT INFECTIONS

Patient Journey

- Novel treatment alternative for patients with **resistance to nucleoside analogs** (standard-of-care)
- **Differentiating from Foscarnet** by:
  - Favorable bioavailability and half-life, allowing for convenient **oral, once daily application**
  - **Favorable risk/benefit ratio** and safety profile

PRITELIVIR POSITIONING
Oral application **without** requirement for hospitalization



[1]Or prodrugs with increased oral bioavailability (valacyclovir or famciclovir)
[2]Cidofovir or topical Imiquimod as salvage treatments

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PRITELIVIR OBTAINED FDA BREAKTHROUGH THERAPY DESIGNATION

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

- **Higher healing rate in single-resistant patients**
  - **Acyclovir-resistant** patients: Pritelivir vs Foscarnet 2:1
- **Favorable safety profile:** no drug-related AEs with Pritelivir in single-resistant patients
- **Healing demonstrated in 63% of patients without treatment options**
  - **Dual-resistant** patients: Acyclovir-resistant and Foscarnet-resistant and/or –intolerant

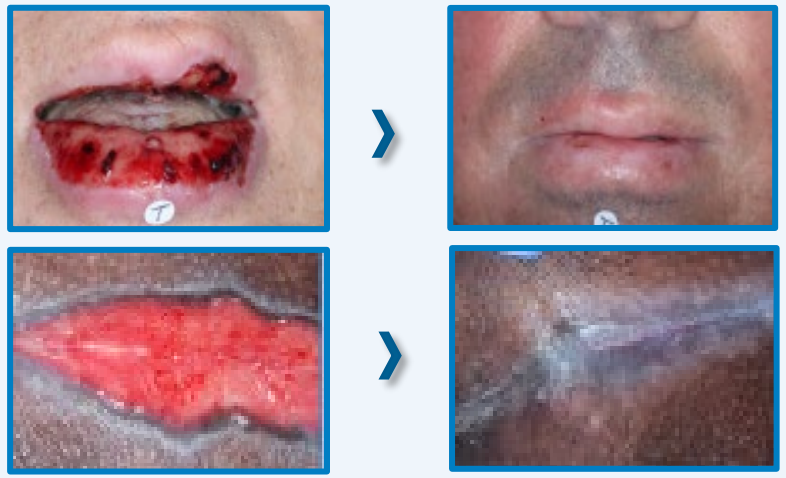
BREAKTHROUGH THERAPY

Summary of healing rates by treatment

Healing Rates	Pritelivir	Foscarnet
Acyclovir-Resistant Pts *Secondary Indication*	**93%** (14/15 pts)	**57%** (4/7 pts)
Dual Resistant Pts *Primary Indication*	**63%** (5/8 pts)	N.A

Data on file

Acyclovir-resistant infection > Post-Pritelivir treatment



Workowski et al., Poster presentation, ID week 2021

All data included in this presentation are preliminary unless explicitly stated otherwise

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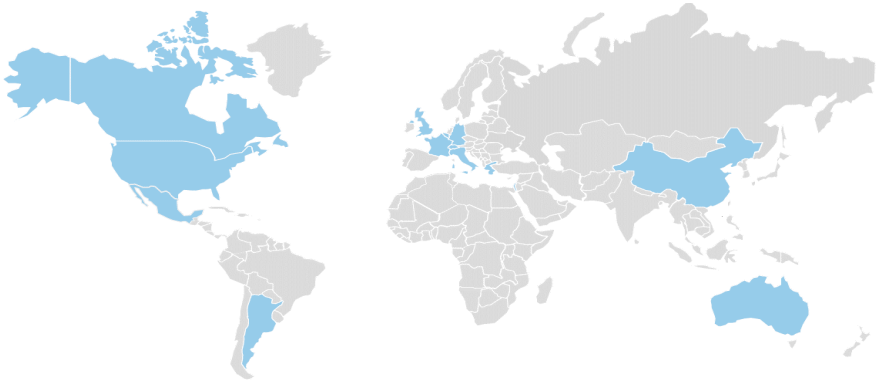
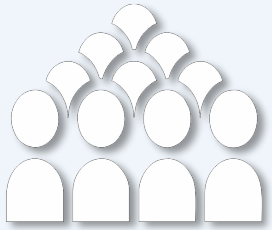
PRITELIVIR PHASE 3 TRIAL IS ACTIVELY ENROLLING PATIENTS

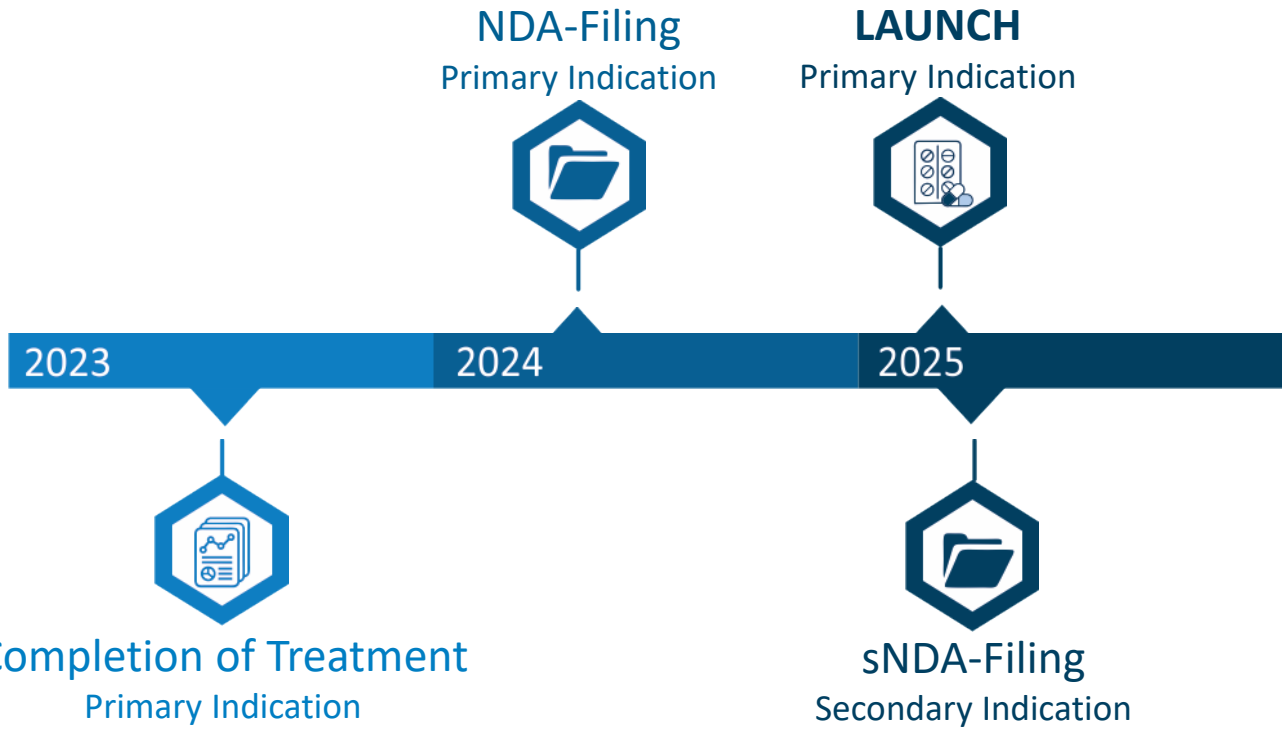
Completion of patient enrollment for primary indication expected in 2023

- **Randomized, open-label, multi-center trial** enrolling up to 150 additional immuno-compromised patients
- Healing rate at day 28 as **Primary Endpoint**
- **Initial approval** targeted in dual-resistant patients (Primary indication)
- **sNDA planned for ACV-resistant patients** (Secondary indication)





- **Patient enrollment at 70 sites in 15 countries**
- **Enrollment on track for NDA filing**



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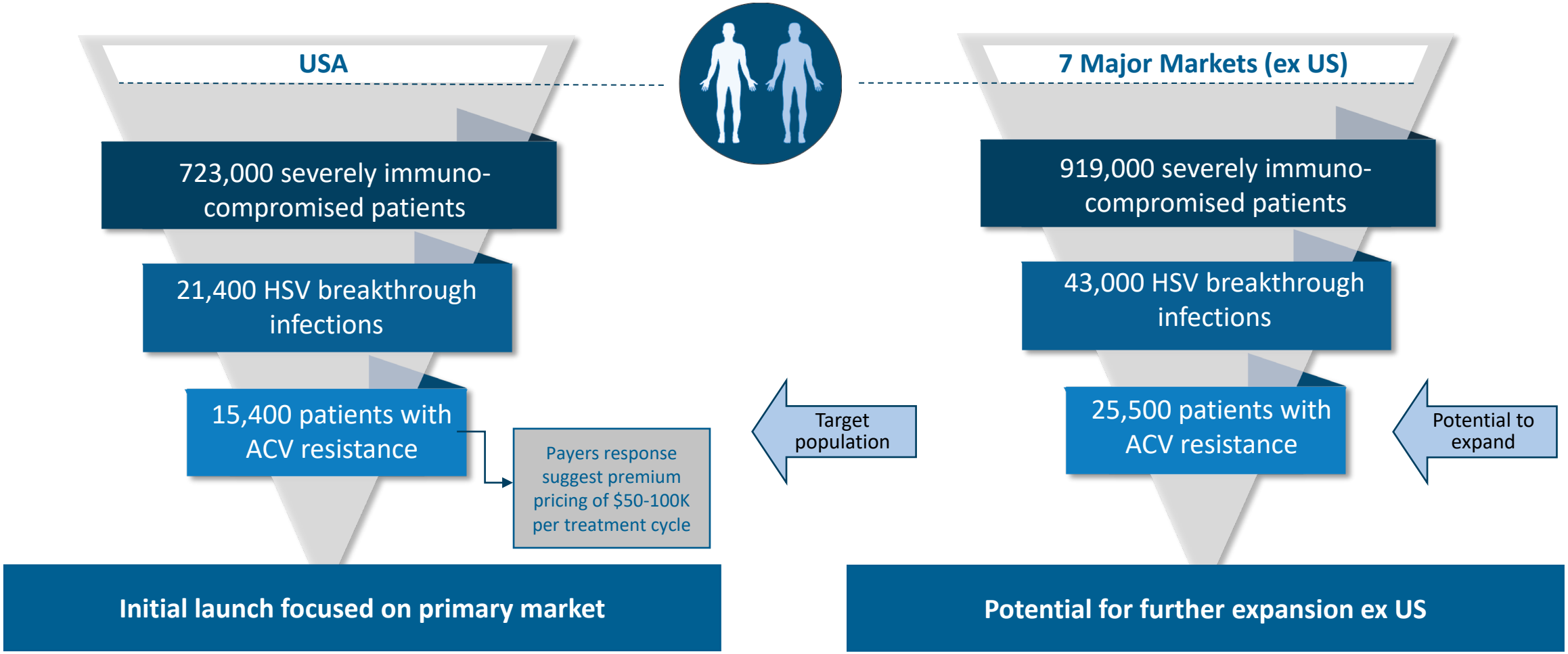
TARGETING A NICHE POPULATION WITH POTENTIAL FOR EXPANSION

Primary use in immunocompromised Acyclovir (ACV)-resistant patients



Multiple references (on file at AiCuris).

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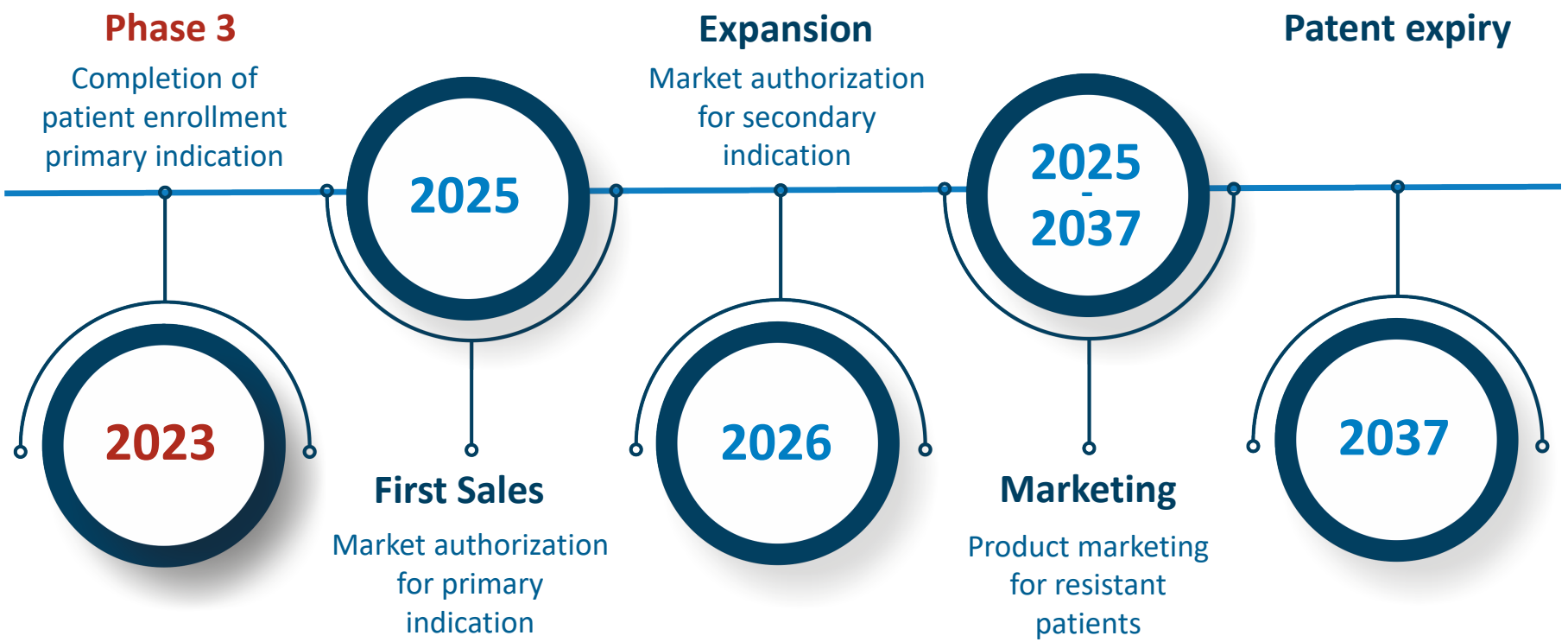
ONGOING DIALOGUE WITH FDA FOR RAPID PATH TO MARKET



Launch Preparation ongoing

- Ongoing dialogue with FDA facilitated by breakthrough desig.
- Medical Awareness activities started
- CMC registration batches manufactured
- AiCuris US presence established

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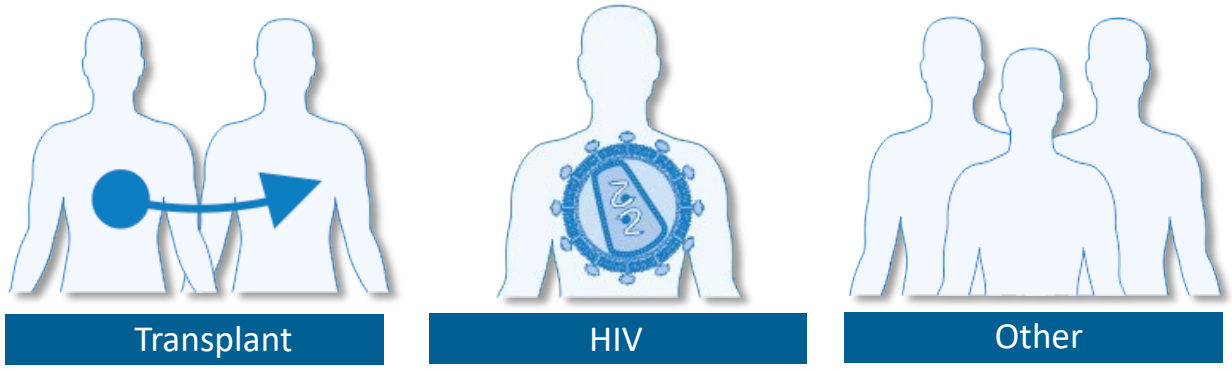
PRITELIVIR IS WELL POSITIONED TO FILL RELEVANT GAPS IN A HIGH-NEED MARKET

- **Early Access Program ongoing**:
  - ~60 patients with more than 80 outbreaks treated in 10 countries
  - Majority are transplant (57%) or HIV-infected (25%) patients
  - 31 out of 44 evaluable patients with documented healing of lesions (70%)[1]



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)

[1]Birkmann et al, oral presentation NIH 2022

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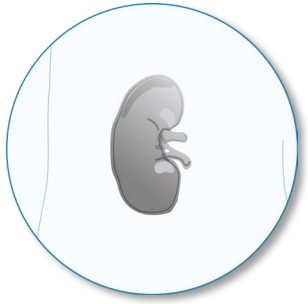
02

AIC468

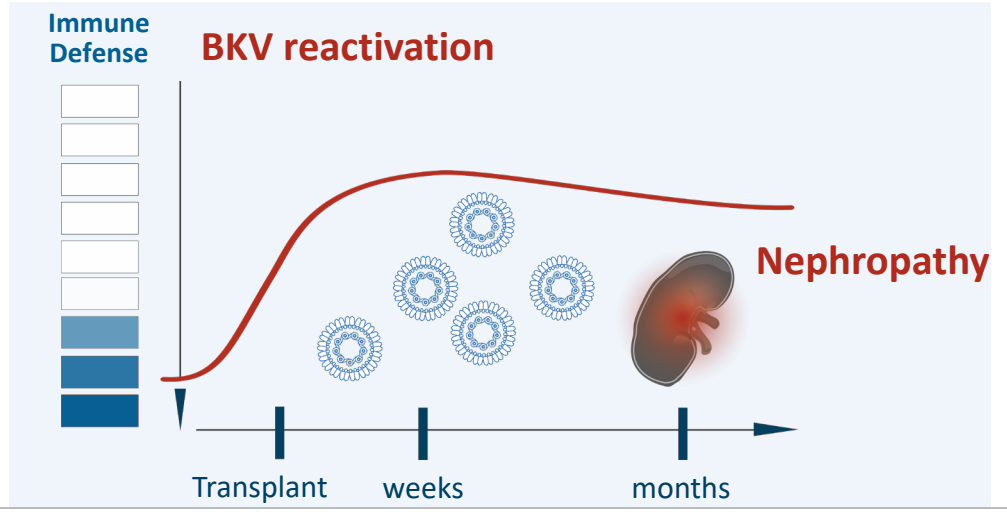
BK VIRUS REACTIVATION LEADS TO SEVERE CONDITIONS AND GRAFT LOSS

In SOT and HSCT transplanted patients

- **>80%** of western population is **latently infected with BKV**
- Reactivation of BKV can lead to **nephropathy in up to 10%**[1] of kidney transplant patients, directly risking **graft loss**
- In HSCT patients, BKV reactivation leads to **severe, hemorrhagic cystitis** (~10%[2])
- The only current treatment option is the **reduction of immune suppression**, further increasing risk of transplant failure and death

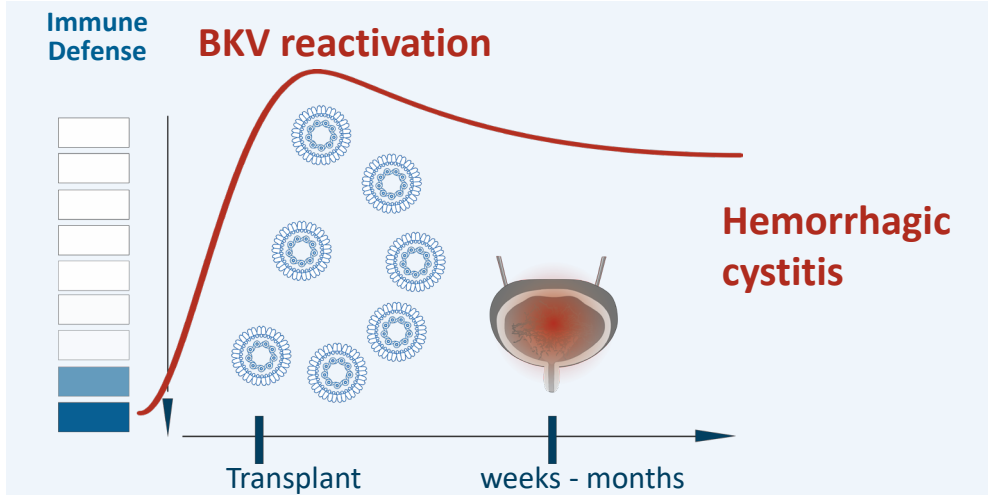


Kidney



Graft loss

Bone-marrow (HSCT)



Dysuria, Hematuria potentially deadly condition[3]

[1]Ambalathingal et al., Clinical Microbiology, 2017
[2] Hricik et al., JASN, 2023
[3]prolonged hospitalization to control bleeding, kidney dysfunction, intense pain

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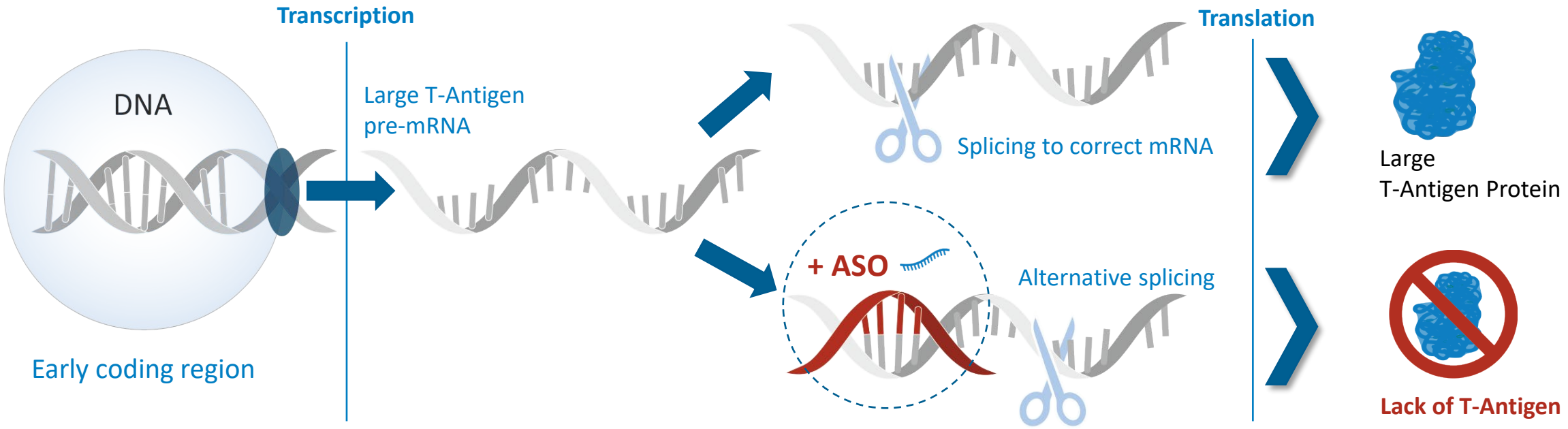
AIC468 AS NOVEL APPROACH TO INHIBIT BK VIRUS REPLICATION

AIC468 – An Antisense Oligonucelotide (ASO)



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

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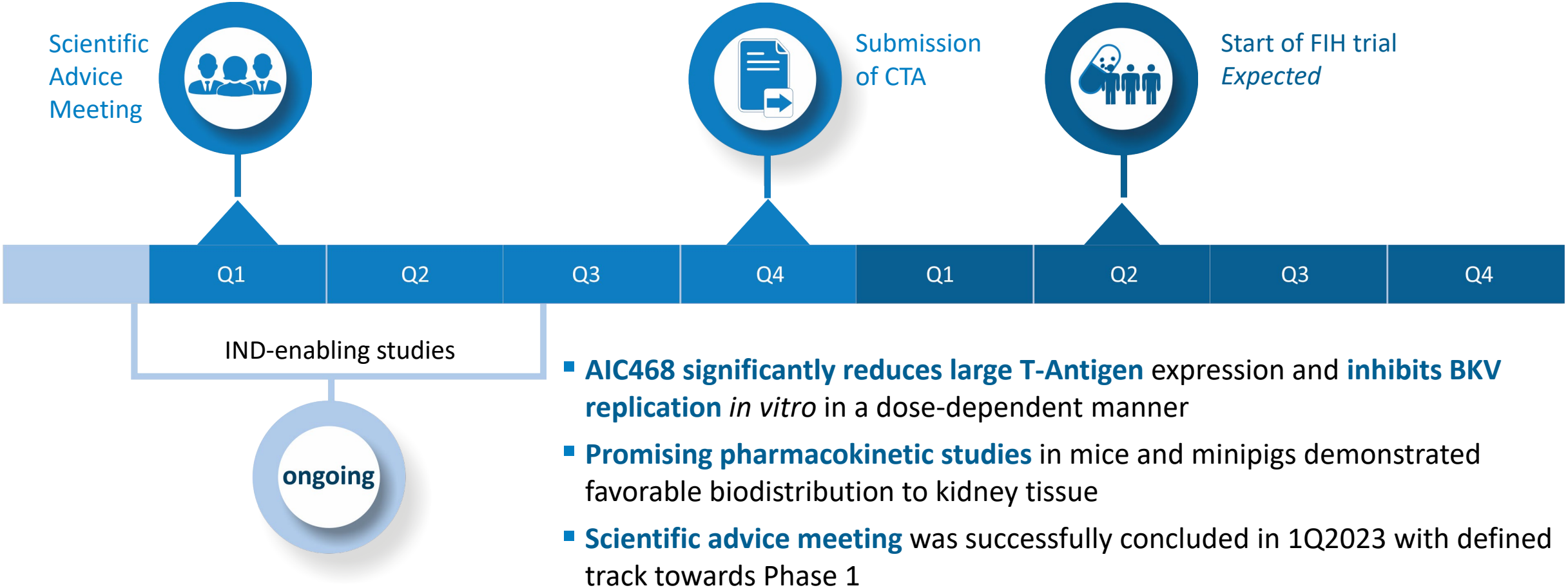
AIC468 CLINICAL TRIAL APPLICATION ON TRACK FOR 2H2023

Phase 1 trial in preparation based on promising preclinical data



- **AIC468 significantly reduces large T-Antigen** expression and **inhibits BKV replication** *in vitro* in a dose-dependent manner
- **Promising pharmacokinetic studies** in mice and minipigs demonstrated favorable biodistribution to kidney tissue
- **Scientific advice meeting** was successfully concluded in 1Q2023 with defined track towards Phase 1
- **IND enabling studies ongoing; First-in-human Trial** start envisioned **1H2024**

All data included in this presentation are preliminary unless explicitly stated otherwise

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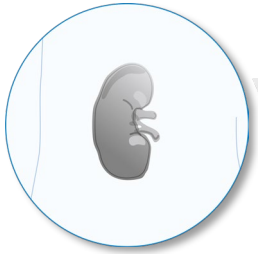
SIGNIFICANT MARKET POTENTIAL IN KIDNEY TRANSPLANTS

Expansion potential in HSCT



7 Major Markets

49,500 Kidney transplant patients

28%

13,900 patients with BK viremia

Target population (Pre-emptive therapy)

7,000 in US

Up to 10% of KT

5,000 patients with BKV nephropathy

Primary Indication with significant market potential

7 Major Markets

68,000 HSCT patients

50%

34,000 patients with BK viruria

Up to 10% of HSCT

6,800 with severe Hemorrhagghic Cystitis

Target population

2,200 in US

Potential for further expansion

Multiple references (on file at AiCuris).

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AIC468 IS IDEALLY POSITIONED TO TACKLE BK VIRUS

Intracellular approach with novel mode-of-action

- **Novel approach** directly targeting the virus in infected cells **overcoming limitations of other approaches in development** (antibodies, cellular immunotherapies)
- **Rapid path to market in primary indication:** pre-emptive treatment of BK viremia in kidney transplant patients to prevent graft loss
- **Significant market potential in primary indication** with option to expand to HSCT
- **Patent filed**

HYBRIDIZE THERAPEUTICS

AiCuris and Hybridize Therapeutics entered worldwide license agreement for a direct-acting RNA-based therapy against BK Virus in 2021

High medical need with **no approved treatment option**

Antisense-oligonucleotide with direct anti-viral activity

Fast development track in primary niche indication

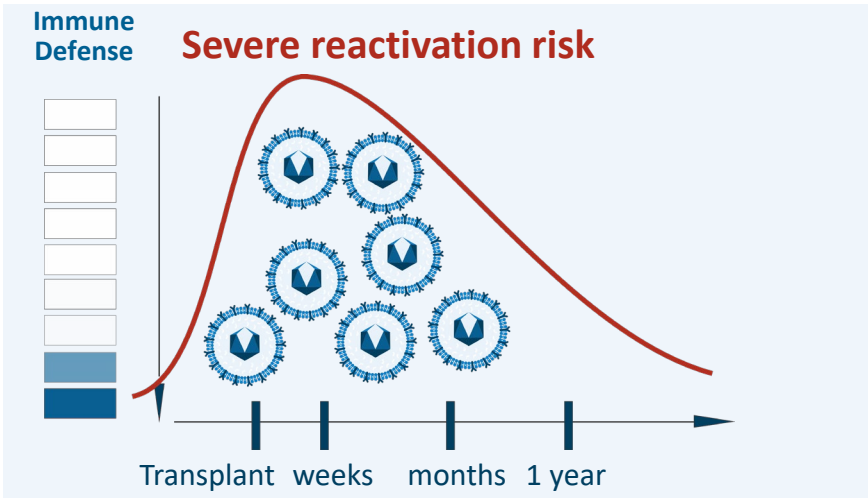
03

Letermovir (AIC246)

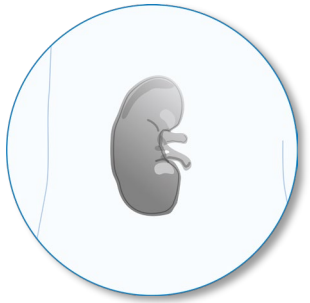
HCMV REACTIVATION LEADS TO INCREASED MORTALITY IN TRANSPLANT PATIENTS

- **>70%** of the adult population is **latently infected** with human cytomegalovirus (HCMV)
- **Reactivation of HCMV** occurs in 60-70% of seropositive HSCT patients and is associated with **increased mortality**
- Prior to Letermovir NDA approval treatment options for HSCT patients were limited to preemptive treatment associated with severe side effects
- Treatment options for SOT patients include the reduction of immuno-suppression, **risking graft loss**

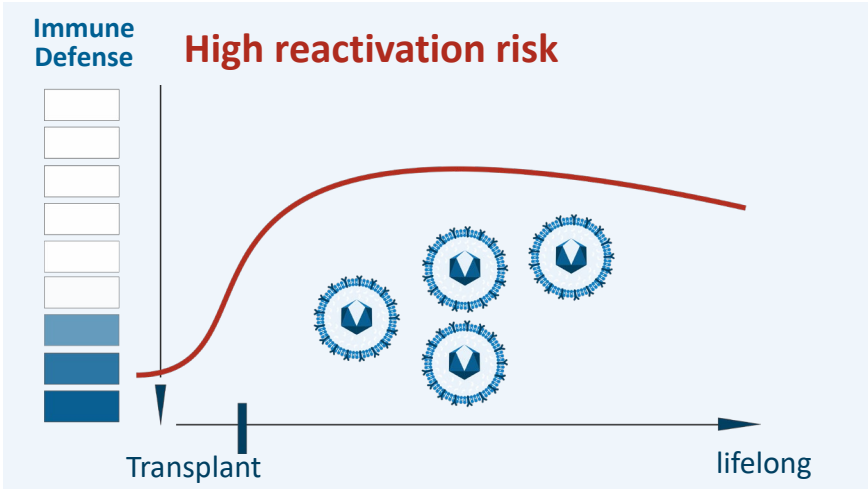
Bone-marrow (HSCT)



Increased mortality



Solid organ (kidney)



Increased risk of graft loss

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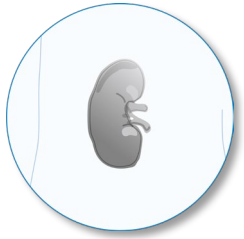
LETERMOVIR MET PRIMARY ENDPOINT IN TWO ADDITIONAL PHASE 3 TRIALS IN 2022

Marketed for HSCT, additional sNDA's submitted

Bone-marrow (HSCT)

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

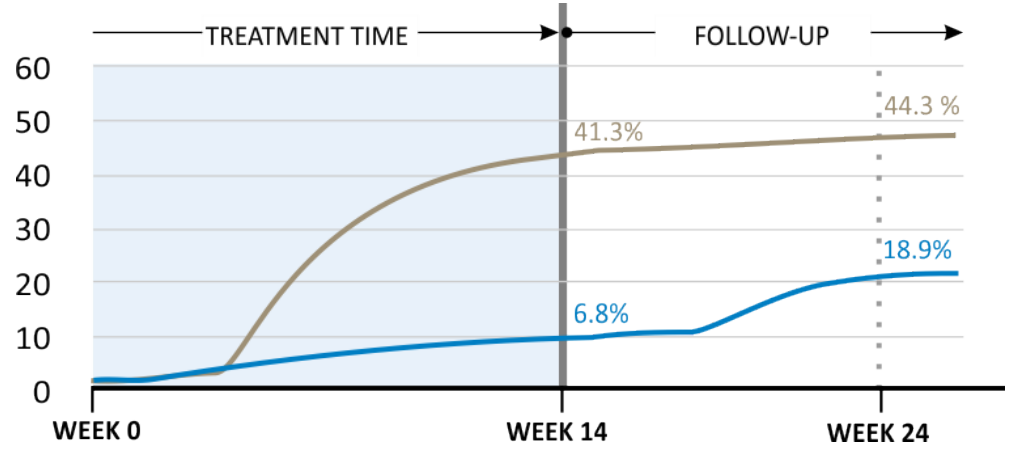


Solid organ (kidney)

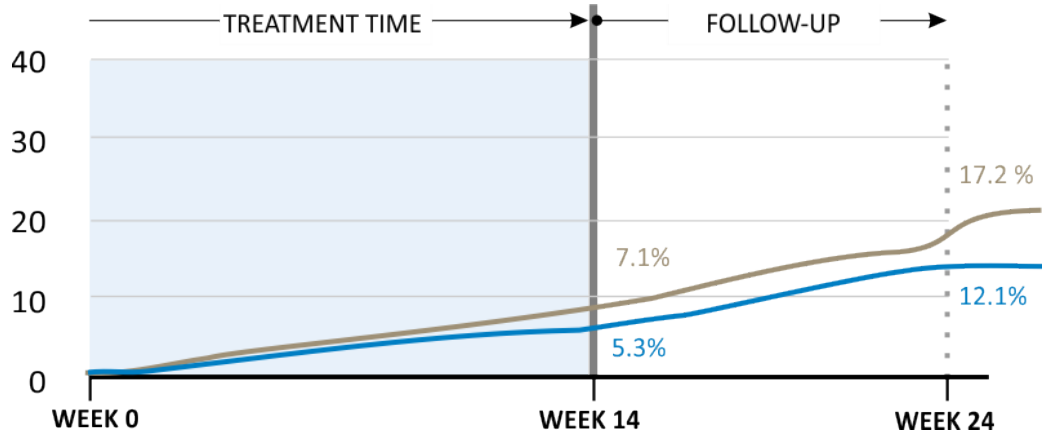
- Phase 3 trial in kidney transplant patients **met primary endpoint**

  (data not shown; ID week 2022; LB2307)
- sNDA submitted 2022, **FDA priority review**

Clinically significant HCMV infection (HSCT)



All-cause Mortality (HSCT)



Marty et al., 2017, NEJM | Ljungman et al., 2019, CID

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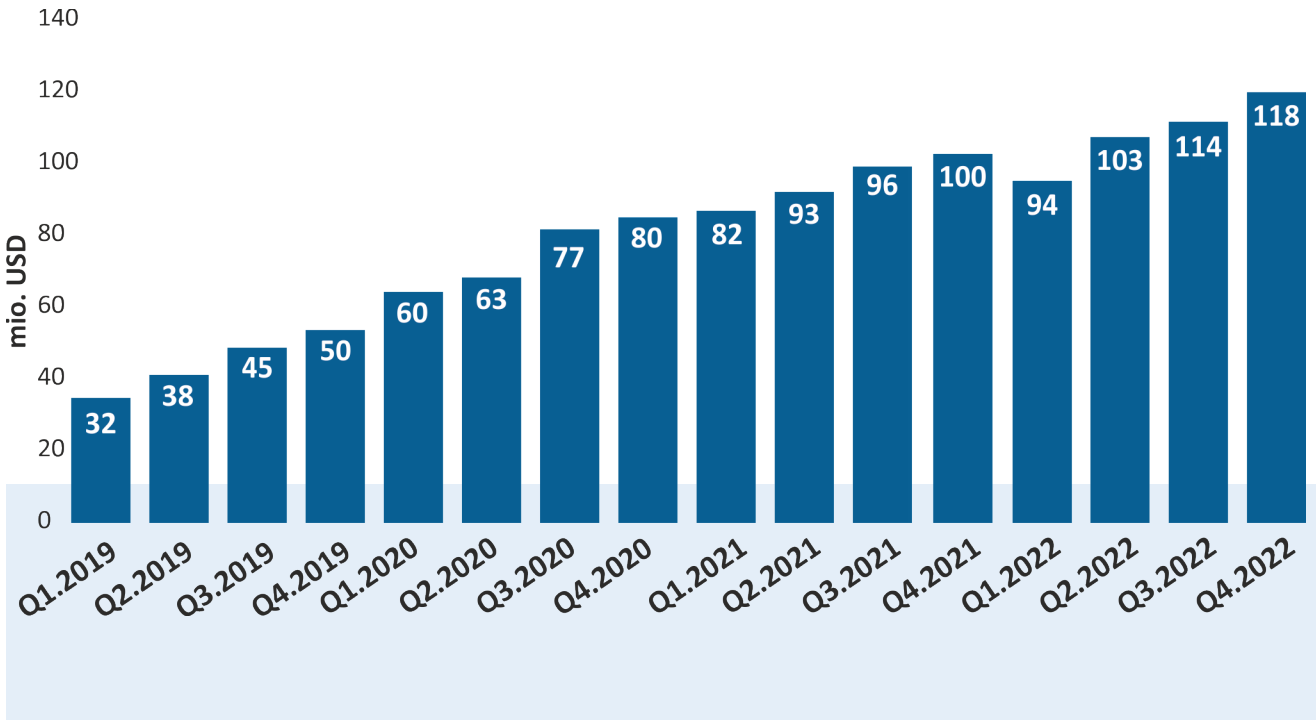
LETERMOVIR GENERATED >$400M NET SALES WITHIN THE INITIAL HSCT LABEL IN 2022

15% Increase Over Net Sales 2021

Worldwide Revenues Prevymis



- >$400M sales within **initial label for limited prophylactic treatment (100days)** for CMV positive HSCT patients
- **sNDA submitted** after two successful phase 3 studies demonstrating
  - improved HSCT patient outcomes with longer treatment duration (200days)
  - non-inferiority to valganciclovir with superior tolerability in kidney transplanted patients
- Additional **market opportunity in solid organ transplants** expected
- Investigator-initiated trials in other SOT's, newborns, HIV and ICU patients might drive additional upside

All data included in this presentation are preliminary unless explicitly stated otherwise

AICURIS PARTICIPATES IN COMMERCIAL SUCCESS BY ROYALTIES & MILESTONE PAYMENTS

A niche indication with blockbuster potential

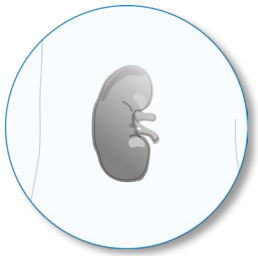
Worldwide

82,000 HSCT patients

38,000 allo-HCST patients

Marketed

Of them 9,100 in US



Worldwide

144,000 SOT patients

92,000 Kidney transplanted patients

Expansion Potential

Of them 25,500 in US

Priority Review

>30K patients are eligible for Letermovir treatment in US only

Multiple references (on file at AiCuris).

AiCuris Anti-infective Cures

LETERMOVIR PROTECTS IMMUNOCOMPROMISED PATIENTS

First-in-class prophylactic treatment for HCMV infection

- **Out-licensed to MSD** (Merck & Co., Inc., Rahway, NJ, USA)
- Regulatory **approved and marketed** in 60 countries for HSC transplants
- Well perceived by the medical community as **“Game Changer”** in HCMV prophylaxis
- **AiCuris participates in commercial success by royalty and milestone payments** (regulatory and sales)

New viral target
with no human counterpart

Prophylactic treatment for immunocompromised patients

Annual Net Sales >$400M:
Quarterly royalty stream to AiCuris

AiCuris
Anti-infective Cures

04

Corporate

DRIVING VALUE THROUGH MARKETING AND FOCUSED R&D

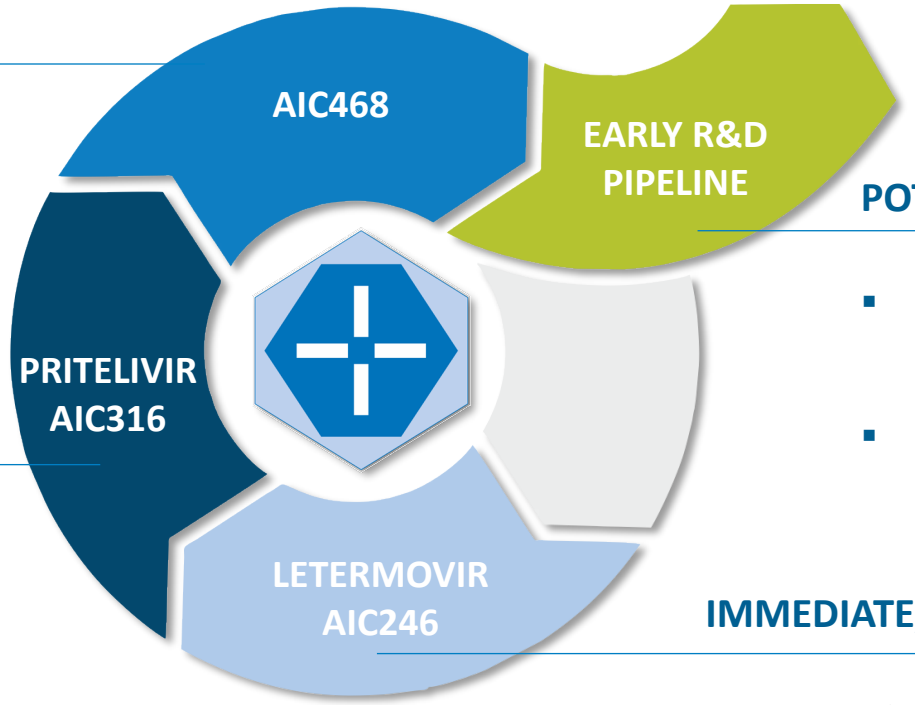
Clear path to becoming fully integrated biopharmaceutical company

SOLID PATH TO LONG TERM VALUE

- Rapid development in an indication without approved treatment options
- Expansion of AiCuris commercial portfolio in the same patient population

DRIVING SHORT TERM VALUE

- First product* launch expected for 2025 and subsequent marketing by AiCuris
- Additional cashflow through partnering outside the US & launch in extended population 2026



POTENTIAL BEYOND

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

IMMEDIATE, CONTINUING CASH FLOW

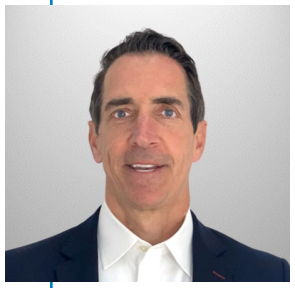
- Income by royalties, regulatory & commercial milestones
- Enabling advancing our R&D portfolio

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

AiCuris Anti-infective Cures

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, & Tetraphase 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 Lorantis

VALUE GENERATION BY MULTIPLE CATALYST OVER THE NEXT 18-24 MONTHS

1H2023

- ✓ Pritelivir: FDA End of Phase 2 meetings finalized
- ✓ Corporate: US subsidiary formed
- ✓ Pritelivir: Registration batches manufactured
- ✓ Letermovir: sNDA (200d treatment) submission accepted
- ✓ Letermovir: sNDA (kidney transplant) accepted for FDA priority review

2H2023

- Pritelivir: Patient enrollment completed for first indication
- Pritelivir: FDA preNDA meeting finalized
- AIC468: Clinical trial application submitted

2024

- Pritelivir: NDA filed
- Pritelivir: Patient enrollment completed for second indication
- AIC468: Start of first in human trial
- Pritelivir: Distribution for supply chain secured
- Pritelivir: NTAP filed

WE ARE IDEALLY POSITIONED FOR FUTURE GROWTH

- Multiple inflection points within 24 months including product launch Pritelivir
- €78M Revenue from commercial royalties, milestone payments & public grants 2022
- €31M Cash/Cash equivalents end of 1Q2023 & expected positive Cash Flow 2023
- Strong Shareholder Base, led by Majority Shareholder ATHOS KG
- Experienced Management & Supervisory Board with Extensive Industry Track Record
- Multi-disciplinary, prize winning R&D team & new commerical subsidiary in the US

Delivering Anti-Infectives to Patients in Need

AiCuris Anti-infective Cures

AiCuris

Anti-infective Cures

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