The Powerhouse for Anti-Infectives

"Committed to making the difference"

39th Annual J.P. Morgan Healthcare Conference
14Jan2021

AiCuris
Anti-infective Cures

Forward Looking Statements

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AiCuris – Company overview

The Powerhouse for Anti-Infectives

1 Company specs

- Founded 2006 as **spin-out from Bayer**'s anti-infective division
- Bringing innovation from research to clinical development: **>20 Phase 1 and 5 phase 2 trials concluded**
- Based in Bayer Life Science Park, **Wuppertal (Germany)**
- Currently **~70 employees**

2 Strong foundation

- **SANTO Holding** (Strüngmann Family Office) as lead investor since inception
- Highly experienced **management team** supported by a strong **Scientific Advisory Board**
- **>50 patent families** (>1000 granted patents worldwide) covering molecules and technologies

4 Innovative pipeline

- Addressing indications with **current unmet need** and **future threats**
- Focus on **novel mechanisms of action** and **overcoming resistance** to create unique commercial opportunities
- **3 clinical stage** assets and several **active pre-clinical programmes**
  - Pritelivir in phase 3, targeting approval in 2023

3 Commercial success

- **First product Letermovir (Prevymis™) marketed since 2017**: growing revenues and "blockbuster" potential
- Exclusive, world-wide license agreement with **global partner Merck & Co**
- **~500m€** in upfront, milestones and other payments received to date

Driven by indication, not limited to one proprietary platform, differentiated by focusing on novel approaches

Flexible, targeted approach in-house supported by scalable, external sub-contracting

Indications

Internationally connected, science driven expert team

Approach

Pre-clinical evaluation in-house with focus on differentiation: novel mechanisms of action

Technology

Diversified technologies with the highest potential in each indication (e.g., small molecules, novel chemical structures, fusion proteins)

In-licensed platforms and collaboration with global research consortia

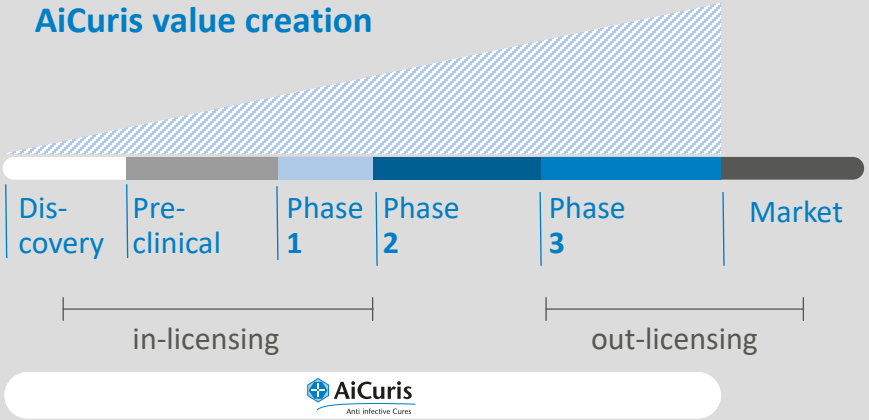
Clinical trial conduct

CRO-network with proven track record – chosen according to target expertise and market

Manufacturing

Well established expert CMC partners and GMP manufacturing – chosen according to technology

AiCuris value creation

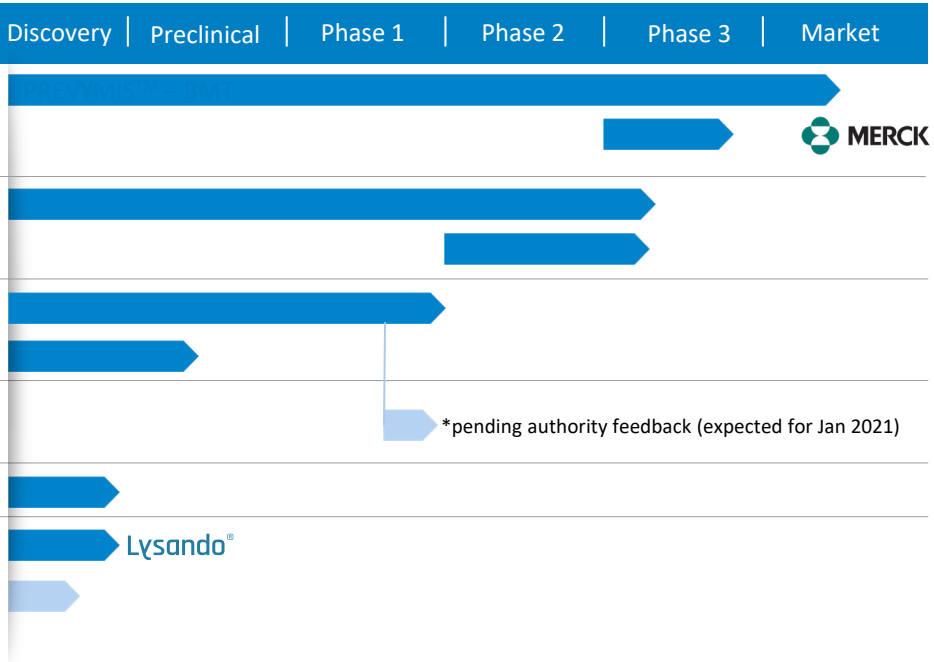


Our goal is to progress projects through pre-clinical and clinical development phases to reach major catalysts

Pipeline overview

Three clinical stage assets and a number of active research programmes

Target pathogen	Indication	Program
Human cytomegalovirus (CMV)	Bone-marrow transplants	Letermovir (Prevymis™)
	Solid-organ transplants	
Herpes simplex virus (HSV)	Acyclovir-resistant infection (ACV-R)	Pritelivir
	Dual-resistant infection	
Hepatitis B Virus (HBV)	HBV Cure	AIC649
		Research
Viruses with pandemic potential	COVID-19 as proof-of-concept (broad-spectrum as target)	AIC649
Adenovirus (AdV)	Keratoconjuctivitis	Research (several)
Gram-negative bacteria	Blood-stream infections	Artilysins™
	Anti-microbial resistance (AMR)	Research (several)



Solving the medical needs of today Preparing for future threats

AiCuris
Anti-infective Cures

Prophylactic treatment for CMV on the market

Spotlight on Letermovir (Prevymis™)

Target pathogen	Indication	Program
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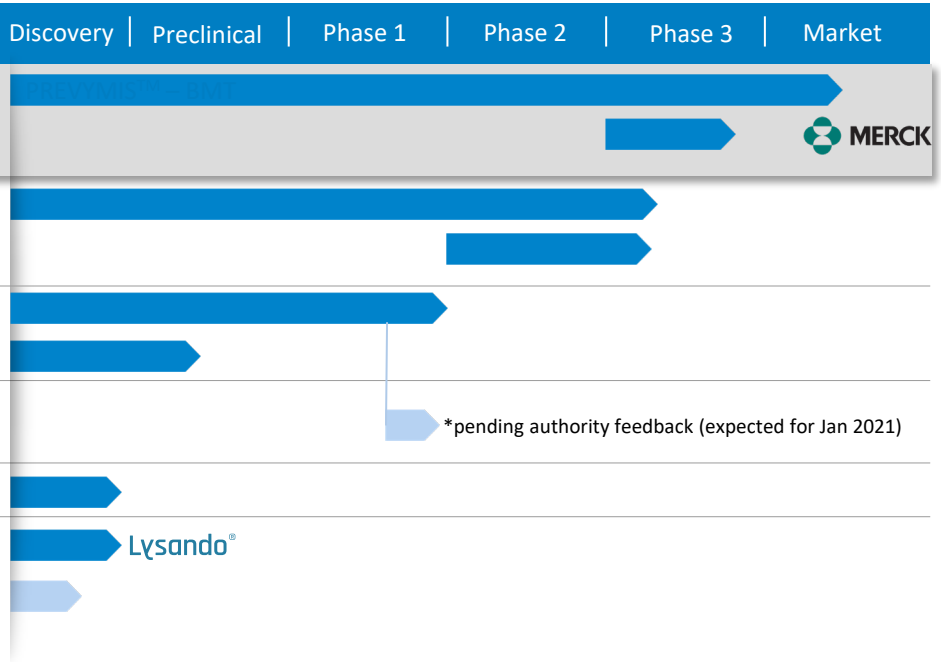


Solving the medical needs of today Preparing for future threats

AiCuris
Anti-infective Cures

First novel treatment for human cytomegalovirus (CMV) infection in more than 15 years

Letermovir – the “Game-Changer”

Approved indication

- **First and only** prophylactic treatment of CMV in adult seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT)
- **Improved survival rate** demonstrated
- Fast uptake: **Q1-Q3 2020 sales of $200m**

Additional indications

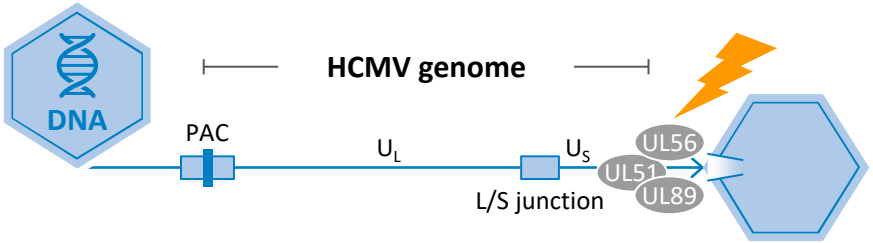
- Solid organ transplants (kidney): Phase 3 ongoing
- Investigator-initiated trials in HIV and ICU patients ongoing

Upcoming milestones

- Phase 3 data for solid organ transplants (kidney) expected in **2022**

Mechanisms of action

- Non-nucleosidic small molecule
- Specific inhibition of HCMV viral terminase
- No human counterpart
- **No side effects**



Novelty of approach

New viral target with no human counterpart

Game changing: Prophylactic treatment possible

€500m cash return to AiCuris to date, **upside** retained

AiCuris
Anti-infective Cures

Treatment for resistant herpes simplex infections now entering phase 3 development

Spotlight on Pritelivir

Target pathogen	Indication	Program
Human cytomegalovirus (CMV)	Bone-marrow transplants	Letermovir (Prevymis™)
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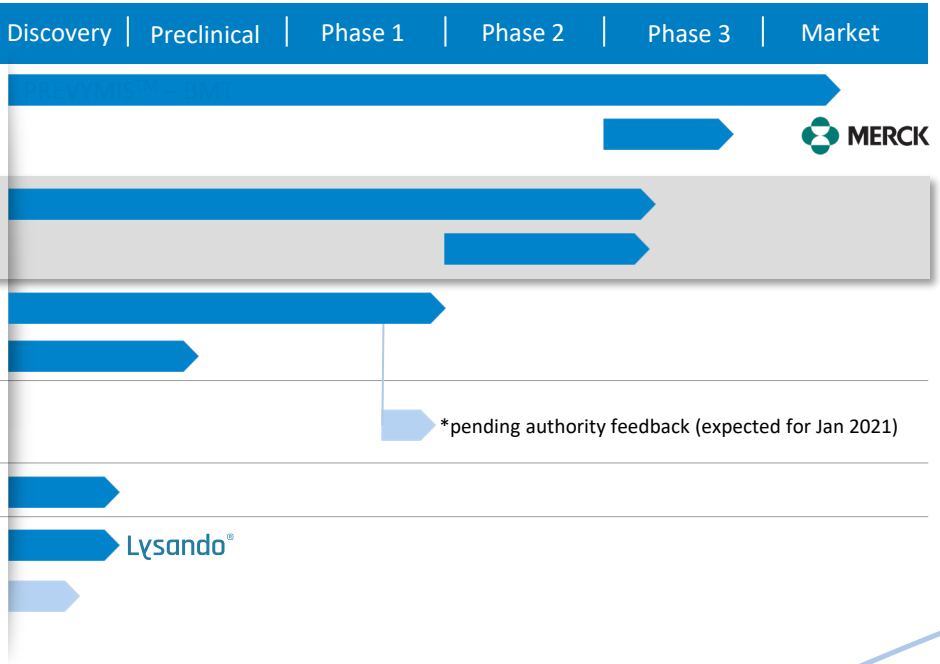

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Anti-infective Cures

Protection against herpes simplex virus (HSV) by a novel mechanism of action

Pritelivir – Targeting the viral helicase-primase

Indications

- **Acyclovir-resistant (ACV-R)** HSV infections in immuno-compromised patients
- Acyclovir- and Foscarnet-resistant HSV infections in immuno-compromised patients (**Dual-resistant**)

Status of development

- U.S. FDA **Breakthrough Therapy Designation**
- Solid Phase 2 data: superiority shown in three trials
- Phase 3 protocol approved by FDA

Upcoming milestones

- **Start of Phase 3 in Q1 2021**
- End of Phase 3 for dual-resistant indication expected in Q4 2022 (ACR-V in Q4 2023)

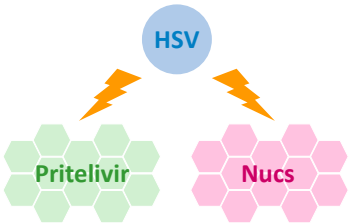
Mechanisms of action

- Non-nucleosidic small molecule
- Inhibition of HSV helicase-primase
- Specific to HSV-1 & HSV-2

Cells protected for >24h due to long half-life

No activation required

Excellent protection of uninfected cells



Present drugs (nucleoside analogs) do not cover sufficient exposure for continuous control of HSV

Viral enzyme (TK) needed for activation of nucleosides

No protection of uninfected cells

Novelty of approach

New viral target in order to inhibit viral replication

Overcomes resistance against current treatments

Prevents infection of cells

Potential peak sales: $200m+

AiCuris Anti-infective Cures

Pritelivir
Promising phase 2 data and phase 3 outline

2 Phase 2 (preliminary interim data)

Pritelivir has shown in **Part A (Acyclovir-resistant)** and **Part B (Dual-resistant)** of the PRIOH-1 trial

- ✓ a cure rate of 91.7% and 83.3%, respectively
- ✓ good safety profile

Summary of cure rates by treatment (Safety Population)

	Pritelivir n/N (%)	Foscarnet % (n/N)
Part A	91.7 (11/12)	50 (3/6)
Part B	83.3 (5/6)	–

3 Phase 3 Outline

- A randomized, open label, multi center, comparative trial, to assess the efficacy and safety of Pritelivir versus Foscarnet for the treatment of acyclovir-resistant mucocutaneous HSV infections in immunocompromised subjects (PRIOH-1)
- Approx. 130 patients in up to 70 sites in >10 countries
- Enrolment expected to commence in Q1 2021

An immune-modulator as part of a combination therapy for the cure of HBV infections

Spotlight on AIC649

Target pathogen	Indication	Program
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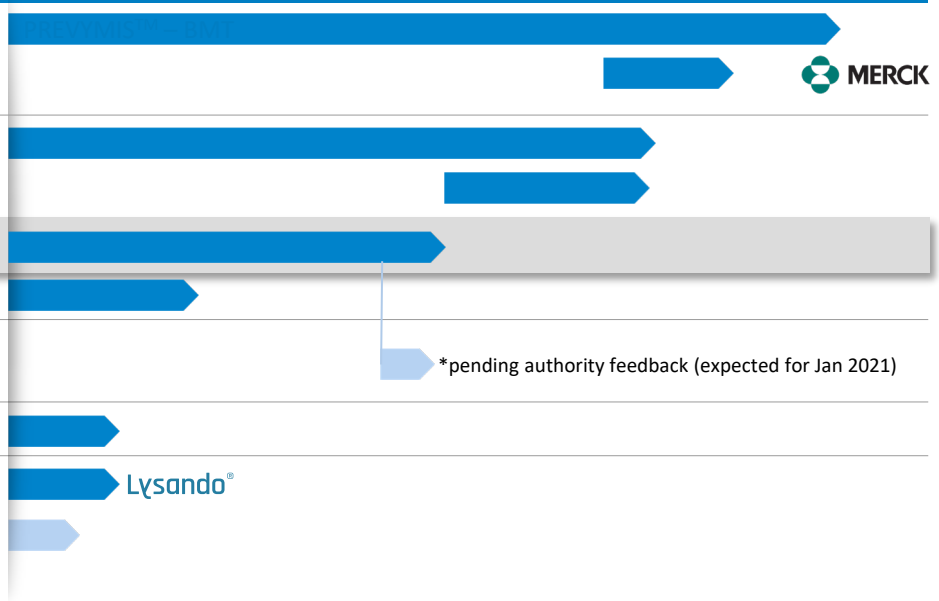

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Anti-infective Cures

A novel therapeutic strategy to achieve functional cure of chronic HBV infection

AIC649 – Modulating the immune response

Indication

- Cure for HBV infections
- Combination approach with SOC

Status of development

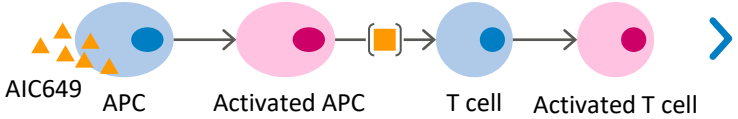
- Preclinical efficacy in relevant animal model showed potential for cure: reduction of sAg and induction of immune response
- Phase 1 trial in HBV-positive patients completed, favorable safety profile shown

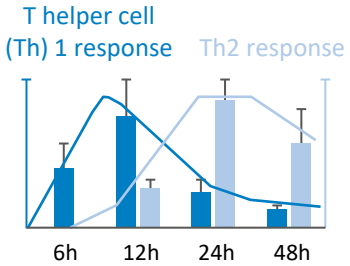
Upcoming milestones

- New production of clinical batch
- Start of Ph1b/2a

Mode of action

- Inactivated parapox virus particle
- Activation of the immune system via toll-like receptor (TLR)- dependent and TLR-independent pathways inducing a natural, self-limiting antiviral state





Novelty of approach

Inactivated virus to boost the antiviral immune response

Achieves reduction of Hepatitis B specific antigens **(HBsAg)**

AiCuris
Anti-infective Cures

Modulation of the immune system: New opportunity to treat several viral infections incl. COVID-19

Spotlight on AIC649

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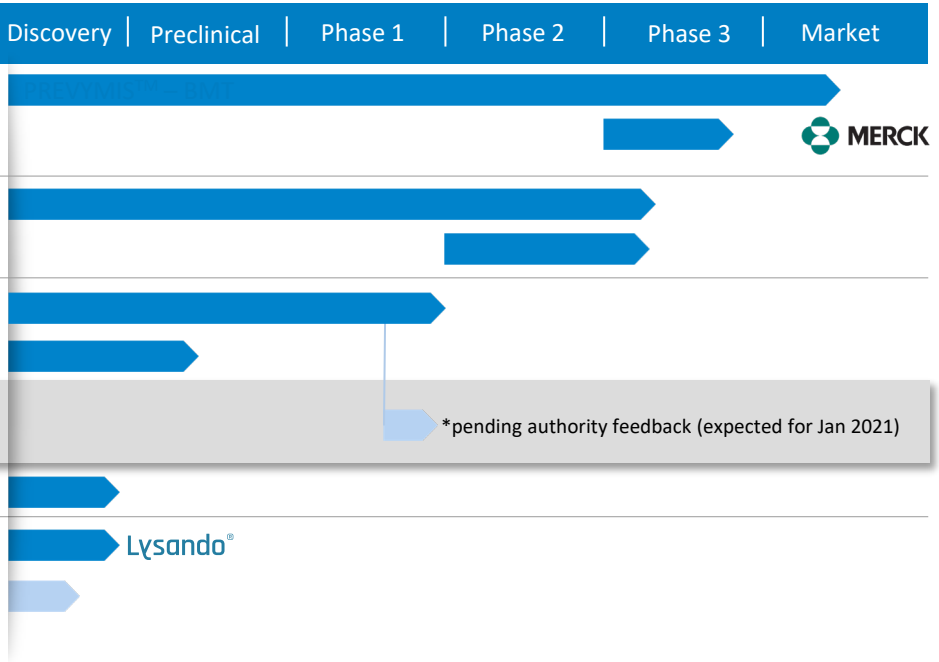


Solving the medical needs of today Preparing for future threats

AiCuris Anti-infective Cures

Potential to boost the immune system against several viral infections offer new opportunity in pandemic preparedness

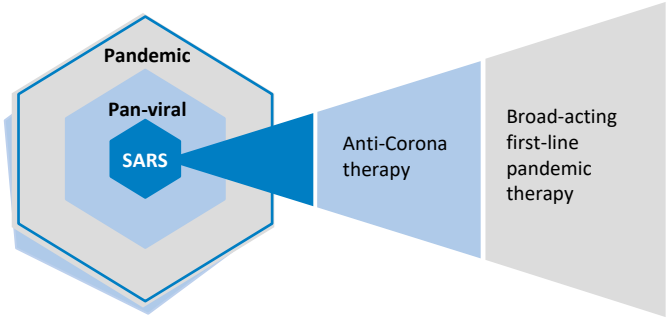
AIC649 – A broad-spectrum antiviral drug

Indications

- **Treatment of COVID-19 infections:** Prevent progression to severe disease in asymptomatic/mild COVID-19 infections (proof-of-concept)
- **Pandemic preparedness**: Prophylactic treatment in other airborne respiratory virus infections envisioned as next development step

Supportive data

- **Favorable safety profile** shown in Phase 1 FIH trial (HBV-positive patients)
- no self-neutralizing immune response
- **Broad anti-viral activity** observed in cell culture and animal models in prophy-lactic as well as treatment settings (e.g., HBV, HCV, HSV, Influenza , HIV/SIV, SARS-CoV-2)



Upcoming milestones

- Agency decision on start of COVID-19 trial in Q1 2021, data read-out planned for Q3 2021
- Ongoing process development and production of clinical batch by 2022 allowing further clinical development

Novelty of approach

Inactivated virus to boost the antiviral immune response

Broad-spectrum anti-viral activity in animal models

Activation (“training”) of **innate immunity**

AiCuris Anti-infective Cures

A sustained pipeline to deliver novel candidates for clinical development

Spotlight on active research programs

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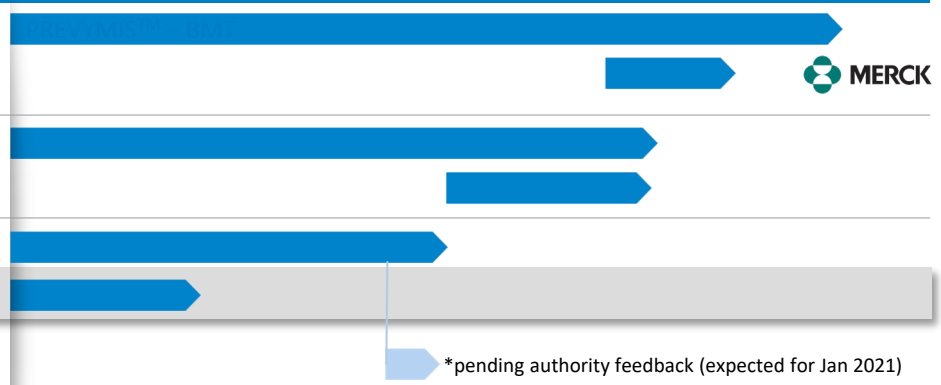
Further In-licensing opportunities		



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AiCuris Anti-infective Cures

Clinical stage projects will yield major catalysts over the upcoming 3 years

Expected Newsflow

Commercial

Human cytomegalovirus (HCMV)

AIC246 (Prevymis®)

MERCK

Current status

Marketed, $200M sales (9m ended Sep 2020)

Unique Selling Point

First-in-class prophylactic drug (game changer)

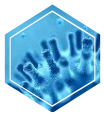
Upcoming catalyst

SOT Phase 3 read-out Q4 2022, approval in Q4 2023 (expected)

Development

Herpes-simplex virus (HSV)

AIC316 (Pritelivir)



Current status

FDA BTD status, Phase 3 start Q1 2021

Unique Selling Point

First-in-class drug, resistance breaker, niche market

Upcoming catalyst

Phase 3 data first indication – Q4 2022*
Phase 3 data second indication – Q4 2023*

* Expected

HBV, COVID-19 and other pandemic viruses

AIC649

Current status

Phase 1 completed (in HBV), clinical safety shown

Unique Selling Point

Broad-spectrum, new mode of action

Upcoming catalyst

Start of COVID-19 trial – expected in Q1 2021 (pending agency approval)

2 phase 2 potential trials (HBV, PREP) to start in 2023

Contact

AiCuris Anti-infective Cures GmbH

Friedrich-Ebert-Str. 475
42117 Wuppertal
Germany

+49 (0)202 317 63 – 0
+49 (0)202 317 63 – 1177
@ info@aicuris.com
www.aicuris.com

AiCuris
Anti-infective Cures