

# **AiCuris**

## **The Powerhouse for Anti-Infectives**

*A case study from a user of funds*

Holger Schmoll, CFO  
EMA/EBE seminar “Emerging Medicinal Products  
– from laboratory to patient use”  
London, 14 Dec 2015

## *The Powerhouse for Anti-Infectives*

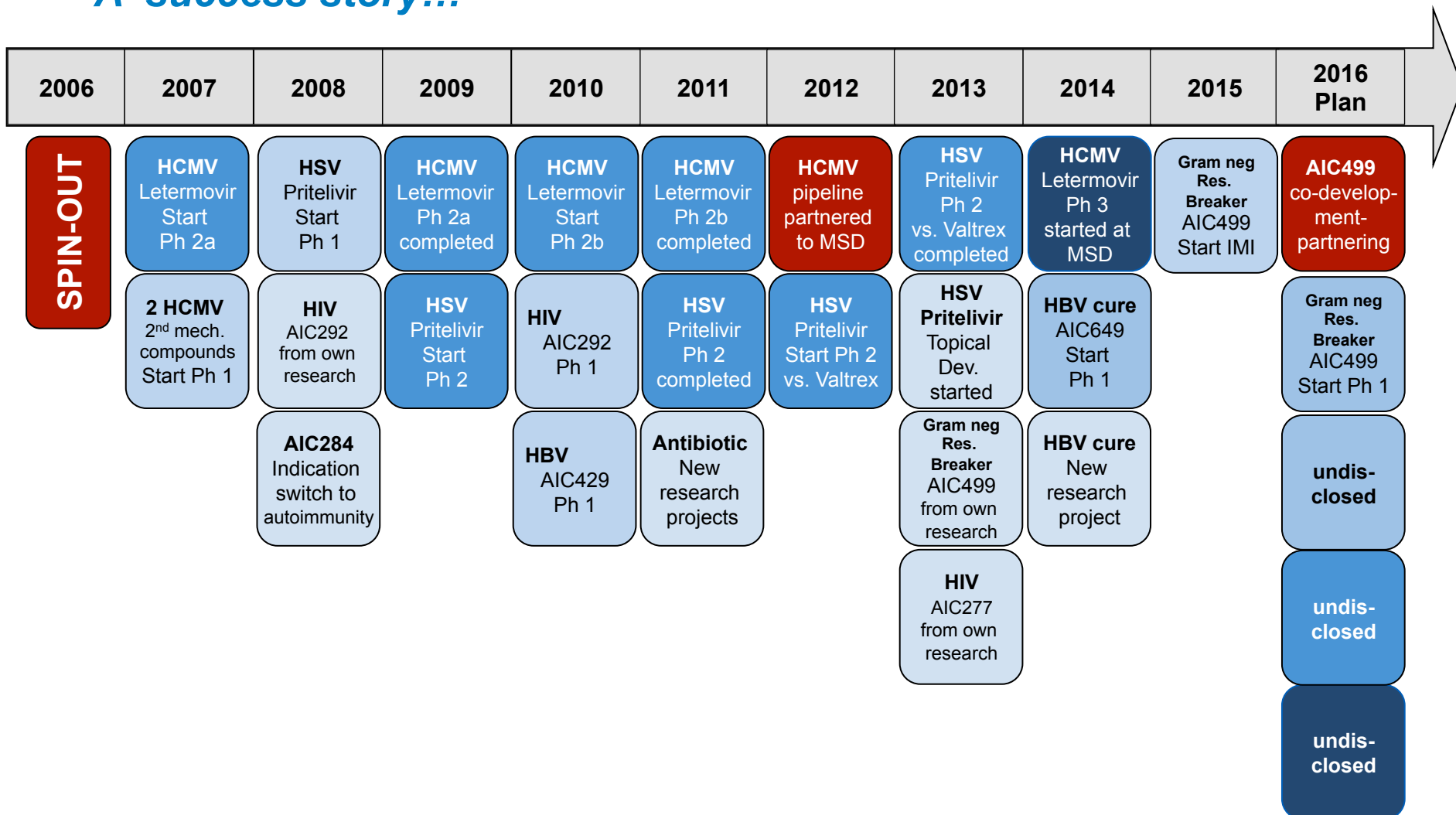
- ◆ Discovery, research and development
  - ◆ for infectious diseases **with high medical need**
  - ◆ of innovative and resistance-breaking antiviral & antibacterial agents **from novel compound classes and/or with novel modes of action**
  - ◆ **9 development programs for mainly specialist/hospital markets**
  - ◆ Research activities in viral indications (Hepatitis B Cure) & hospital antibiotics

- ◆ Founded in 2006, spin-out of Bayer
- ◆ Approx. 50 FTE, located in Wuppertal
- ◆ Majority shareholder: SANTO Holding
- ◆ HCMV licensing deal with Merck & Co. in 2012

Indication	Discovery	Preclinical	Phase I	Phase II	Phase III
Letermovir - HCMV <small>[Licensed to Merck &amp; Co (MSD), USA]</small>					
HCMV					
HCMV					
HCMV <small>[Licensed to Merck &amp; Co (MSD), USA]</small>					
Pritelivir - HSV oral					
Pritelivir - HSV topical					
Hepatitis B and fibrosis					
Hepatitis B					
Hospital antibiotic (Gram.neg.) <small>supported by IMI</small>					
Hospital antibiotic <small>(Gram neg.)</small>					
Hospital antibiotic <small>(Gram neg.)</small>					
Auto-immune diseases					

# AiCuris: Founded 9 years ago....

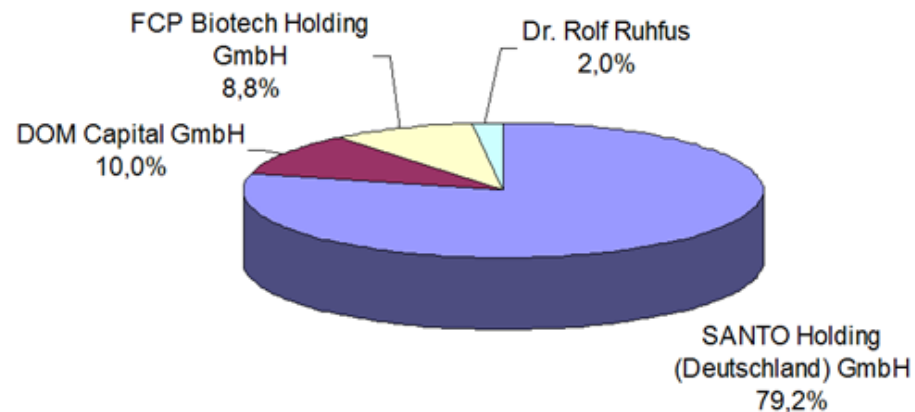
*A success story...*



## Private equity (Family Offices)

# AiCuris – a privately-owned company

- ◆ Majority investor from the beginning is SANTO Holding, owned and controlled by the Strüngmann brothers (former owners of Hexal)
- ◆ Other family offices and a private investor hold together 20% of the shares.
- ◆ Peak equity investment by private shareholders 2006-2012  
~ 200m€



# Two big family offices in Germany

Two family offices are the most important investors in German Biotech industry

- ◆ Dietmar Hopp (co-founder of SAP) > 1 bn €
- ◆ Andreas & Thomas Strüngmann (former owners of Hexal) ~ 1 bn €

Long-term oriented, strategic investors

each invested in several Biotech companies

in most cases major shareholders or with strategic share

focused on private companies

opportunistic exit scenarios

**AiCuris' success  
was only possible based on  
backing by our  
private investors**

**Investment in our team  
and our scientific expertise,  
not in one project!**

## **A few words regarding SME status**



## EU SME definition

***The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro.***

*Extract of Article 2 of the Annex of Recommendation 2003/361/EC*

**AiCuris fulfills all criteria**

Enterprise category	Headcount: Annual Work Unit (AWU)	Annual turnover	or	Annual balance sheet total
Medium-sized	< 250 ✓	≤ €50 million (in 1996 € 40 million) ✓	or	≤ €43 million (in 1996 € 27 million) ✓
Small	< 50	≤ €10 million (in 1996 € 7 million)	or	≤ €10 million (in 1996 € 5 million)
Micro	< 10	≤ €2 million (previously not defined)	or	≤ €2 million (previously not defined)

## EU SME definition

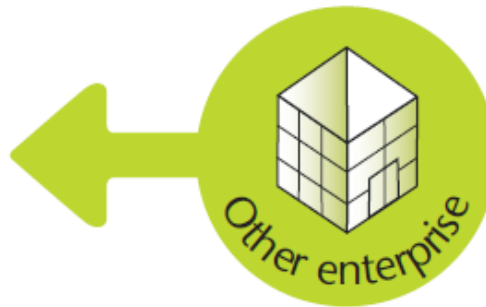
### LINKED ENTERPRISES

My enterprise holds more than 50% of the shareholders' or members' voting rights in another and/or another holds more than 50% in mine.

AiCuris



Santo  
Holding



**Criterial for AiCuris  
as Santo Holding is  
majority investor**

All 100% of the linked enterprise's data must be added to those of your enterprise to determine if you comply with the staff headcount and financial thresholds of the definition.

***The result:***

## ***AiCuris is no SME according to EU definition***

- ◆ **EU is neglecting a changing environment and difficult financing situation for small / medium R&D companies**
  - ◆ Private investors / family offices fill the gap resulting from reluctant VC funds
  - ◆ “Business Angel” investments limited to 1.25 m€ (not adequate for Biotech companies)
  - ◆ Definition of “institutional investors” not clear (VCs, Family Offices)
  - ◆ Definition of “no dominant influence exists” not clear

**IMI**

- ◆ **COMBACTE-MAGNET** („Combatting bacterial resistance in Europe - molecules against Gram negative infections”) project started on 1st Jan 2015
- ◆ AiCuris is participating with AIC499, a resistance-breaking, Gram-neg. hospital antibiotic candidate

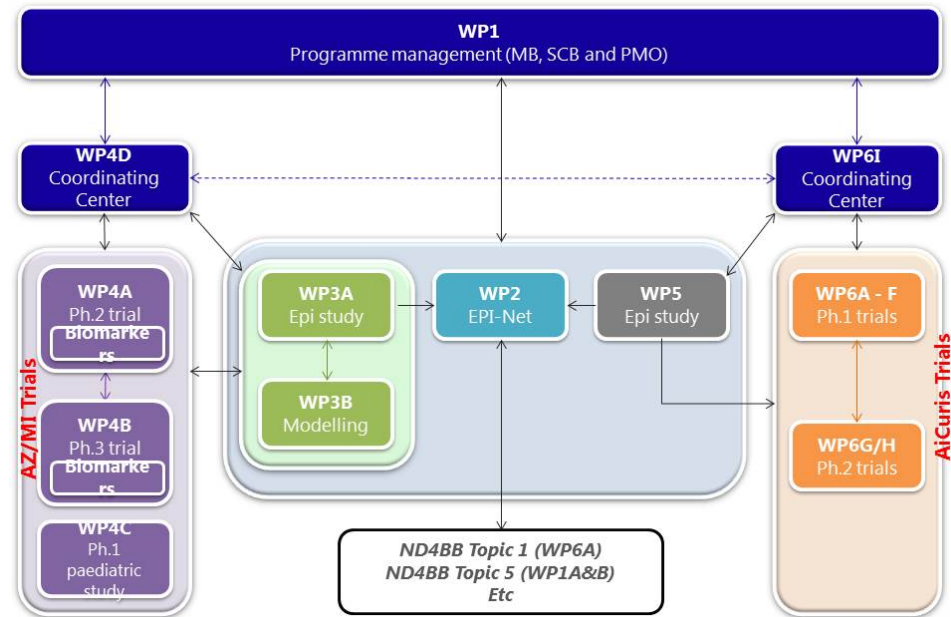
in-kind-contribution:

- ◆ Personnel
  - ◆ Compound and clinical material (Drug substance/Drug product)
  - ◆ Tasks by subcontractors
  - ◆ Co-financing of consortium
- 
- ◆ Conduct of 6 Phase1- and 2 Phase2 trials by the consortium



**ND4BB**  
COMBACTE

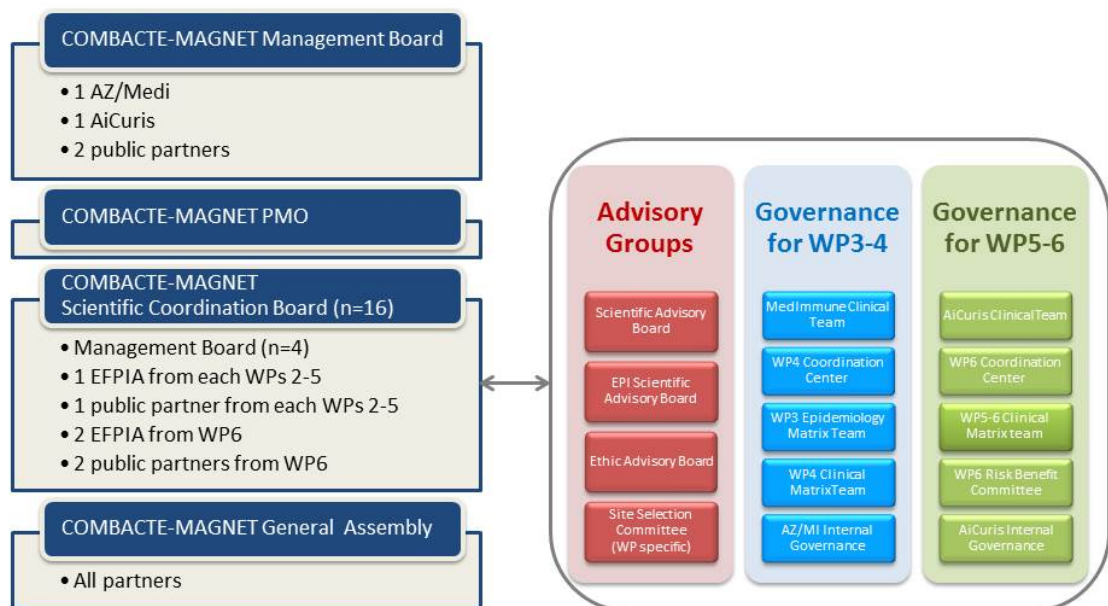
- ◆ EFPIA Companies:  
**AiCuris, Astra Zeneca, Basilea, GSK, Sanofi**
- ◆ 34 academic partners /SMEs from 10 European countries



## Challenges of a IMI collaboration

- ◆ IP (Background, Foreground, Sideground)
- ◆ Business interests vs. academic interests (e.g. publications)
- ◆ Flexibility vs. „Description of Work“
- ◆ Organization / Governance

### COMBACTE-MAGNET GOVERNANCE STRUCTURE



## **VCs and EIB**



## ***VCs - Partner for a limited time***

- ◆ VC companies are worldwide the most important providers for risk capital and thus should be perfect partners for R&D-focused companies
- ◆ Matching problems in business models:
  - ◆ Investment volumes at least of European VCs in most cases not sufficient for Phase 2/3 development
  - ◆ Investment timelines limited due to demands of LPs for mid-term risk-investments
  - ◆ Sustainability of Biotech companies vs. need of VC for cash-back to LPs
  - ◆ Partly focus on “lean PoC-results” makes exits more difficult

**Biotech needs long-term and sufficient investments to become sustainable**

- ◆ EIB InnovFin Program seems to be an adequate instrument to support risk-investments in Biotechs by loans or equity / mezzanine models (risk-sharing)
- ◆ Special interest of AiCuris on **InnovFin Infectious Diseases**
- ◆ 1<sup>st</sup> discussions in July, follow-up with project presentation early October

since then ... ???

**Hopefully later more ...**

# Thank you!

Further questions?

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