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”
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AiCuris

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Discovery</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
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<tbody>
<tr>
<td>Letermovir - HCMV</td>
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<td>[Licensed to Merck &amp; Co (MSD), USA]</td>
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<td>Pritelivir - HSV oral</td>
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<td>Pritelivir - HSV topical</td>
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<td>Hepatitis B and fibrosis</td>
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<td>Hepatitis B</td>
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<td>Hospital antibiotic (Gram neg.)</td>
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<td>supported by IMI</td>
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<td>Auto-immune diseases</td>
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## AiCuris: Founded 9 years ago…. 
### A success story…

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2006</td>
<td>HCMV Letermovir Start Ph 2a</td>
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<tr>
<td>2007</td>
<td>HSV Pritelivir Start Ph 1</td>
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<tr>
<td>2008</td>
<td>HCMV Letermovir Start Ph 2a completed</td>
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<tr>
<td>2009</td>
<td>HCMV Letermovir Start Ph 2b</td>
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<tr>
<td>2010</td>
<td>HCMV Letermovir Ph 2b completed</td>
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<tr>
<td>2011</td>
<td>HCMV pipeline partnered to MSD</td>
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<td>2012</td>
<td>HSV Pritelivir Ph 2 vs. Valtrex completed</td>
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<tr>
<td>2013</td>
<td>HSV Pritelivir Topical Dev. started</td>
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<td>2014</td>
<td>HSV Pritelivir from own research</td>
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<td>2015</td>
<td>Gram neg Res. Breaker AIC499 Start IMI</td>
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<td>2016</td>
<td>AIC499 co-development-partnering</td>
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</tbody>
</table>

### SPIN-OUT

- **2006**
  - HCMV Letermovir Start Ph 2a
  - HSV Pritelivir Start Ph 1
  - HIV AIC292 from own research

- **2007**
  - HSV Pritelivir Start Ph 2a completed
  - HIV AIC292 Ph 1

- **2008**
  - HSV Pritelivir Start Ph 2b
  - HIV AIC292 Ph 2 completed

- **2009**
  - Antibiotic New research projects

- **2010**
  - HSV Pritelivir Start Ph 2 vs. Valtrex completed

- **2011**
  - HSV Pritelivir Topical Dev. started

- **2012**
  - HSV Pritelivir from own research

- **2013**
  - HSV Pritelivir from own research

- **2014**
  - HSV Pritelivir Start Ph 2 vs. Valtrex completed

- **2015**
  - HSV Pritelivir from own research

- **2016**
  - HSV Pritelivir from own research
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
Our experiences

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

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 fonds
  - “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
THE INNOVATIVE MEDICINES INITIATIVE (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
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
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.

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

- 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
- 1st discussions in July, follow-up with project presentation early October

since then . . . ???

Hopefully later more . . .
Thank you!

Further questions?

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