Paradigm shifts in vaccine development: From empirical approaches into the center of biotech industry

A CIÊNCIA EM LA - Laboratório Associado De Oeiras

LISBON, FEBRUARY 18, 2009

Alexander von Gabain

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Microbial infections – key threat of human life

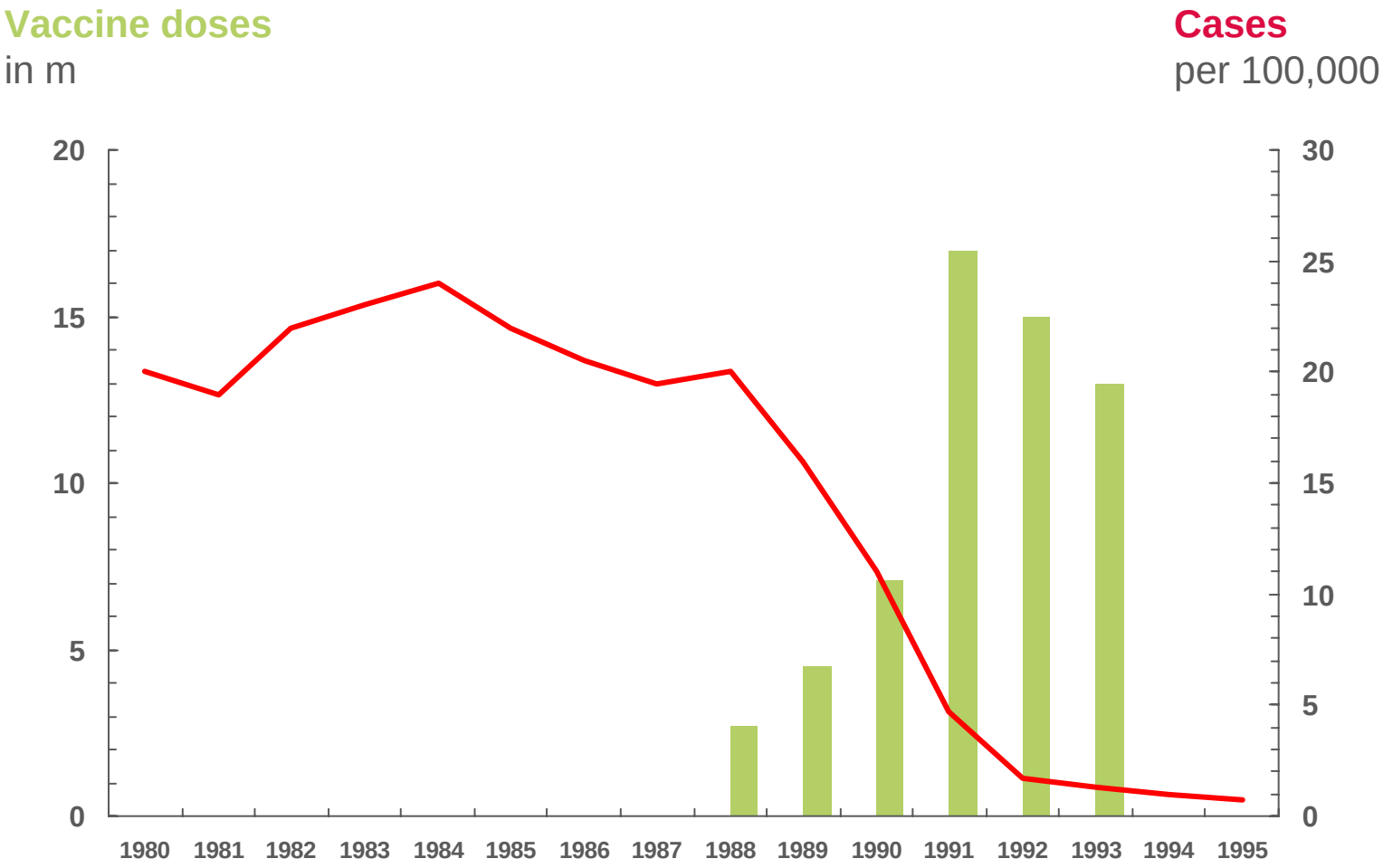
OVERVIEW

- » Terminate every 4th human life
- » 13 million deaths per year in developing countries
- » Three major killers: Malaria, AIDS and Tuberculosis
- » Pandemic influenza
- » Multi-drug resistant microbes
- » Novel emerging pathogens
- » Bioterrorism

Worldwide **approx. 500,000** people killed by the annual flu epidemic
Estimated **50,000,000** people killed by pandemic flu **1918**

Drastic decrease of HIB Meningitis after introduction of new vaccine in US

VACCINES WORK



The vaccine field: challenges ahead and new paradigms

FORCES AT WORK

High medical need for new indications: e.g. infectious diseases, cancer, allergy, … list of vaccines short, list of pathogens long

Existing vaccines often with suboptimal efficacy: e.g. in neonates or elderly or with side effects

"Come-back of vaccines"

Novel technologies & scientific progress in micro- and immune-biology: e.g. HBV, Pneumo, HIB, Rotavirus, JEV, HPV

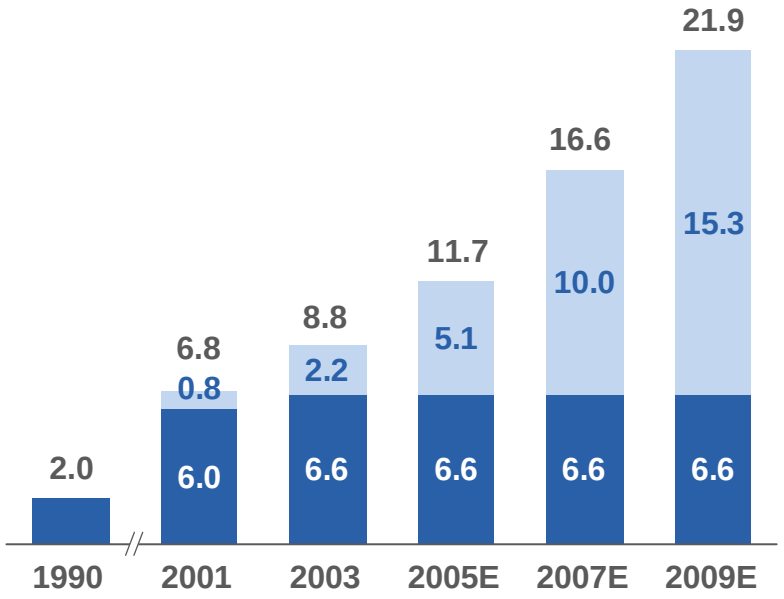
Academia, industry and NGOs to develop vaccines for the developed and developing world: e.g.TB, Malaria, HIV, JEV, Pneumo

Innovation will grow in an attractive medical arena currently dominated by major players

- Traditional and combinations
- Novel and therapeutic vaccines

GLOBAL VACCINE MARKET

US$ bn



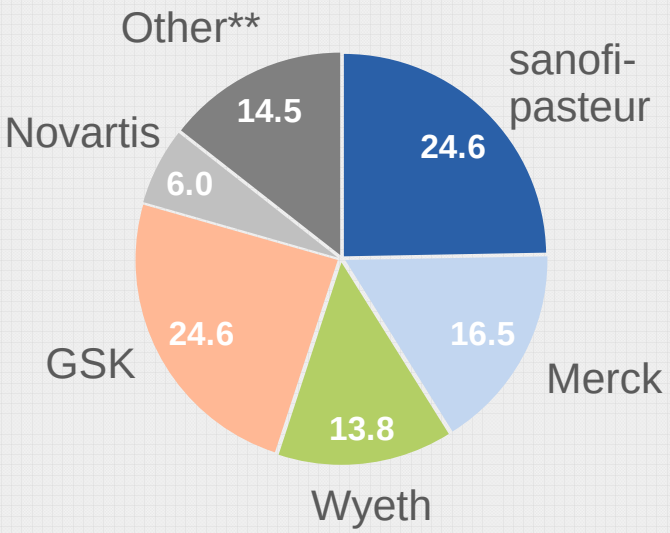
Expected CAGR 2003 - 2009

» Global vaccine market 16%

» Novel and improved vaccines 38%

Industry landscape in 2006*

% of market share

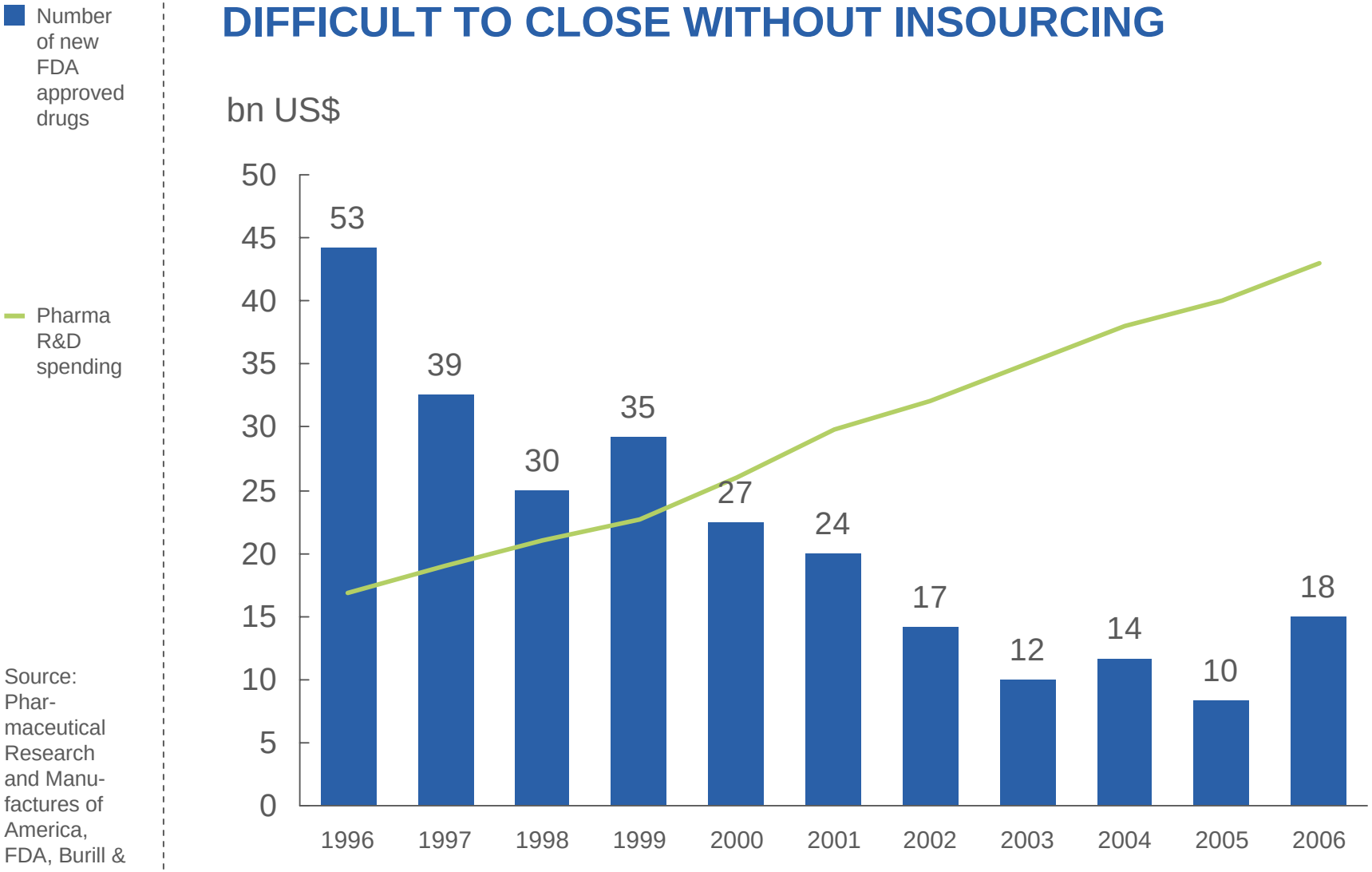


* sanofi-pasteur – World Market Analysis 2006

** New Players in US/EU and developing countries

The innovation gap of the established pharma and vaccine industry - a fact

DIFFICULT TO CLOSE WITHOUT INSOURCING



Source: Pharmaceutical Research and Manufactures of America, FDA, Burill & Co.

Pharma and biotech products take time, need significant investments and are not risk free

WITHOUT RISK AND INCENTIVES NO NOVEL DRUGS

	Research	Development (pre-clinical)	Clinical development			Submission of license	Product licensing
			Phase I 1st year	Phase II 1 - 2 year	Phase III 3 - 4 year		
Likelihood of success (percent)	5	10	10 - 20	20 - 50	50 - 90	90 - 95	99
Cost (m US$)	10 - 250	20 - 225	20 - 200	50 - 175	100 - 125	10 - 15	5 - 10
				Σ 215 - 1.000			
Time (years)	4 - 6	1 - 2		4 - 6		1	

A key naivety of academic people is to underestimate costs and complexity of product development

A PRODUCT REQUIRES MUCH MORE THAN AN OUTLOOK STATEMENT IN THE "DISCUSSION SECTION" OF A PAPER

Margaret Heckler (top US health government official and Bob Gallo at a press conference held on March 4, **1984**:

"How many years will it be before there is a marketable HIV vaccine?"

"We estimate two years……"

"What type of vaccine will it be…"

"A subunit vaccine……"

Source: Shots in the dark, Jon Cohen

Drug and vaccine development needs gigantic investments

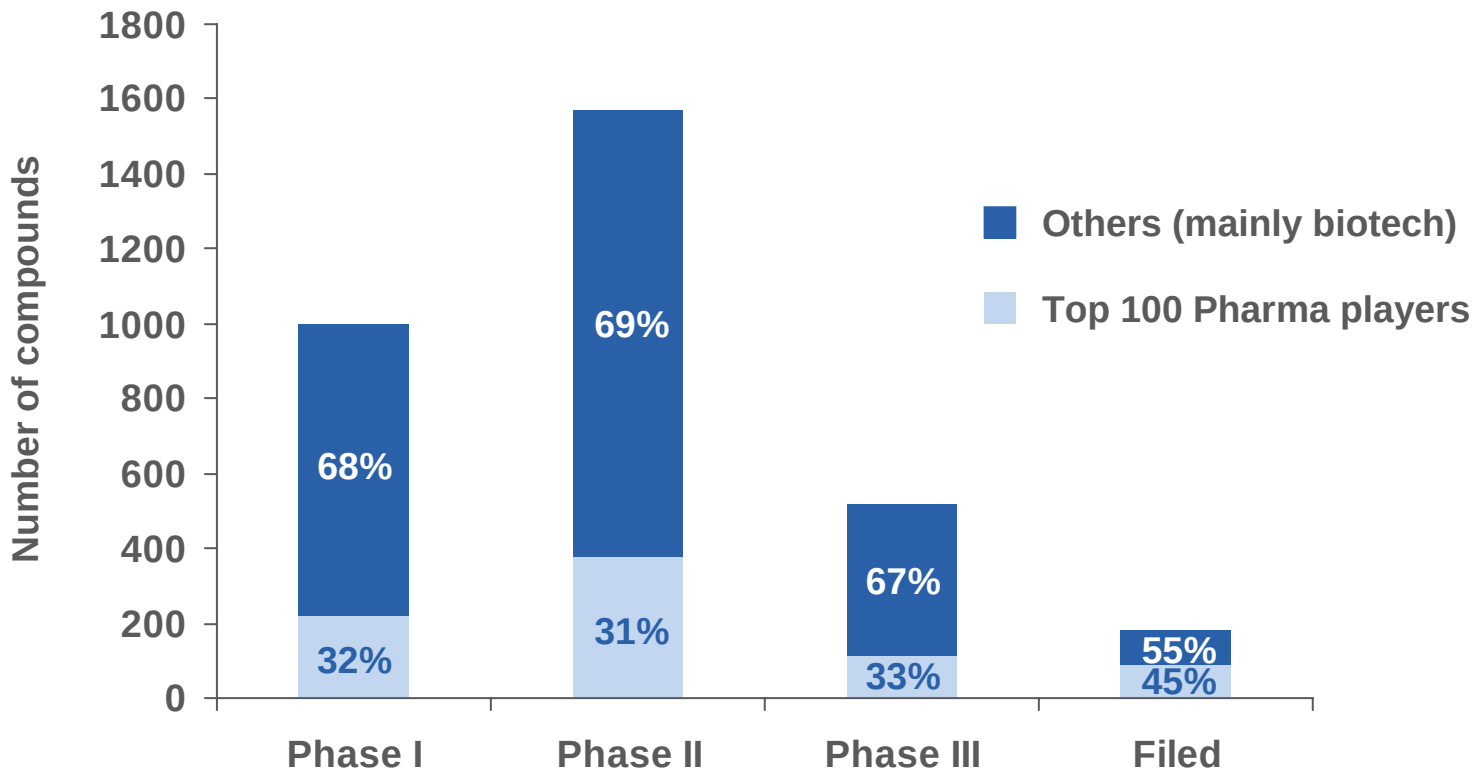
NO NEW DRUGS WITHOUT ENTREPRENEURSHIP

If you think research is expensive, try disease

Mary Lasker (1901-1994)

Biotech industry provides hope: essential part of product pipeline comes from smaller biotech

COMPOUNDS IN DEVELOPMENT BY COMPANY SIZE



Source: PharmaProjects, BCG

Many examples for innovation driven by New Players

EXAMPLES

Innovation	Technology	Resulting products/candidates	New Players
» New antigens	AIP®, RV	S. aureus, Pneumo (prot.), MenB, …	Chiron*, Intercell
» New adjuvants	CpG, MPL, IC31®, ISS	Improved Flu, HBV, HPV, Tuberculosis…	Coley**, Corixa***, Intercell, Dynavax
» New vectors	Chimerivax, Adenovirus, MVA	Dengue, Tuberculosis, HIV, Smallpox..	Acambis, Crucell, Bavarian Nordic
» New administration	Nasal, transdermal	Flu, Travelers' Diarrhea…	Aviron***, Iomai*****
» Therapeutic vaccines	T-cell activation	Hepatitis C, Cancer, …	Intercell, Dendreon
» New production	Cell culture	JEV, Flu, …	Acambis, Crucell
	PS-conjugates	Pneumo, Men, …	Intercell, Glycovaxyn

* Now Novartis

** Now Pfizer

*** Now GSK

**** Now Medimmune

***** Now Intercell

Intercell, an international biotech player, a spin off from a public/private research center of excellence

History:

Spin off from the Campus Vienna Biocenter, IMP and University 1998. Today 388 employees from 33 nations in Vienna, Edinburgh & Washington DC

Partners:

Merck (USA), Sanofi Aventis, Novartis, Wyeth, Kirin, SSI, Biological E, EC, NIH, CDC, WRAIR, AERAS foundation, Karolinska, MPI, GBF and many more academic organizations

Products:

Prophylactic & therapeutic vaccines; JEV vaccine registered, 7 vaccines in phase I to III trials

Funding:

Since 2005 listed at the ATX (ICLL): Today's Market cap: approx. $ 1.5 bn. Since 2007 profitable

People:

» **Key Management**: G. Zettlmeissl (CEO), A. v. Gabain (CSO and founder), T. Lingelbach (COO) & W. Lanthaler (CFO)

» **Supervisory board**: M. Gréco (Chair), E.G. Afting, S. Bakali, D. Ebsworth, J. Sulat, H. Wigzell

» **SAB**: R. Ahmed, H. Blum, S. Cohen, F.X. Heinz, S. Kaufmann, S. Normark, H. Wigzell

For more information: www.intercell.com

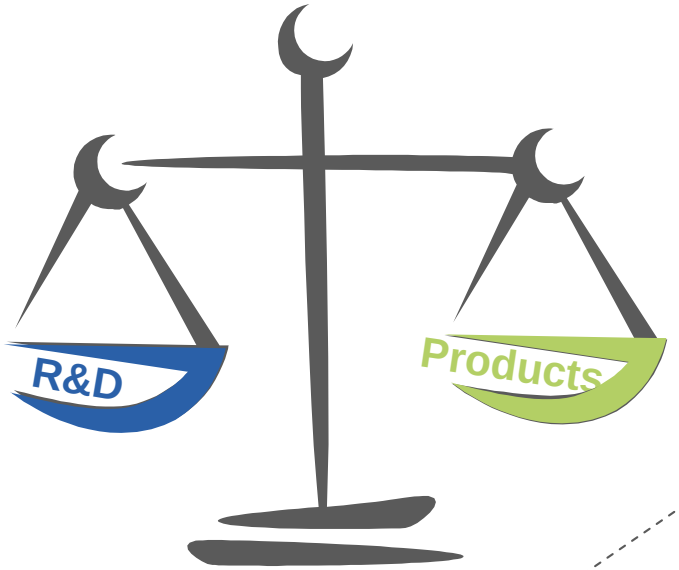
History and strategic development of the company

AN AUSTRIAN BIOTECH PLAYER MOVES INTO THE EUROPEAN TOP LEAGUE

	"Start up"	"First steps"	"Growth"
Time	1998 - 2002	2002 - 2004	2004 - 2008
Core assets	» Academic excellence » Visionary technologies	» Efficient product development » Implementation of core technologies	» JEV clinical success (Novartis) » AIP and IC31® (Merck, Sanofi, Kirin, Wyeth)
Stra-tegy	» Transformation from academia to industry	» Risk diversifi-cation	» Acquisition of further technology platforms (IOMAI)

Financing history of Intercell - Investors' trust is a building block for biotech

THE ART OF BIOTECH BUILDING



* Gross proceeds in € m

Grants from:
WWFF
FGG
AWS
EU
NIH
PATH

VC investors:
TVM
Apax
Nomura
MPM
NIB Capital
GLSV
…
…

Building a portfolio: Product and developmental pipeline

PRODUCT DEVELOPMENT

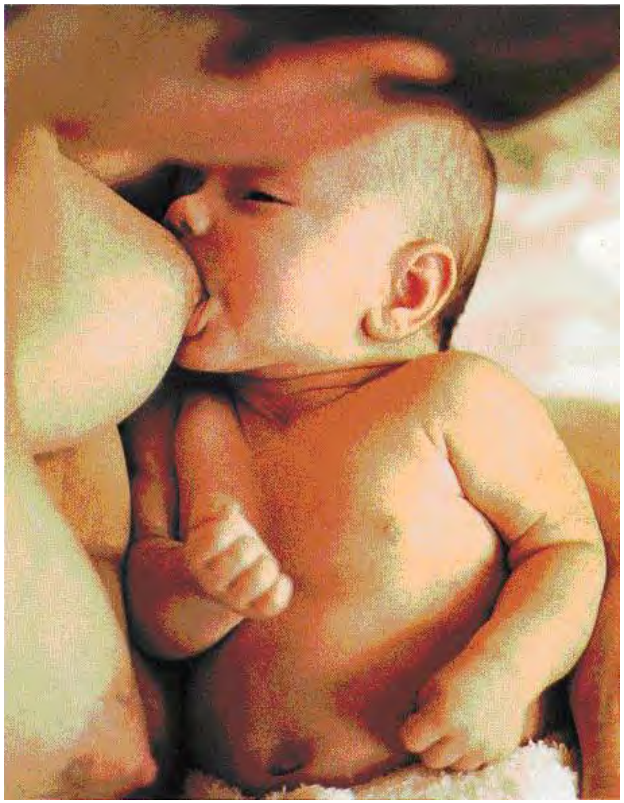
	Product	Market opportunity (in EUR m)	Status	Expected next milestones	Commercialization partner
Travelers' Vaccines	1 **IXIARO® – Japanese Encephalitis Prophylactic Vaccine**	250 – 350	Approved AUS; positive opinion EU; approval US expected early 2009	» Country approvals in various territories » Expansion of label (children)	Novartis, CSL, Biological E
	2 **Travelers' Diarrhea Prophylactic Vaccine Patch**	>500	Phase II	» Pivotal Phase III start H1 2009	In-house
Nosocomial Vaccines	3 **S. aureus Prophylactic Vaccine**	>3,000	Phase II/III *	» Efficacy data mid 2009 » Pivotal Phase III	Merck & Co
	4 **Pseudomonas Prophylactic Vaccine**	>1,500	Phase II	» Efficacy data H2 2009 » Pivotal Phase III	In-house
Others	5 **Pandemic Flu Vaccine**	tbd	Phase I/II	» Phase II start H1 2009	In-house, funded by HHS
	6 **Seasonal Flu Vaccine**	>1,000	Phase I	» Phase II start	Novartis
	7 **Tuberculosis Prophylactic Vaccine**	>500	Phase I/II	» Phase II start	sanofi pasteur/ SSI, funded by AERAS
	8 **Pneumococcus Prophylactic Vaccine**	>3,000	Pre-clinical	» Phase I start	In-house, funded by PATH

*sequential design

Basic concepts for active and passive vaccinations

TYPES OF VACCINATIONS

A natural approach to provide a passive prophylactic vaccination*...



Passive:
(e.g. human monoclonal antibodies)

» Prophylactic

» Therapeutic

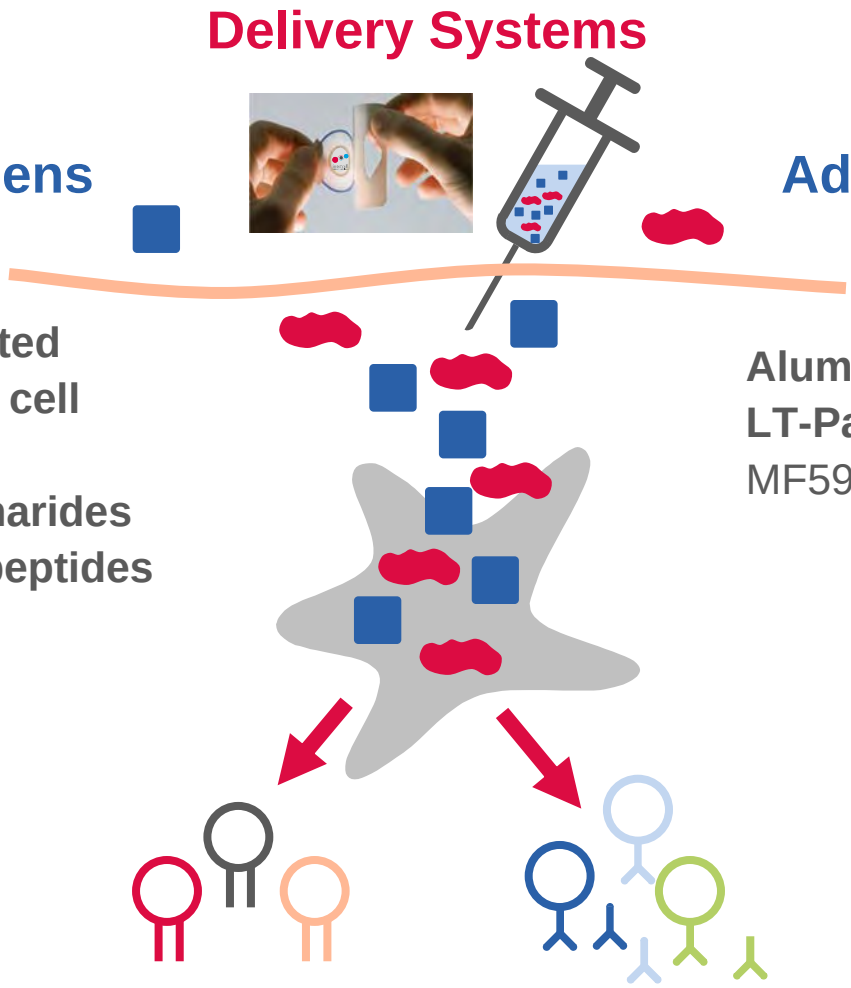
Active
(e.g. recombinant vaccine antigens)

» Prophylactic

» Therapeutic

* Desmond Morris, Bodywatching: A Field Guide to the Human Species (1995)

Essentials of vaccines



Combination of complementary technology platforms

TECHNOLOGIES

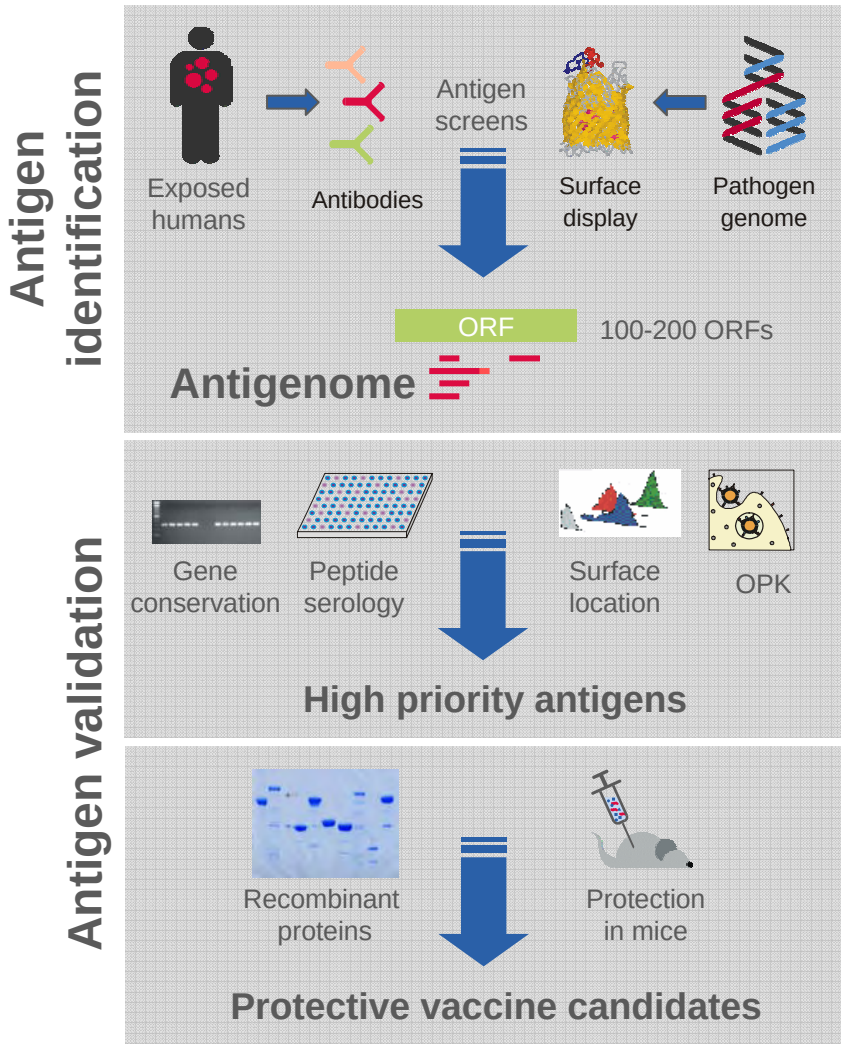
intercell SMART VACCINES

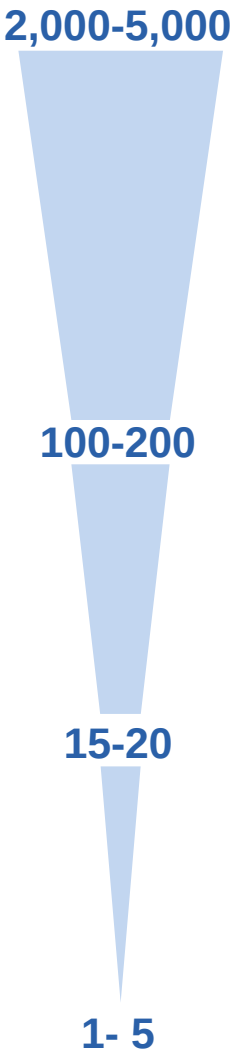
ANTIGENS	ADJUVANTS	VACCINE PATCH
Antigen Identification for vaccines and antibodies (AIP®)	**Vaccine Improvement Program – IC31®/LT**	**Needle Free Vaccine Patch Technology**
» S. aureus (vaccine*/ antibody*)	» Hepatitis C therapeutic vaccine	» Travelers' Diarrhea vaccine
» Pseudomonas (vaccine/antibody)	» Flu vaccine**	» Pandemic Flu vaccine
» Pneumococcus (vaccine/antibody***)	» Tuberculosis vaccines****	» Reduction of injections (e.g. children vaccines)
» Group A Streptococcus (vaccine*/antibody)	» Cancer vaccines	
» Group B Streptococcus (vaccine**/antibody)	» Allergy vaccines	
» Borrelia (vaccine)	» Others*****	
» C. difficile (vaccine/antibody)		
» Others		

Combination of three complementary technology platforms enables the development of novel vaccine and antibody products

* Partnered with Merck & Co
** Partnered with Novartis
*** Partnered with Kirin
**** Partnered with sanofi pasteur
***** Partnered with Wyeth

Finding the proper antigens: AIP® the antigenome technology





Etz et al. (2001) J. Bacteriol. 183, 6924-6935.

Etz et al. (2002) PNAS 99, 6573-6578.

Henics et al. (2003) BioTechniques 35, 196-202.

Nagy et al. (2004) Genomics, Proteomics & Vaccines, ed. Grandi

Meinke et al. (2004) Curr. Opin. Microbiol., 7:314-320

Nagy et al, Expert Rev Infect. Therap 2008, 6, 21

The antigenome technology detects potent vaccine antigens and antibody targets

THE FEATURES

- Disease specific, expressed in infected humans
- Surface exposed **or** secreted
- Essential for bacterial survival
- Often shared between related pathogens

Example: The next generation Pneumococcal vaccine

Pneumo

FROM ANTIGENOME TO VACCINE CANDIDATE

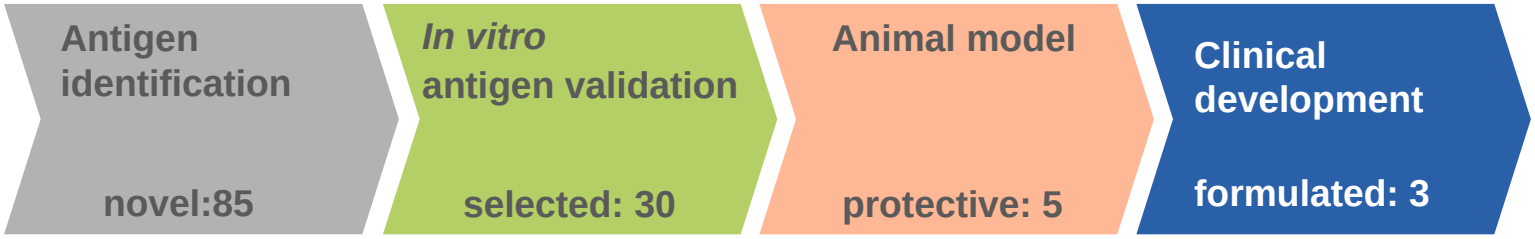
Current vaccines

» Vaccines are available based on polysaccharides; 7-valent conjugated (children) and 23-valent non-conjugated (elderly)

» Disadvantage of polysaccharide-based vaccines

- partial coverage (90 different serotypes)
- emergence of non-vaccine serotypes
- serotype switching by horizontal gene transfer
- complex manufacturing, very high price

PROTEIN SUBUNIT VACCINE WITH HIGHLY CONSERVED ANTIGENS THAT INDUCES PROTCTIVE ANTIBODIES

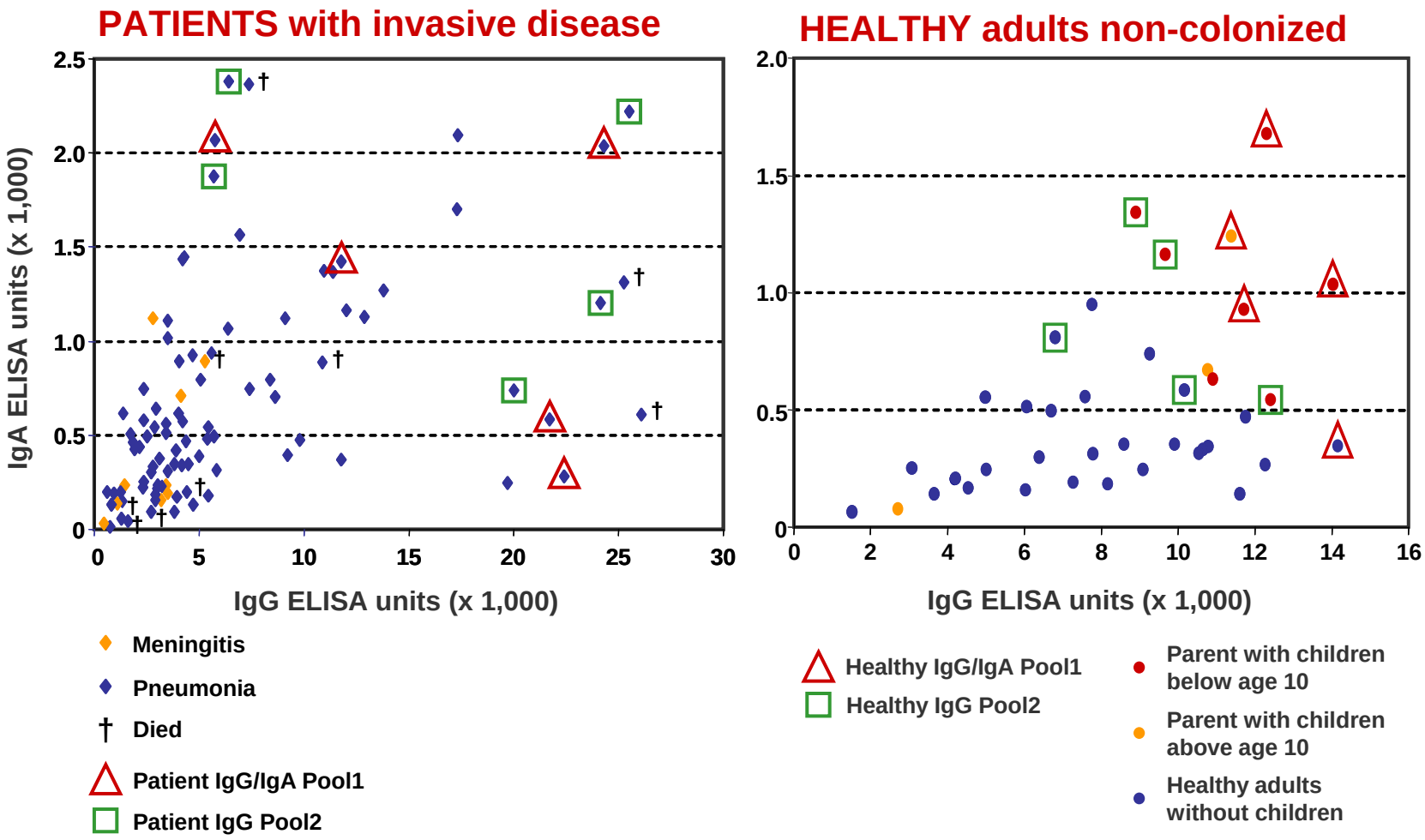


Giefing et al.
J. Exp. Med.
205:117, 2008.

Selection of proper sera based on antibody levels

Pneumo

EXAMPLE S. PNEUMONIAE VACCINE

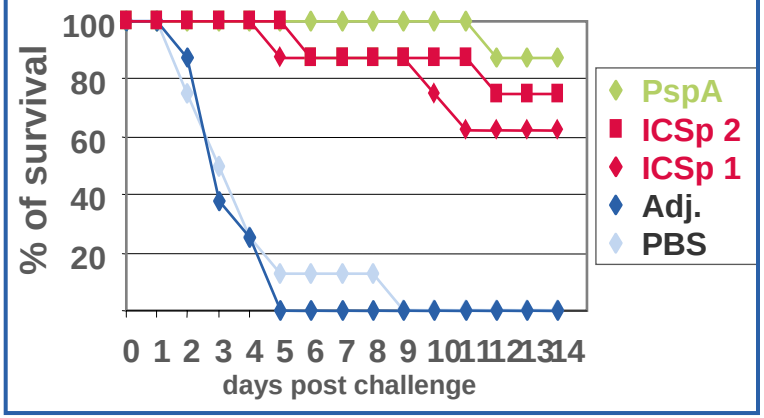


Giefing et al.
J. Exp. Med.
205:117, 2008.

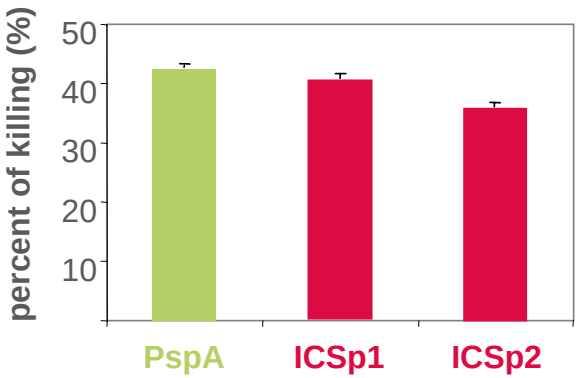
Features of the highly conserved pneumococcal antigen candidates

Pneumo

Protection from lethal challenge in mice

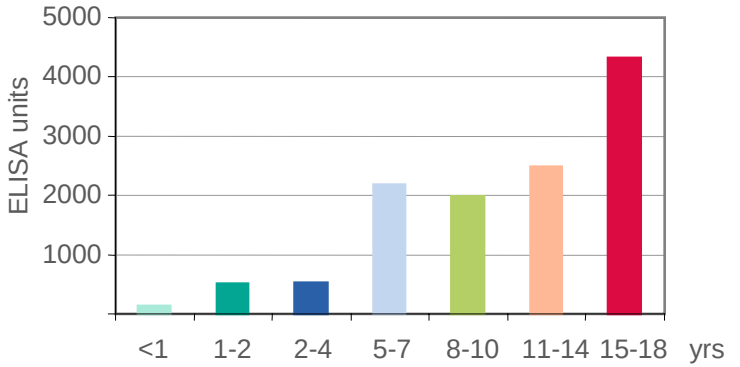


In vitro opsonophagocytic killing by antigen-specific antibodies



High sequence conservation in 90 serotypes

Increasing levels of ag-specific natural antibodies during childhood



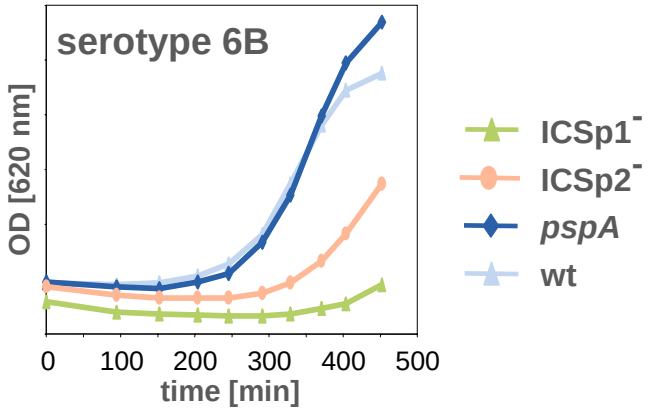
PspA: Protective control antigen, not conserved

Functional characterization of the S. pneumoniae lead antigens

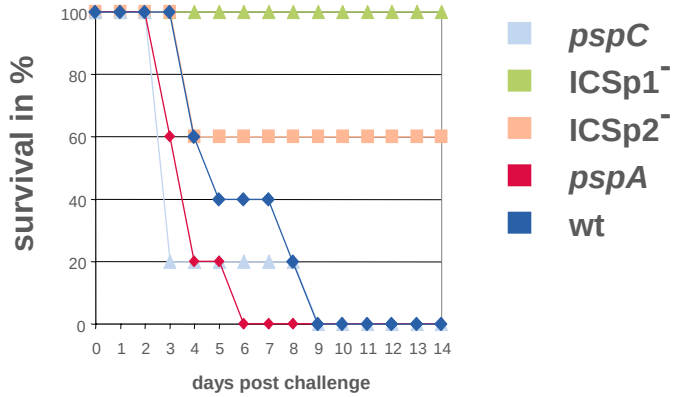
Pneumo

KNOCK-OUT ANALYSIS REVEALS PIVOTAL FUNCTION

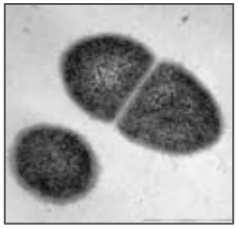
Phenotype *in vitro* – growth is impeded



Pathogenicity – virulence is lost or reduced



serotype 6B dose: 10^6 cfu challenge: i.p.



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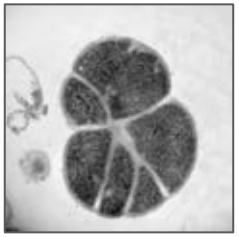
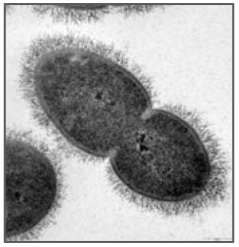
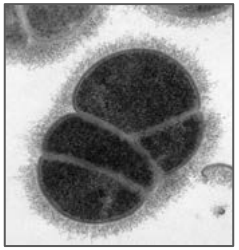


ICSp1-



pMU-ICSp1



pMU1328

Giefing et al.
J. Exp. Med.
205:117, 2008.

Study of the Pneumo vaccine in animal models

Pneumo

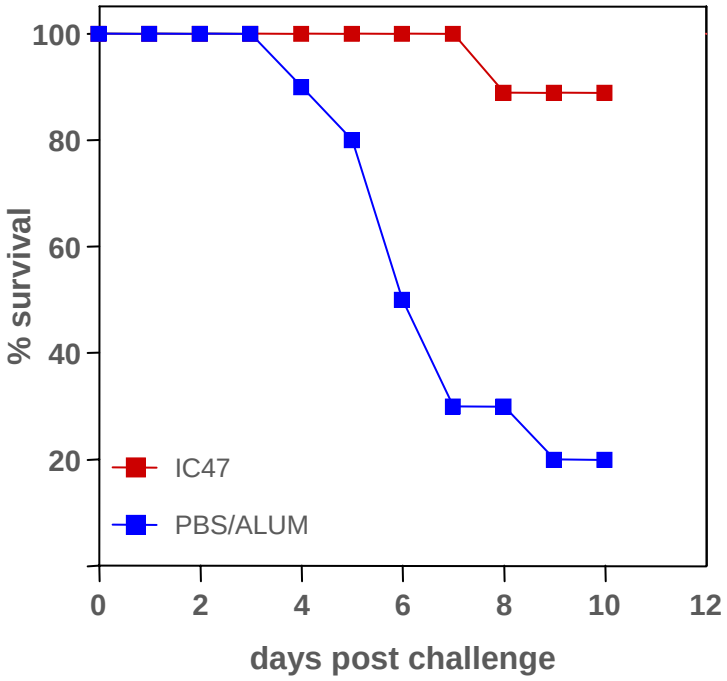
PROTECTION FROM LETHAL SEPSIS AND PNEUMONIA

IC47

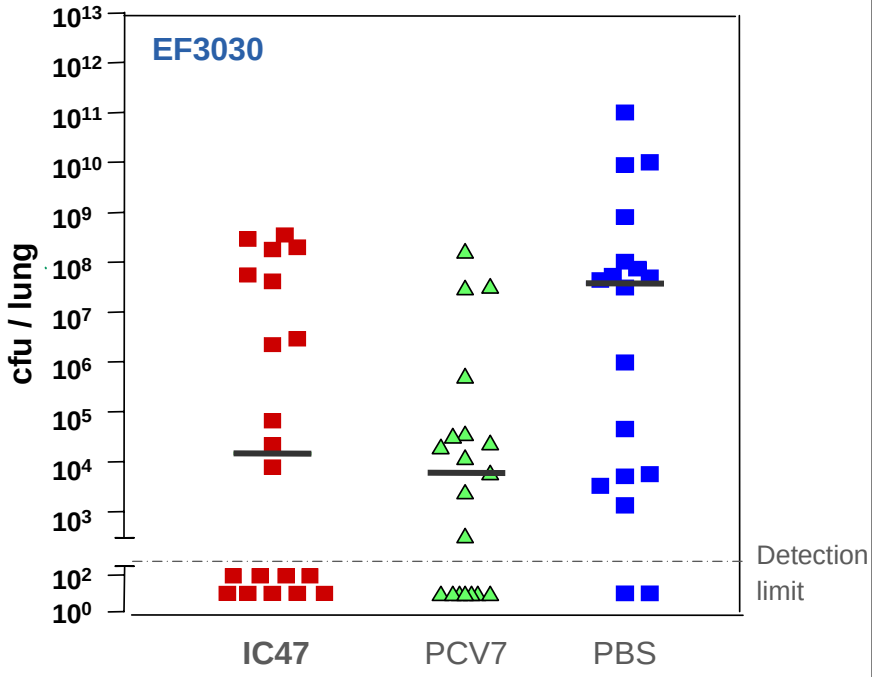
PcsB-N
StkP-C
PsaA
ALUM

PCV7
=
Prevnar®

Sepsis induced with serotype 6B

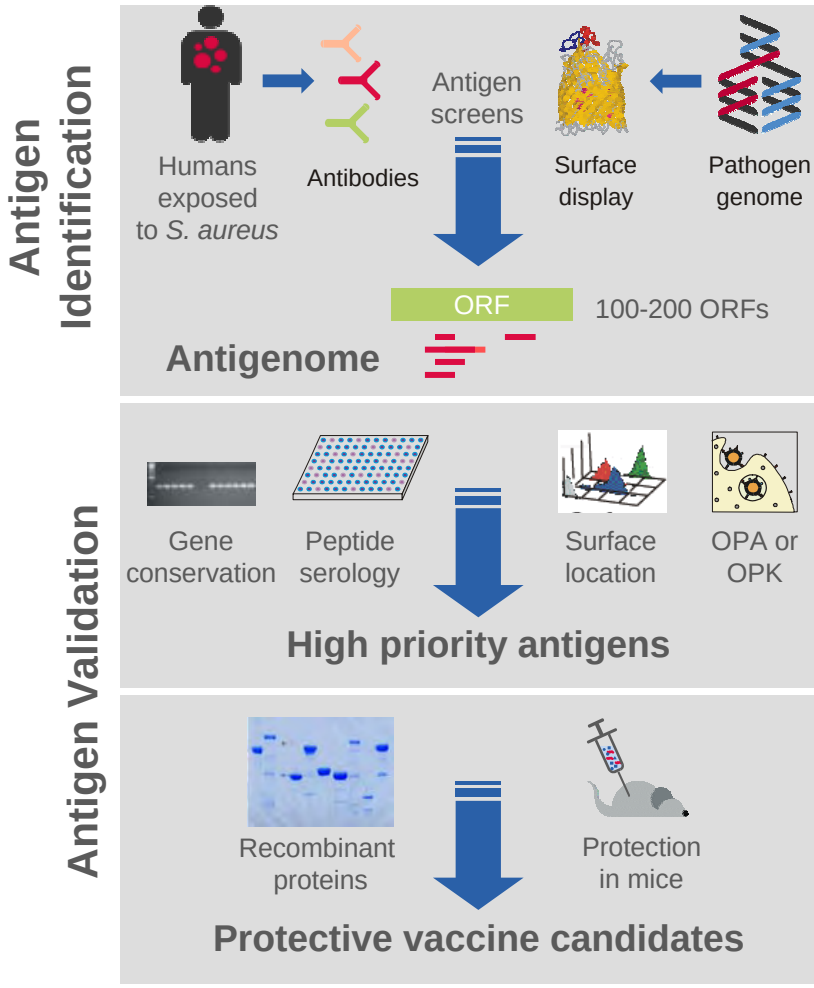


Pneumonia induced with serotype 19F



A S. aureus vaccine – based on AIP® target identification

AIP® – ANTIGEN IDENTIFICATION



The Vaccine

- IsdB expressed & highly conserved in all tested S. aureus isolates (including MRSA and VISA strains)
- Vaccine-induced protection demonstrated
  - Antibody titer correlates with protection
  - Anti-IsdB antibodies have functional activity
- S. aureus passaged 10x in IsdB-immunized mice did not develop resistance to IsdB vaccination

Etz H et al. PNAS 2002; 99:6573-6578. Henics T et al. BioTechniques 2003; 35:196-20; Meinke A et al. Curr Opin Microbiol. 2004; 7:314-320; Kuklin NA et al. Infect. Imm. 2006 Apr; 74(4):2215-2223.

ORF = Open Reading Frame

OPA = Opsono-phagocytic activity

OPK = Opsono-phagocytic killing

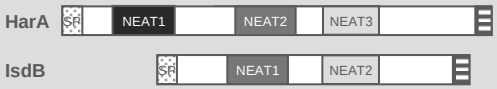
VISA = Vancomycin-intermediate S. aureus

Again the identified antigen used for the vaccine: an Achilles‘ heal of S. aureus life cycle

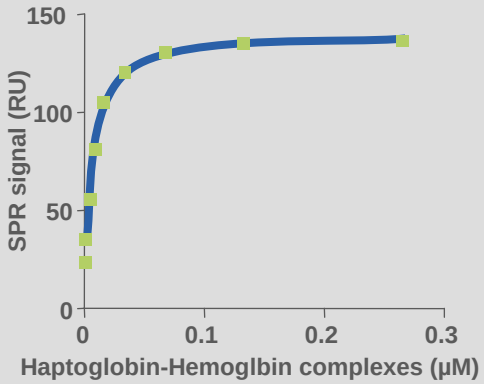
STRUCTURE AND FUNCTION OF THE VACCINE ANTIGEN, Isd B

Supportive research

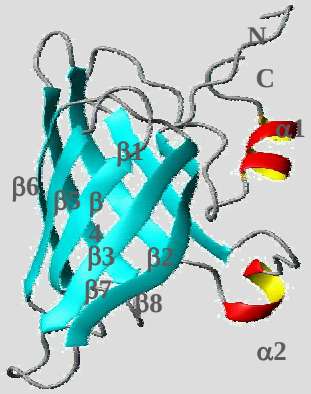
Domain structure



Ligand binding, role in iron acquisition



NMR structure



BLOCK OF FUNCTION: REDUCES BACTERIAL SURVIVAL

Dryla et al. Mol. Microbiol, 49, 2003

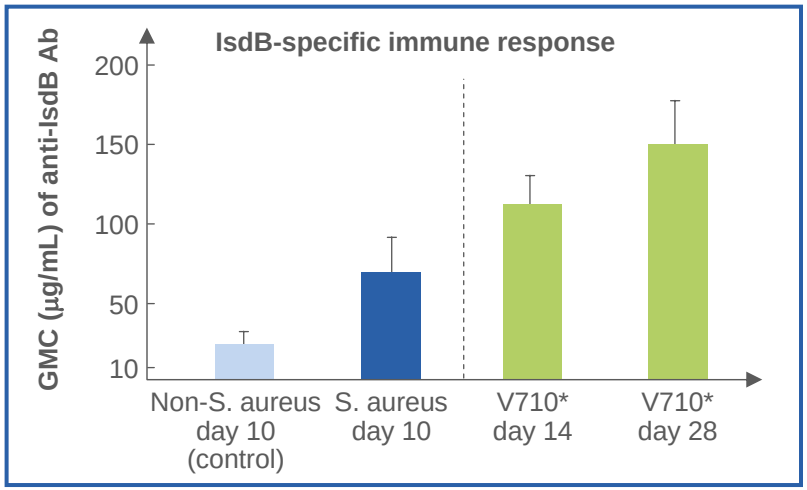
Dryla et al. J. Bact. 189 , 2007

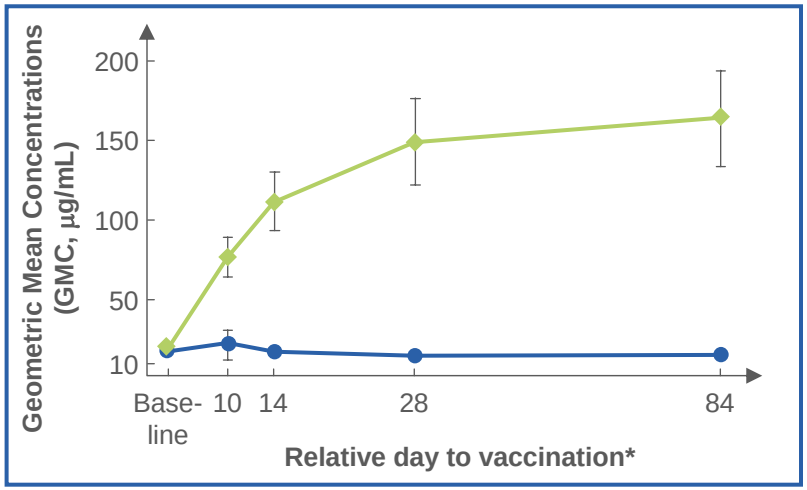
Fast and sustained IsdB-specific immune response

SELECTED CLINICAL DATA

V710 60 µg (n = 41)

Placebo (n = 10)





» Epidemiology studies show that IsdB antibody titers are elevated in protected individuals

» Anamnestic response detected as early as 10 days

» Sustained response over at least 84 days

* Harro et al. Inter. Sym. Staph & Staph Infect (ISSSI), Sep 2008

Source: Merck & Co

Broad Phase II/III efficacy clinical program is ongoing

S. AUREUS VACCINE STATUS

Cardiothoracic surgery (Phase II/III)*

» **Primary Outcome:** Prevention of serious S. aureus infections for 90 days following cardiothoracic surgery

» Efficacy data expected for mid 2009

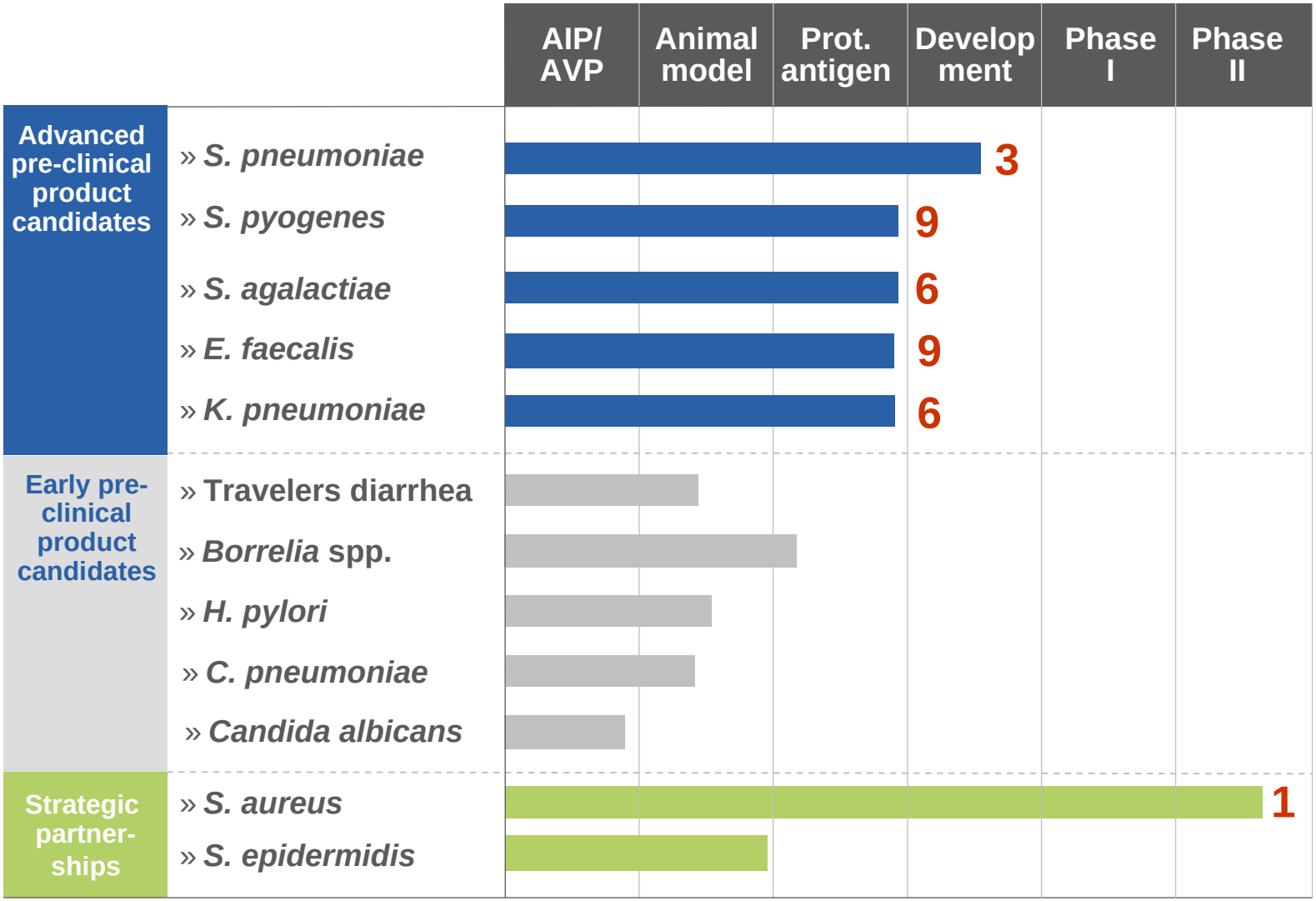
End-stage kidney disease / dialysis (Phase II)

» **Primary Outcome:** Safety and immuno-genicity in patients with end-stage kidney disease and hemodialysis

» Data expected for end 2009

*sequential design

Vaccine portfolio based on ANTIGENome technology in pre-clinical development

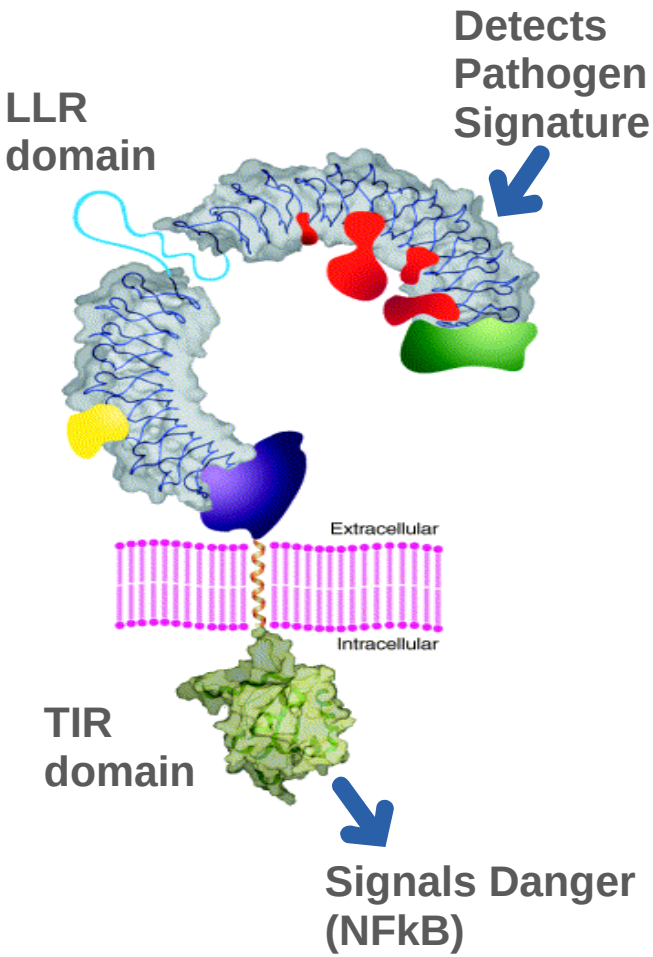


Source: Intercell

A new concept in immunology

SENSORS OF INNATE IMMUNITY: TOLL-LIKE RECEPTORS (TLRS)

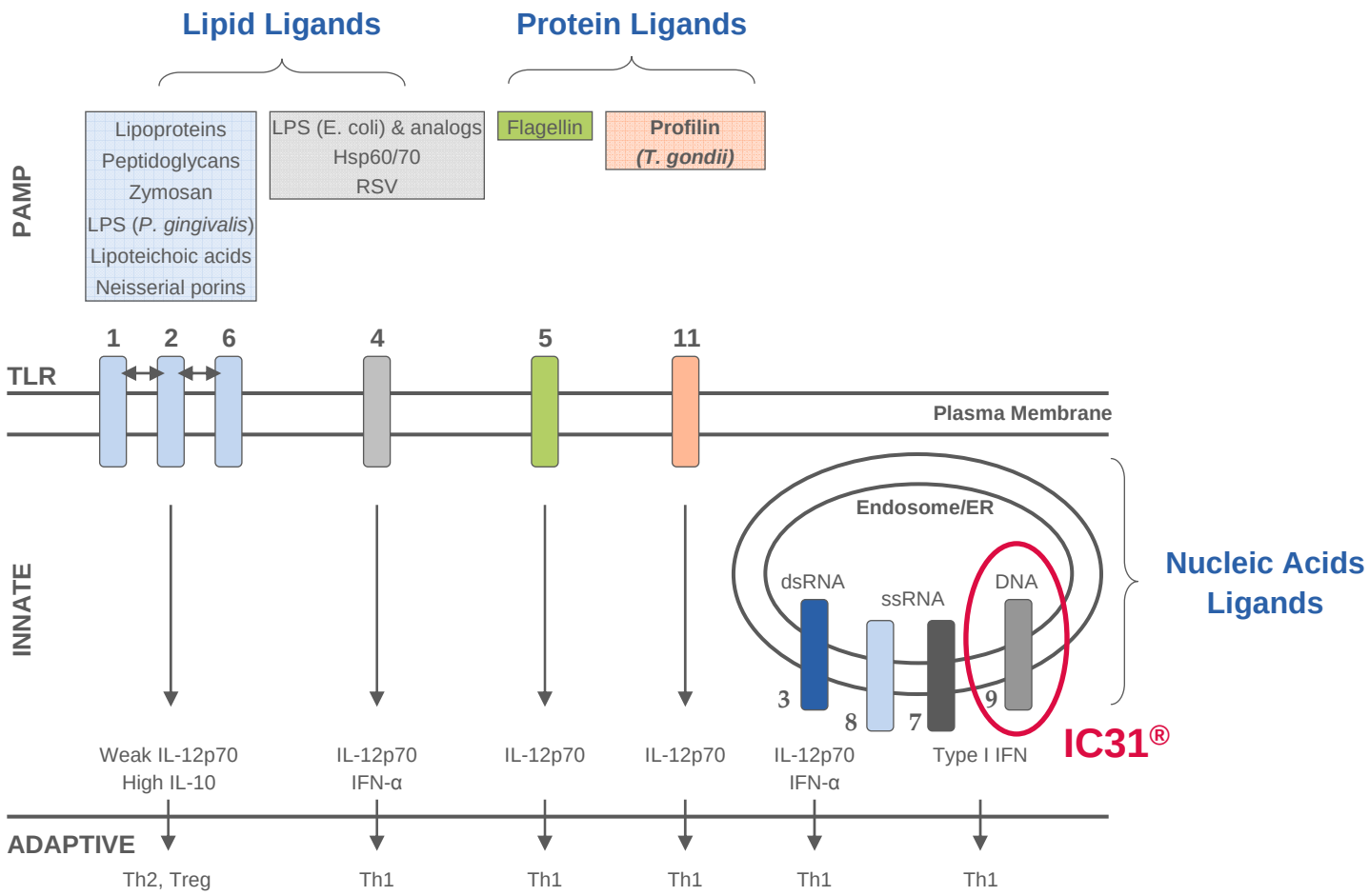
B. Lemaitre et al**. 1996** Cell 86:973-983



Bell et al, Trends Immunol. 24:528,2003

The Toll-like receptor family – targets for the next generation adjuvants

PAMPS AND THE INDUCTION OF TYPE-1 DRIVEN IMMUNITY*

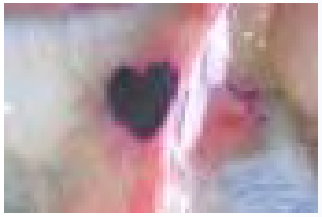


* Adapted from Kwissa et al., Expert Rev Vaccines 2007; Pulendran & Ahmed, Cell 2006

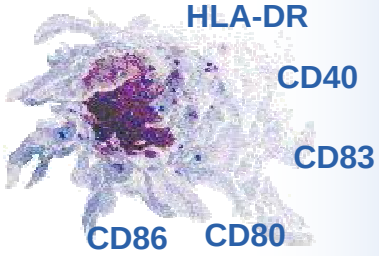
IC31®: a TLR agonist comprising two chemically defined biodegradable components

» **KLK:**
antimicrobial peptide H-KLKL$_5$KLK-OH

- Type 2 immune responses (+ proteins)
- Depot formation at injection site



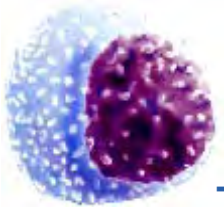
- Enhancement of antigen and ODN1a uptake by APC



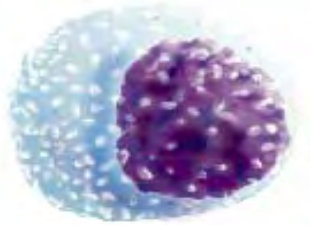
» **ODN1a:**
oligodeoxynucleotide oligo-(dIdC)$_{13}$ phosphodiester, ssDNA

- Type 1 induction
- Activation of APC (Dendritic Cells)
- TLR-9 / MyD88-dependent signaling

Potent and sustained Th-1 / type 2 responses



T cell



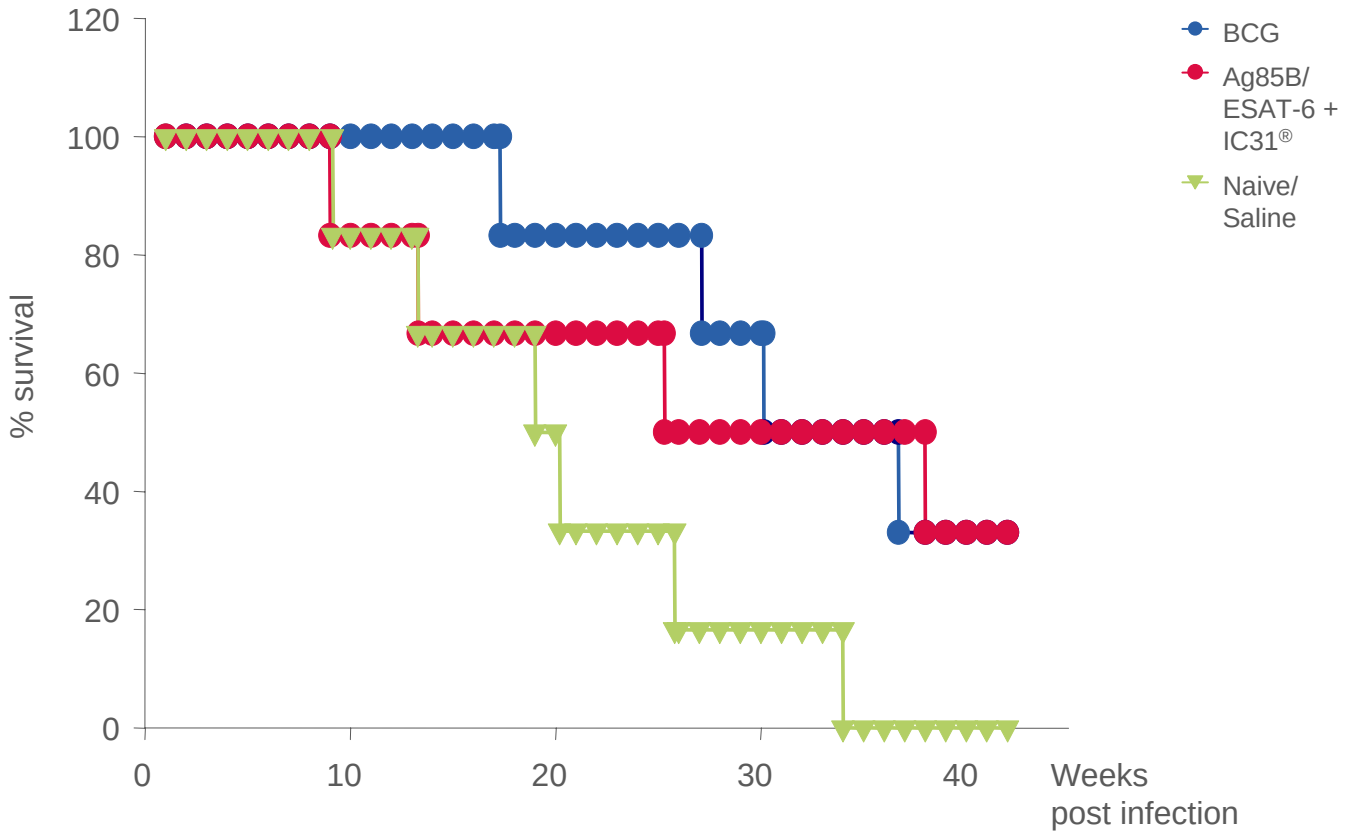
B cell

Fritz et al., Vaccine 2004, 2:3274
Kritsch et al, J Chromatography, 2005 822:263
Schellack et al, Vaccine 2006, 24:5461
Agger et al, Vaccine 2006, 24:5452
Lingnau et al, Exp. Rev. Vaccines 2007
Riedl et al, Vaccine, 2008, 26, 3461
Aichinger et al, Cell Biol 2008, 32, 1149
Kamath et al, Eur. J. Immunol, 2008, 38, 1247

Protective immunity of a novel TB subunit vaccine adjuvanted with IC31®

TB

PRECLINICAL EVALUATION – SURVIVAL (GUINEA PIG)*



* 3x i.m. injection, 4-week interval

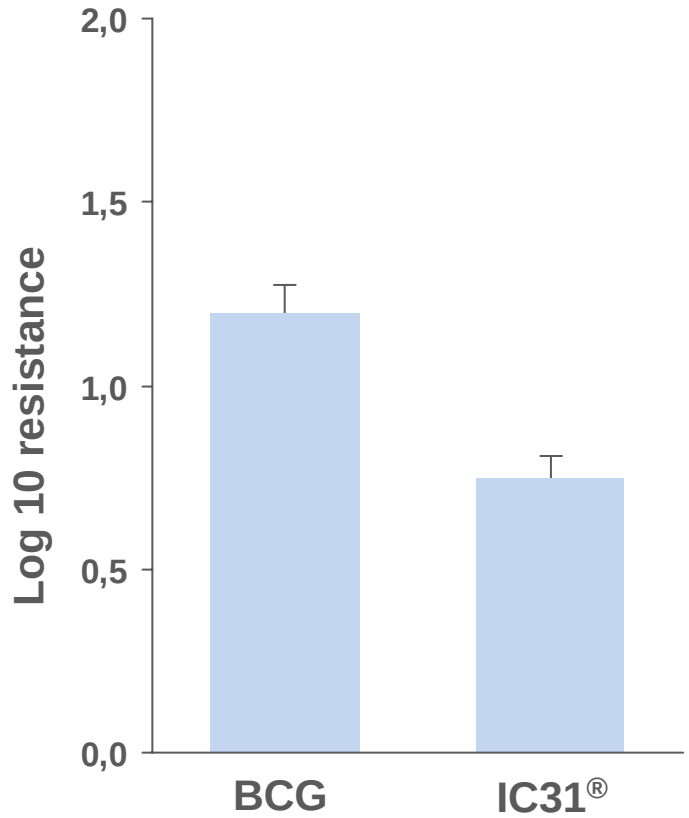
Aerosol infection; 16 weeks after first injection

Protectivity is linked to IFN- γ producing T-cells indicative for Th-1 driven immunity

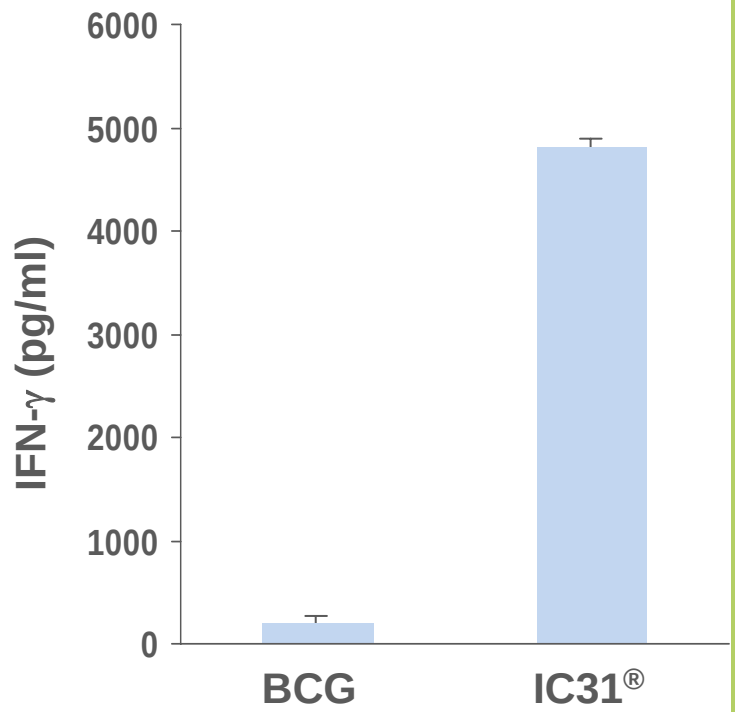
TB

DEFINITION OF PROTECTION MARKERS (MOUSE MODEL)

RESIDUAL BACTERIA (lung)



IFN-γ production

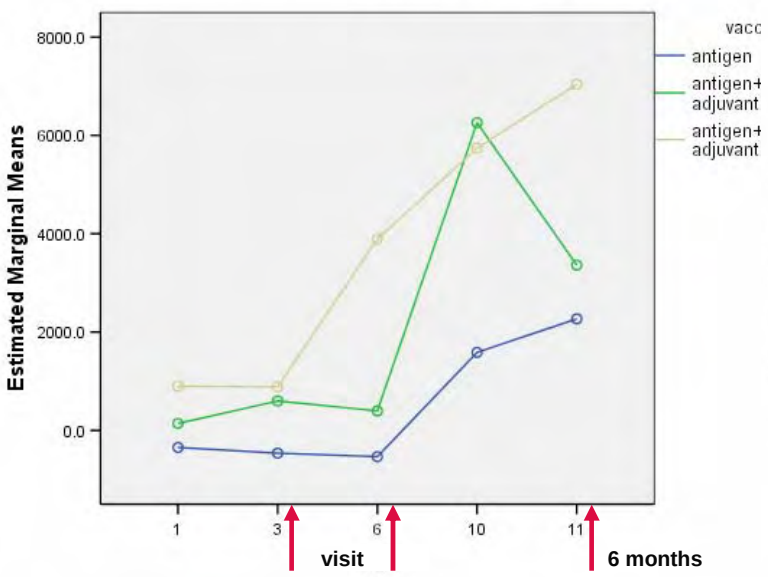


Induction of antigen-specific T-cells in humans vaccinated with the novel TB subunit vaccines

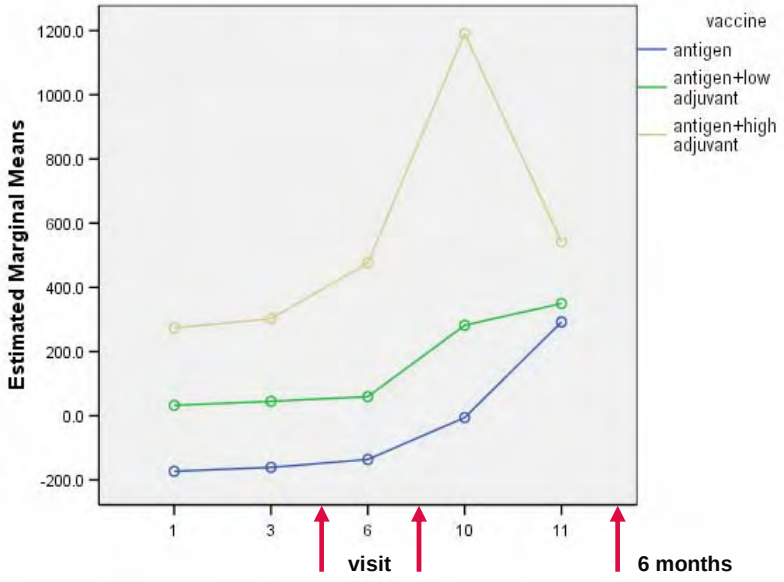
TB

DATA FROM TB PHASE I STUDY: STRONG T_H-1 INDUCTION

IFN-γ in T-cell supernatants
(Ag85B/ESAT-6-specific ELISA; Estimated Marginal Means)

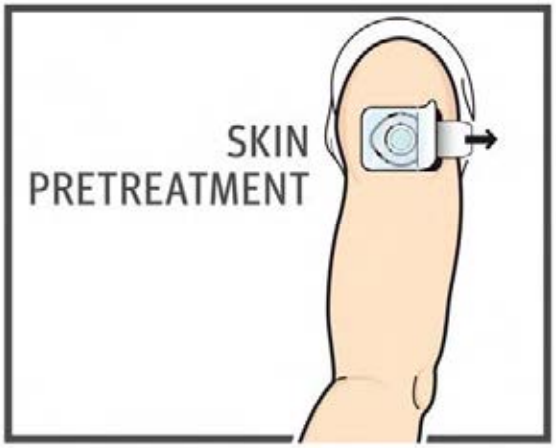


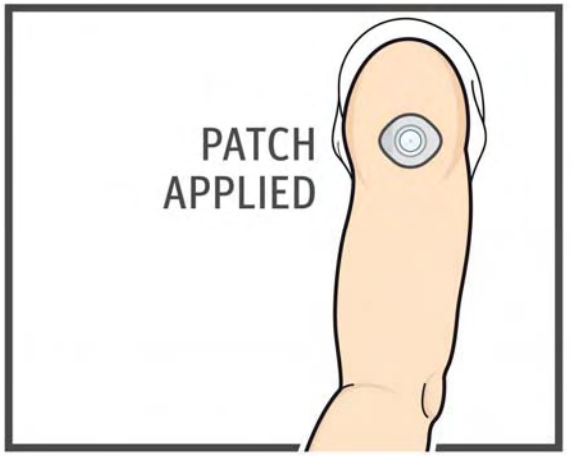
Frequency of IFN-γ prod. T-cells
(Ag85B/ESAT-6-specific ELISpot; Estimated Marginal Means)



Travelers' Diarrhea vaccine patch: First vaccine delivered with a patch

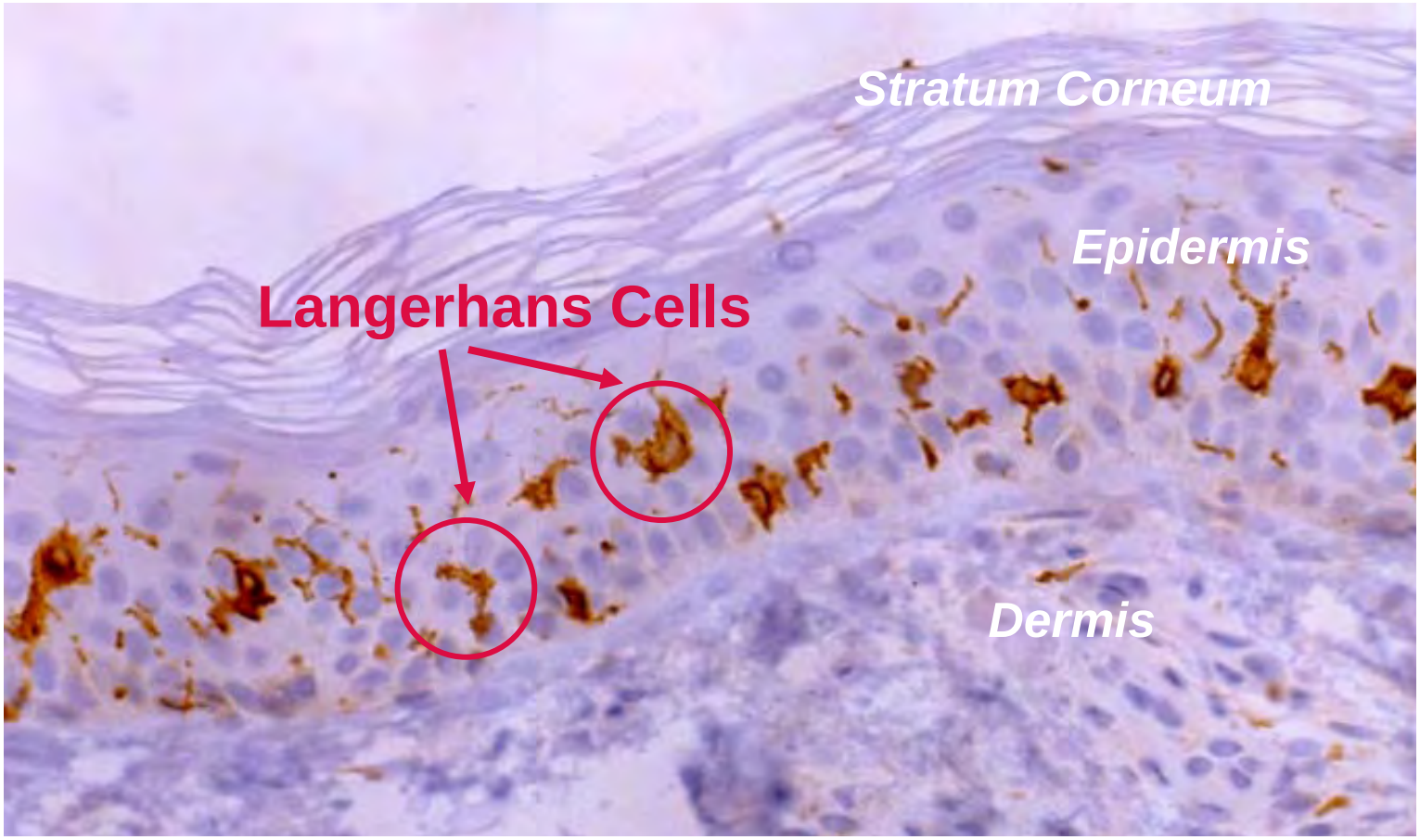
SKIN PRETREATMENT AND VACCINE PATCH





The skin – a dense population of antigen presenting cells

RATIONALE AND MECHANISM

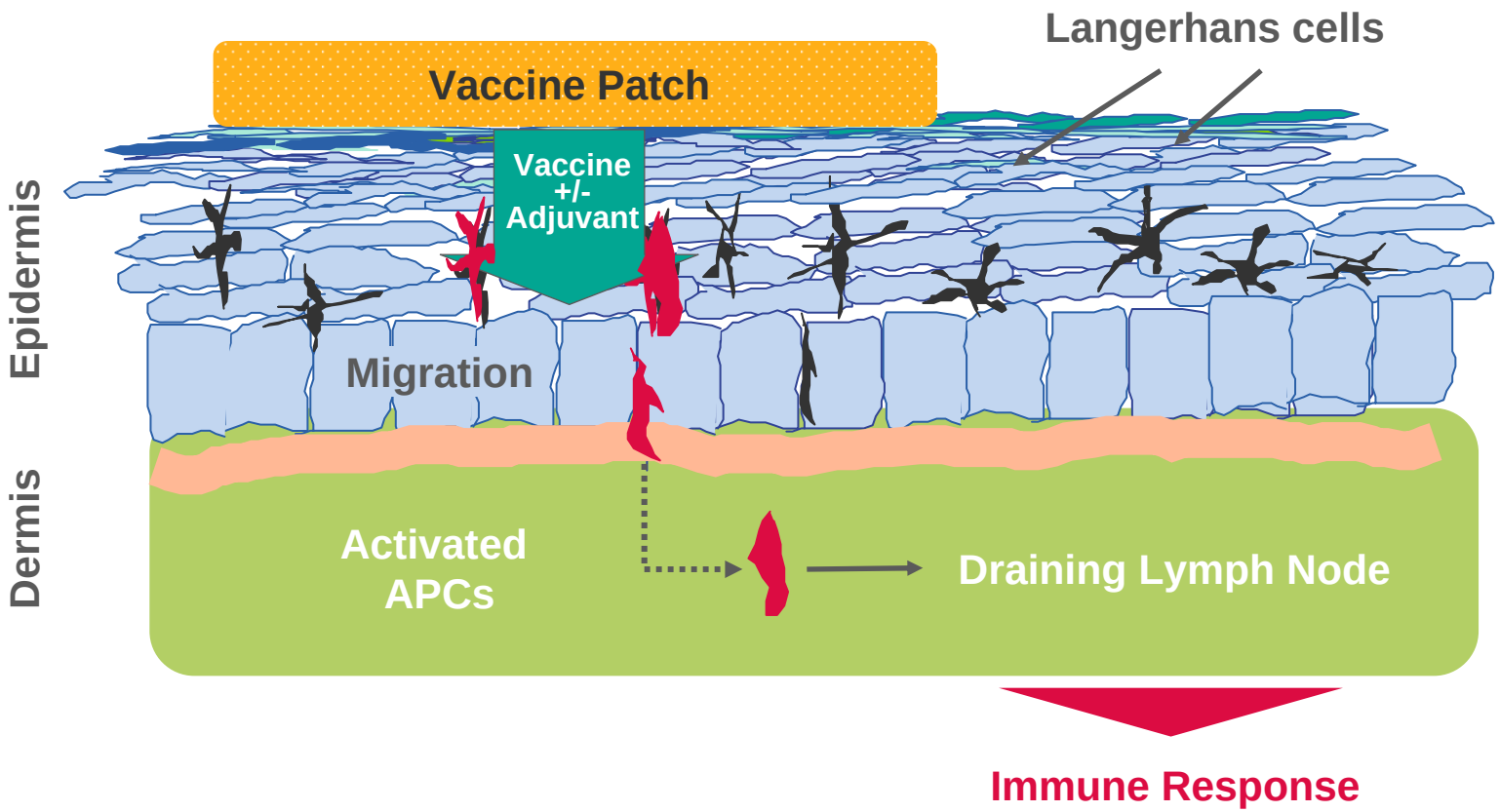


Source: Glenn et al, Nature Med, 2000

Biopsy of human skin magnified 400 x

Transcutaneous immunization – capitalizes on the skin immune system

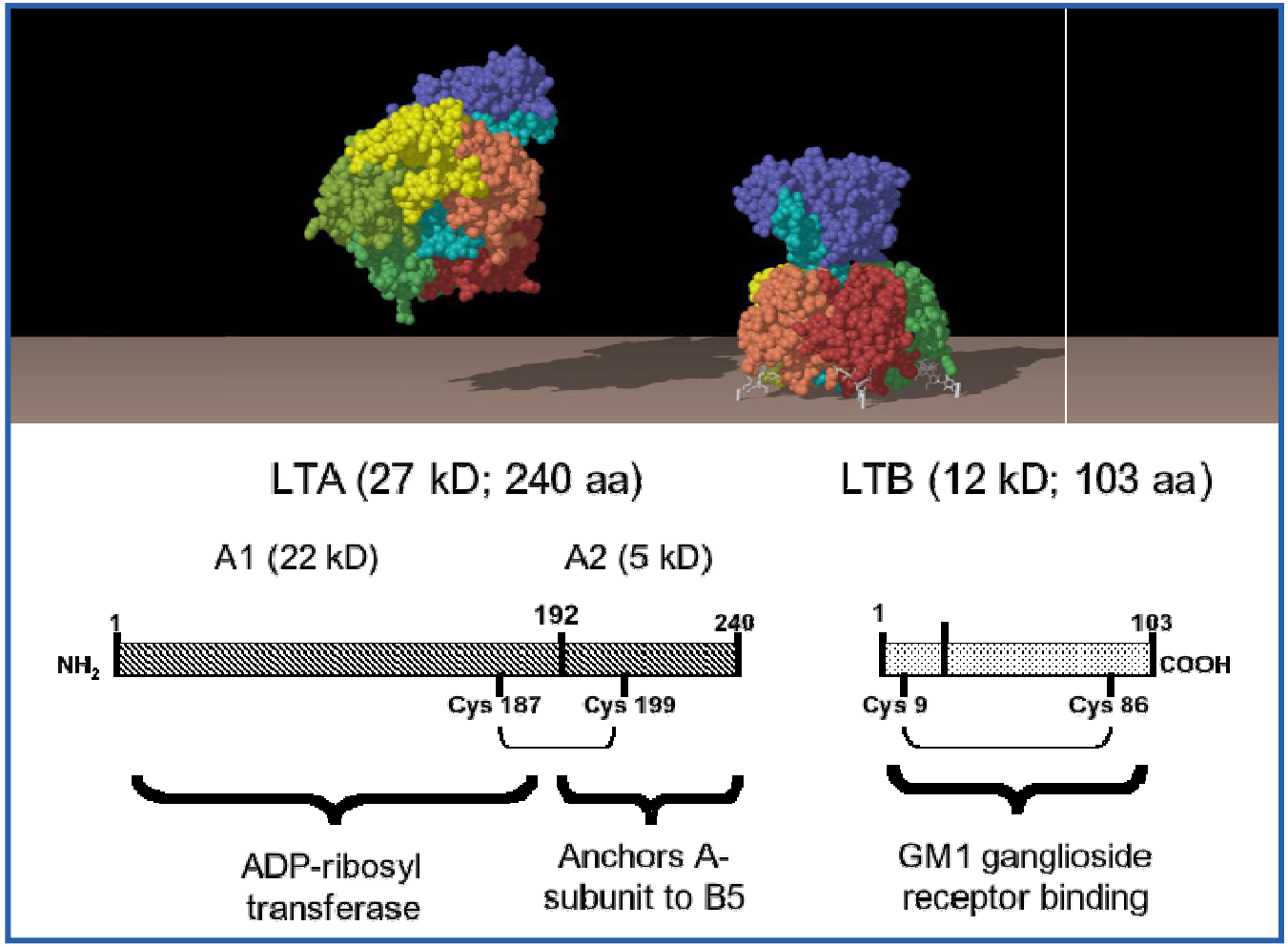
MODE OF ACTION



LT antigen and adjuvant in one – proof of principle of the patch technology

ETEC

OVERVIEW



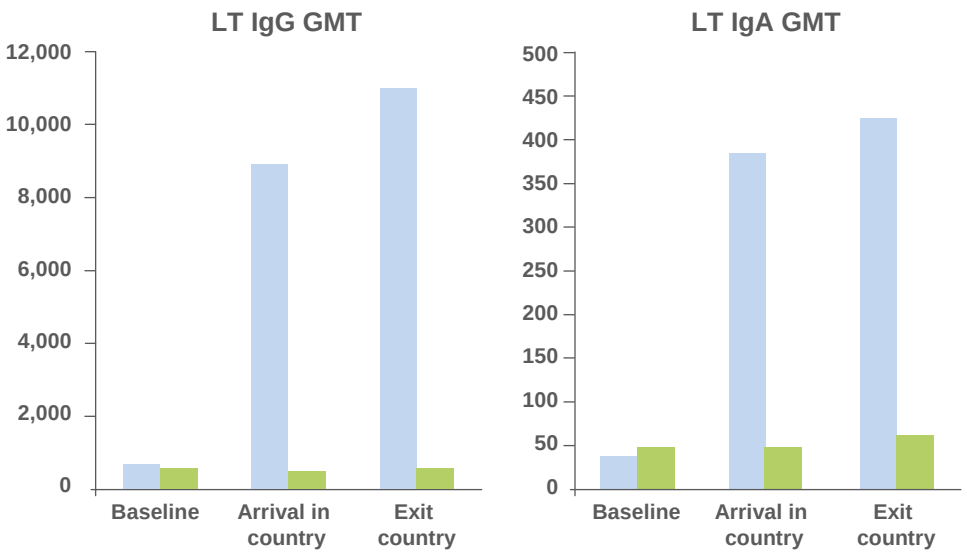
Immunogenicity and efficacy proof for Travelers' Diarrhea vaccine patch

PHASE II RESULTS*

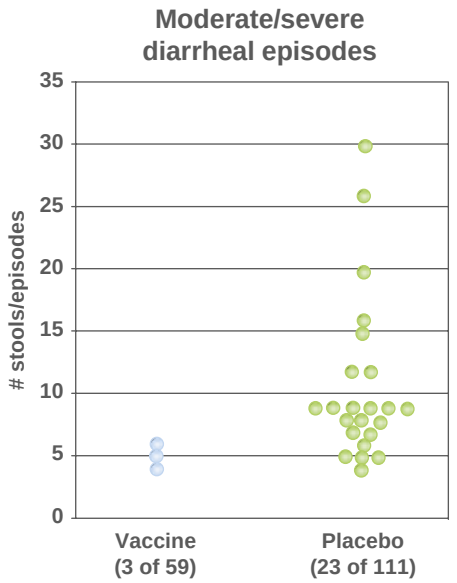
Vaccinees (n=59)

Placebo (n=111)

Excellent immunogenicity**



Compelling efficacy**



Proposed indication

Active immunization against moderate to severe Travelers' Diarrhea

* Published in The Lancet, June 2008
** 2 vaccinations with patch at days 0 and 14-21; travel to South America 7 days post 2nd vaccination with patch

Acknowledgement

Eszter Nagy

Greg Glenn

Alexander von Gabain

Intercell Vienna

Jonathan Adshead
Astrid Aufinger
Sharmila Bakshi
Tamás Berke
Manfred Berger
Pär Comstedt
Alena Egyed
Andrea Fritzer
Dieter Gelbmann
Carmen Giefing
Markus Hanner
Kira Jelencsics
Christoph Klade
Karen Lingnau
Zoltan Magyarics
Florian Mayer-Rönne
Birgit Noiges
Martin Oleksiewicz
Verena Olivier
Albina Poljak
Christoph Reinisch
Karin Riedl
Rosemarie Riedl
Ulrike Samen
Robert Schlegl
Petra Schlick
Wolfgang Schüler
Sanja Selak
Beatrice Senn
Margarita Smidt
Julie Sommer
Ingmar Stoll
Erik Thiele Orberg
Zehra Claire Visram
Kerstin Westritschnig
Benjamin Wizel
David Zimmel
Nicole Scharnagl

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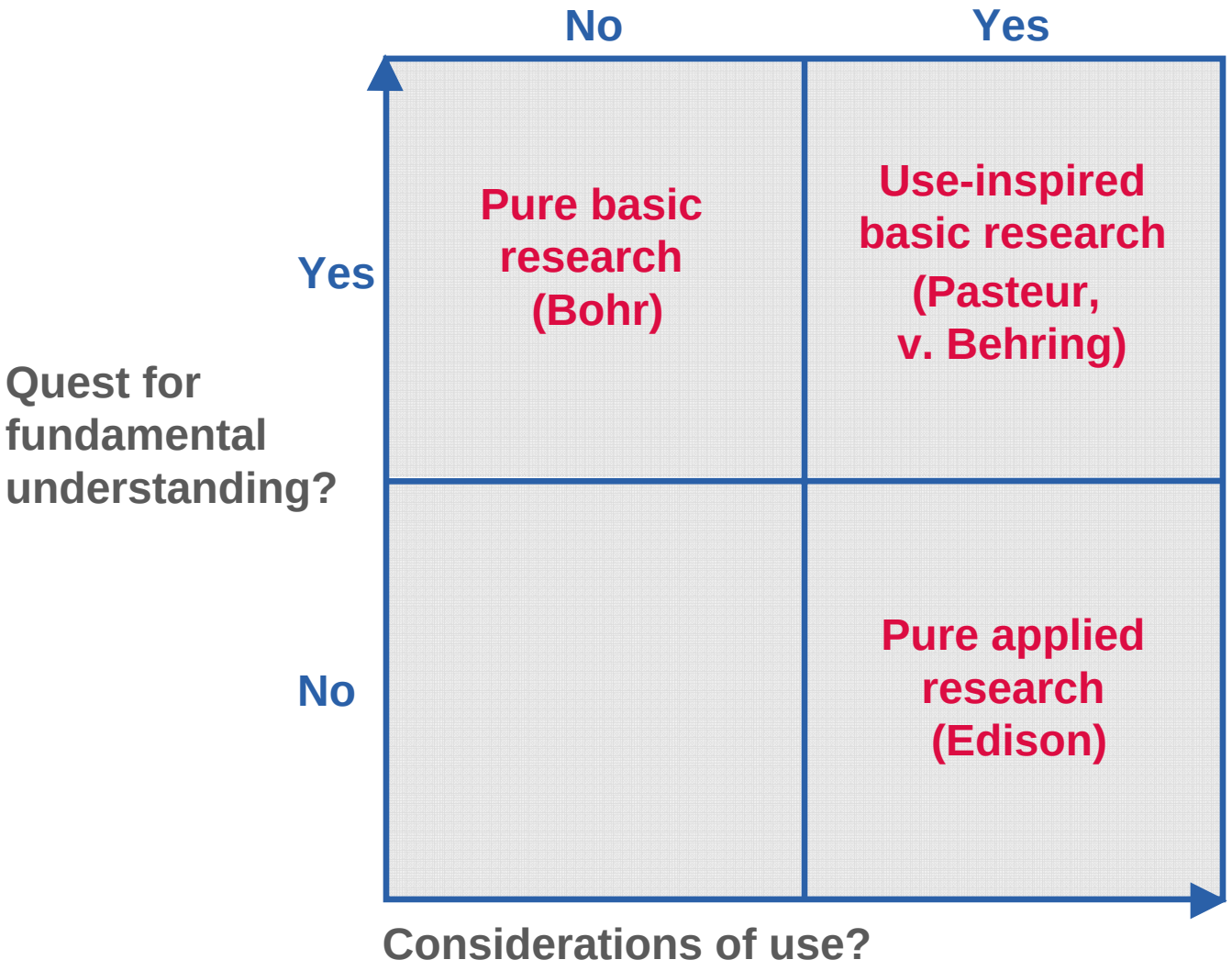
Entrepreneurship – a forbidden city for a professor?

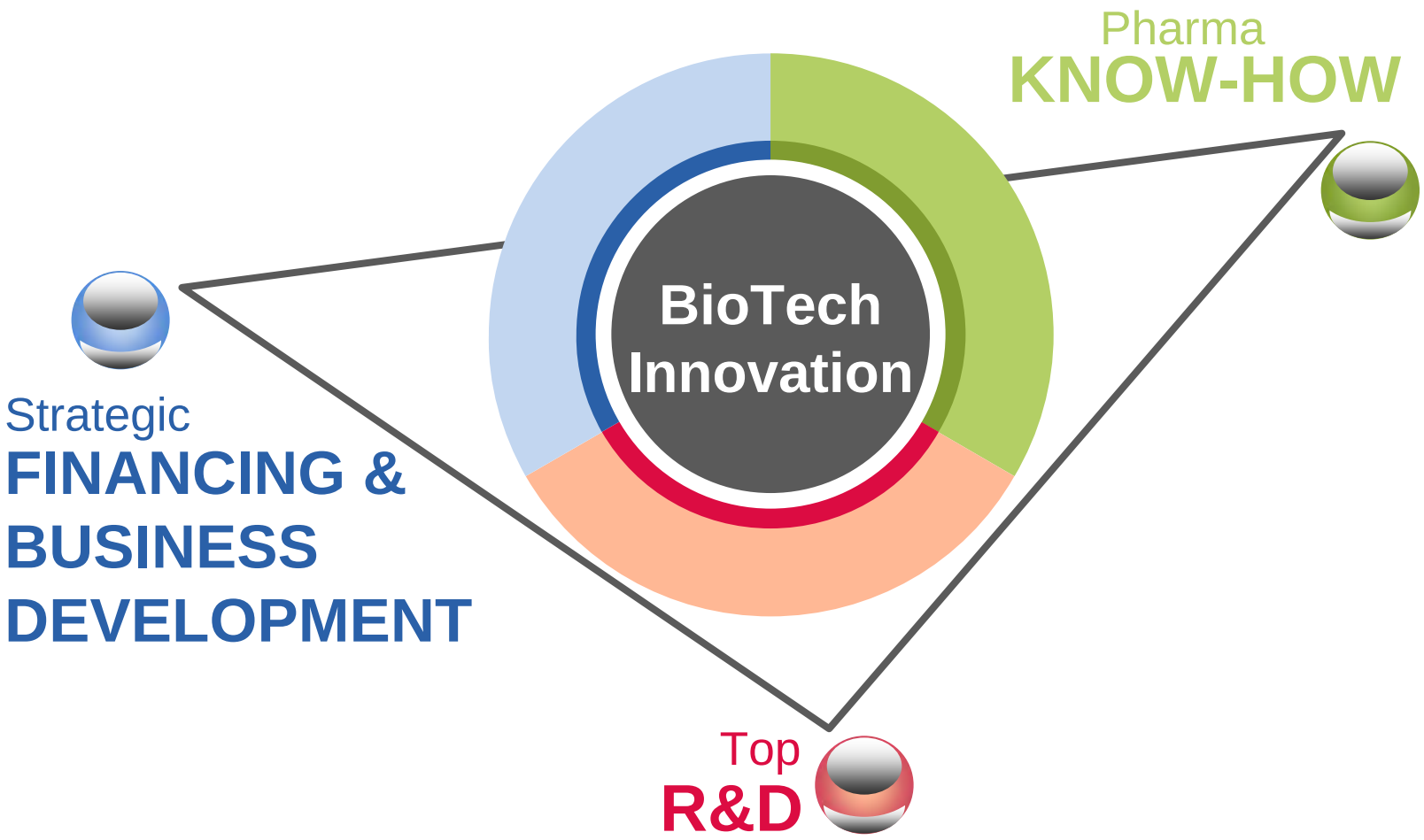
Back to a translational tradition in Europe: Quadrant Model of Scientific Research

RESEARCH IS INSPIRED BY ENTREPRENEURIAL SPIRIT



Building biotech companies: The competence triangle

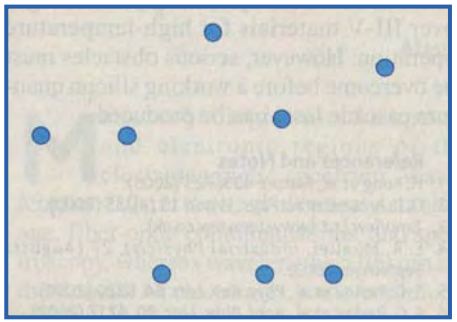
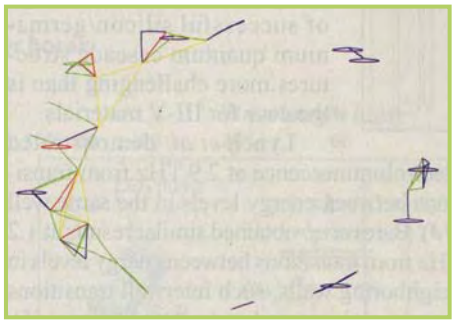
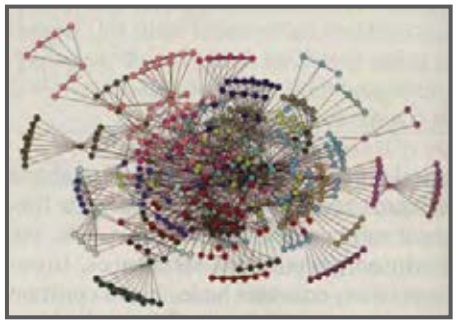
EXCELLENCE IN RESEARCH DOES NOT SUFFICE



How to form an efficient team with strong individuals in the biotech triangle?



- Go for the best individuals
- Make sure they understand the masterplan & the risk to fail
- Make sure they form a strong team
- Create respect for the involved competence areas
- Encourage everybody to bargain on the strength/weakness profile of the other team members

Source:
Science,
Vol. 308, p. 640

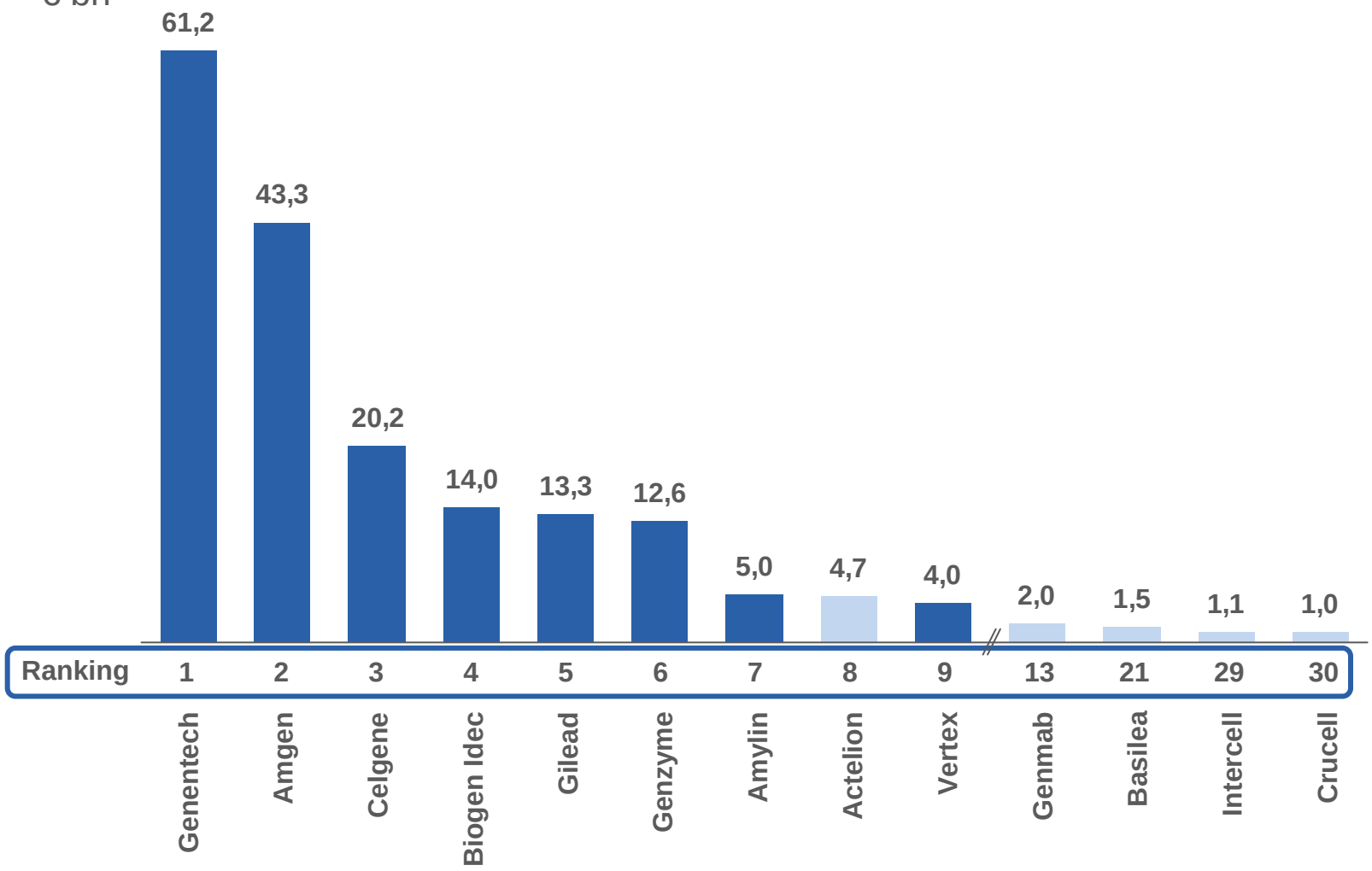
Biotech can create significant value, but Europe still has a long way to go

BIOTECH MARKET UPDATE

US

Europe

MARKET VALUES AND RANKING



Source: FactSet as of 21st September, 2007

Europe has strong assets to support a strong entrepreneurial-driven biotech industry

HOW TO CAPITALIZE ON THE ASSETS

» High level of education

» Solid academic base

» Top science at many historical power houses of research: EMBO, Pasteur, Karolinska, Cambridge, Oxford, Max Planck, IMP etc..

» Increasing number of Centers of Excellence

» Long tradition of pharma development

» Excellent clinical institutions with the potential to carry out studies

» Growing interaction between the national bio-medical scenes

» Scientific output in biotech is even larger than in the USA

Lessons to be learned for Europe

IT'S NOT TOO LATE

» Accept the financing tools that have built the US Biotech industry (VCs, stock markets, etc…) – there is no European way to create Biotech industry

» Make our continent attractive for international VCs

» Prepare incentive structures in legal and tax regulations that encourage investment and entrepreneurship

» Stop the incentive structure for half professor/half entrepreneur players in protected academic shelters

» Stop subsidizing biotech industries with more public money than private investment

» Accept failures without moral attitude and recognize the value of company built up *per se*

» Expand the horizon of life science students towards biotech industry