

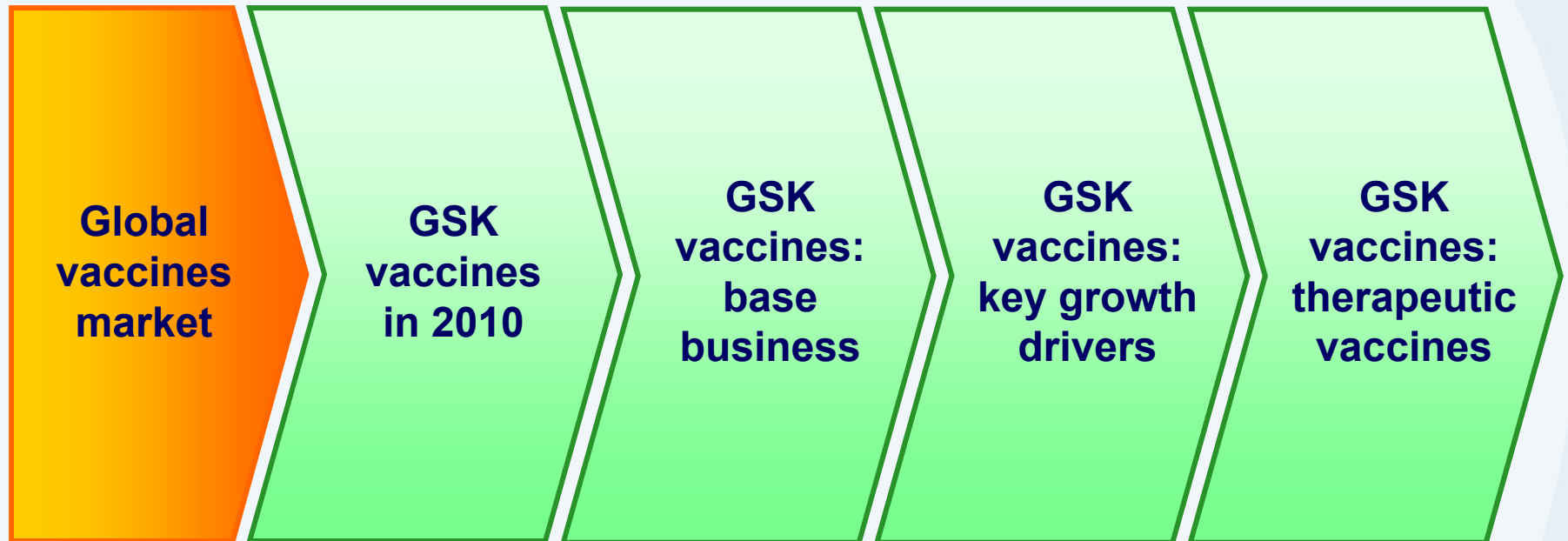
# **GSK VACCINES IN 2010**

**Thomas Breuer, MD, MSc**

Senior Vice President, Head of Global Development  
GSK Biologicals



# Today's agenda

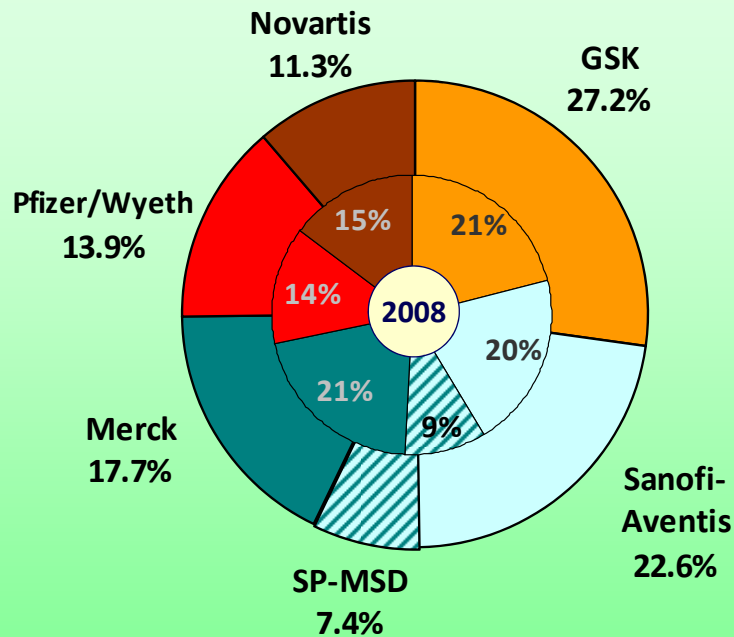


# Vaccines business characteristics

- Few global players and high barriers to entry
  - Complex manufacturing
  - Large scale investment
- Long product life cycles
  - Complex intellectual property
- High probability of R&D success
  - 70% post-POC
- New technology/novel products
- Better pricing
- Operating margin comparable to pharmaceutical products
- Heightened awareness
- New markets

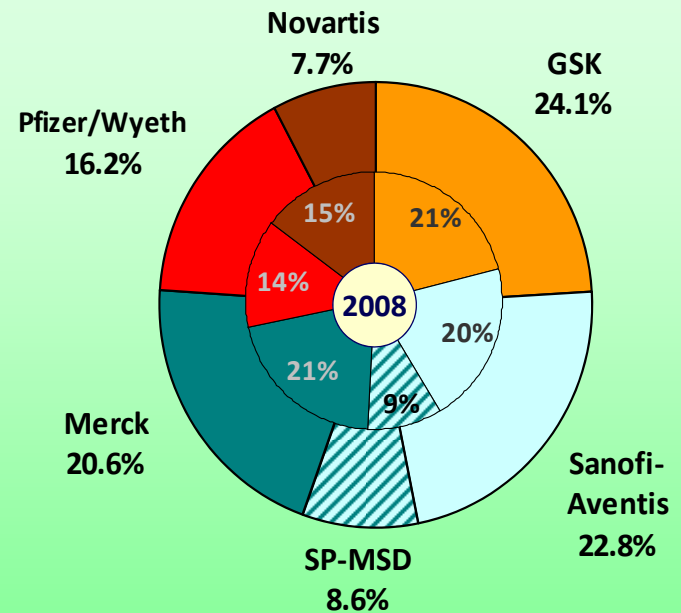
# Global vaccines market 2009

## 2009 total sales



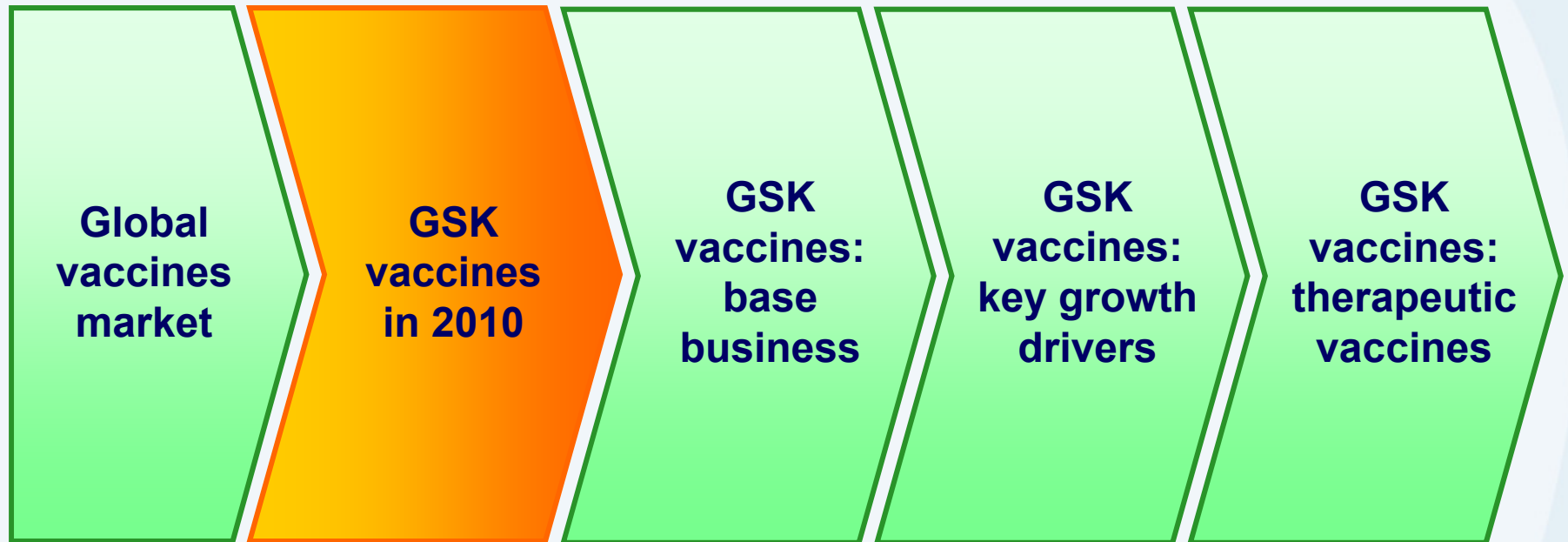
**Total 2009 = \$21,493m**

## 2009 excluding H1N1



**Total 2009 excl. H1N1 = \$18,432m**

# Today's agenda



# GSK vaccines business

2009 sales £3.7 billion (+30%)

Vaccines represent 13%  
of total GSK sales

Recent approvals:

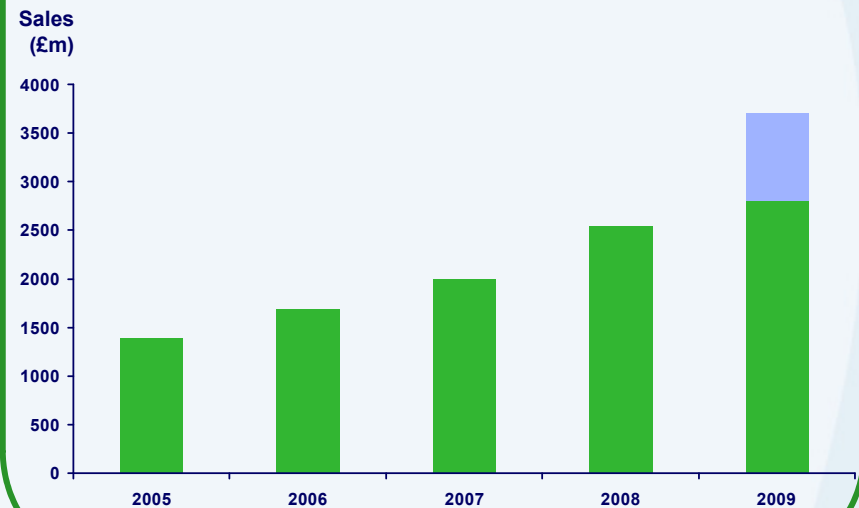
US: *Cervarix*

EU: *Synflorix*

Pandemic: *Pandemrix*; *Arepanrix*

Increased Emerging Market presence

+19% CAGR excl. H1N1  
since 2005



# GSK vaccines business

**Over 30 approved vaccines and 20  
in development**

**Distributed 1.4 billion vaccine doses  
in 182 countries in 2009**

**9,500 employees worldwide, including  
over 1650 scientists**

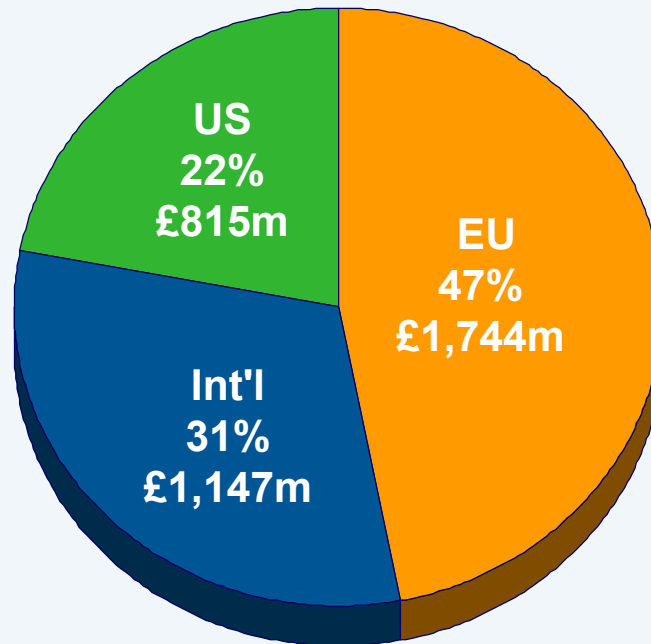
**Global manufacturing network:  
15 sites around the globe**

**Succession plan for management  
of vaccines business**



# GSK vaccines: broad geographic opportunity

**GSK vaccines 2009 sales  
£3.7bn**





# Geographical opportunity

## US

 **Engerix-B®**

**Havrix®**  
Hepatitis A Vaccine,  
Inactivated

**TWINRIX®**

**BOOSTRIX®**

**Infanrix®**

**Pediarix™**

**Fluarix™**

**FluLaval™**  
Influenza Virus  
Vaccine

**Rotarix®**  
Rotavirus Vaccine,  
Live, Oral

**Kinrix™**

## Emerging Markets

**Cervarix™** 

**Infanrix** 

**Rotarix™**  
Rotavirus Vaccine,  
Live, Oral

**Fluarix™**

**Synflorix** 

**BOOSTRIX®**

**Havrix®**  
Hepatitis A Vaccine,  
Inactivated

## Japan

**Cervarix™** 

# GSK has the broadest vaccine portfolio in EM

	GSK	Merck	Sanofi	Pfizer	Novartis
DTPw combos	✓		✓		✓
DTPa combos	✓		✓		
MMR / <i>Varicella</i>	✓	✓	✓		
Hepatitis A	✓	✓	✓		
Rotavirus	✓	✓			
Meningococcal	✓		✓		d
Pneumococcal	✓			✓	
Influenza	✓		✓		✓
HPV	✓	✓			
Malaria	d				
Dengue	d		d		

✓ = available in EM; d = in development

# Emerging markets opportunity



## China



£116m  
+36%  
(2009)

### Licensed vaccines

- *Infanrix, Infanrix-Hib, Boostrix, Fluarix, Engerix-B, Hiberix, Havrix, Twinrix, Priorix, Varilrix*

### Vaccines in development

- *Cervarix* (phase III trials ongoing in China); *Infanrix-IPV/Hib* (IND)

### Joint venture with Neptunus

- Co-development of seasonal and pre-pandemic/pandemic influenza vaccines

### Joint venture with Walvax

- Develop and manufacture paediatric vaccines for use in China *Priorix* and other paediatric vaccines



## Brazil



£117m  
+10%  
(2009)

### Over 25 year collaboration with Brazilian Ministry of Health (Fiocruz)

### Long term governmental contracts

### Technology transfer agreements

- Oral polio vaccine (1980's)
- *Hiberix* (1998)
- *Priorix* (2003)
- *Rotarix* (2008)
  - Included in National Immunization Programme
- *Synflorix* (2009)
  - Inclusion in National Immunization Programme

# Opportunity in Japan

Japanese vaccine market  
underdeveloped: £500m in 2009

*Cervarix* first HPV vaccine  
approved in Japan

*Rotarix* first rotavirus vaccine  
filed in Japan

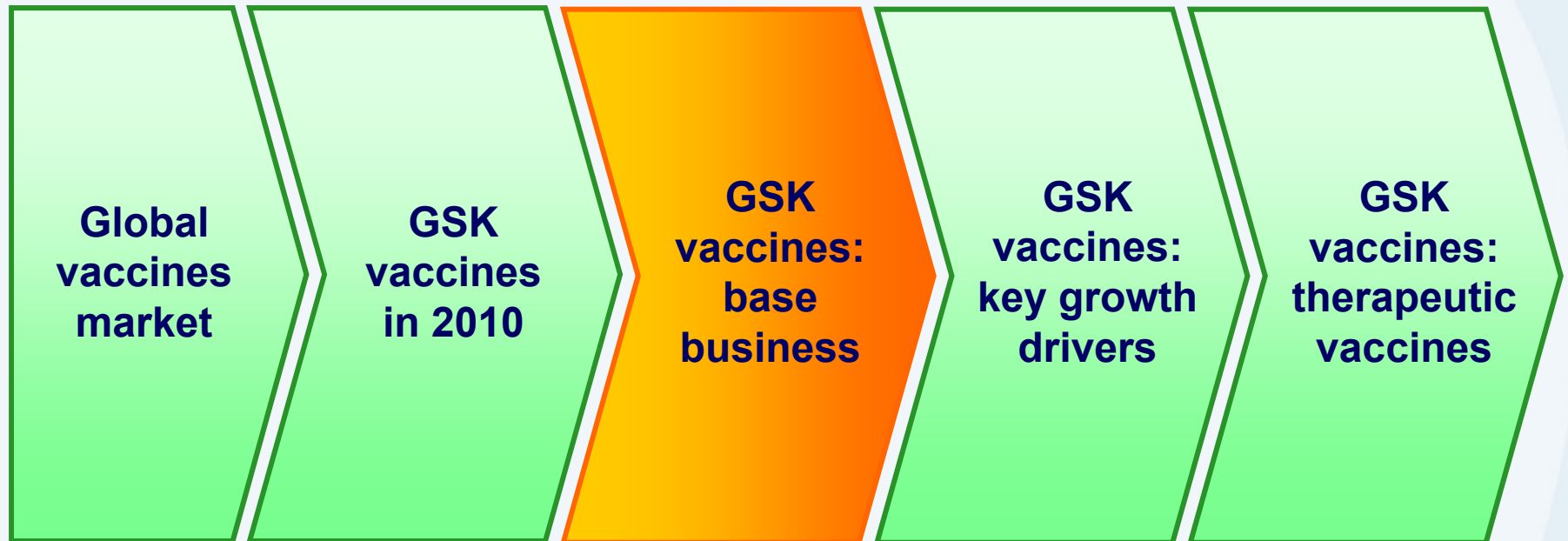
GSK key supplier of H1N1 pandemic  
vaccine to Japanese government

Partnership with Kaketsuken in flu  
and flu cell-culture

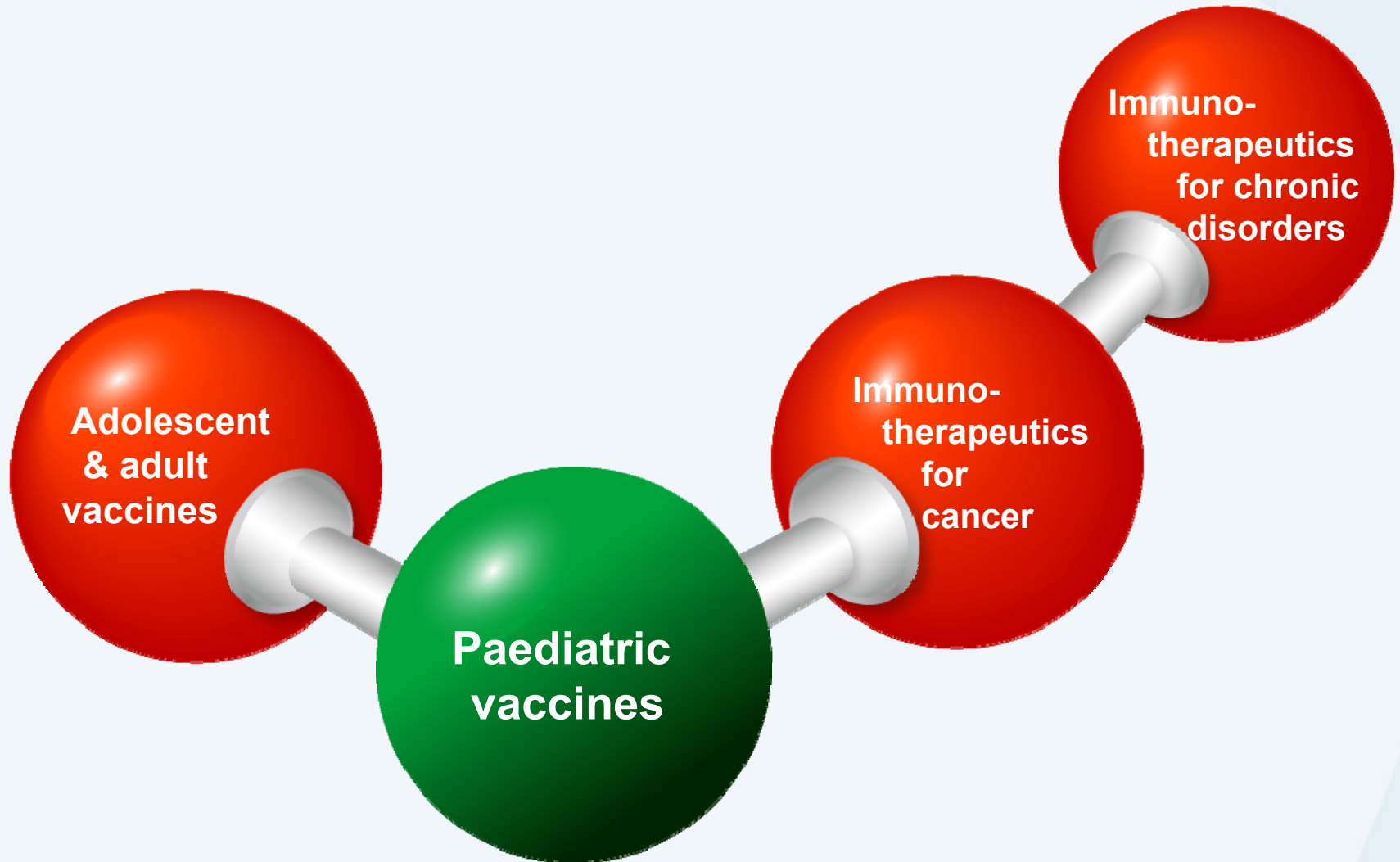
Japan fully integrated into key global  
phase III clinical trial programmes



# Today's agenda



# Evolution of a diversified business



# GSK vaccines: base business

- Strong heritage in paediatric and hepatitis vaccines including several world firsts
- Significant sales contribution from:
  - *Infanrix* family
    - £649m (2009)
  - Hepatitis vaccines
    - £665m (2009)
  - *Boostrix*
    - £139m (2009)
- Continuing innovation
  - e.g. Heptavalent combination vaccine (phase II)

# GSK vaccines: a rich pipeline

Phase I	Phase II	Phase III	Submitted
HIV	Tuberculosis	<i>Mosquirix</i> <sup>TM</sup> Malaria	<i>MenHibrix</i> <sup>TM</sup> (HibMenCY-TT)
Cytomegalovirus	Herpes Zoster	New generation seasonal flu	
NTHi-Pneumo	Dengue	MAGE-A3 ASCI Non-Small Cell Lung Cancer <sup>1</sup>	<b>Approved</b>
Alzheimer's disease	WT1 Acute myelogenous leukaemia <sup>1</sup>	MAGE-A3 ASCI Melanoma <sup>1</sup>	<i>Cervarix</i> <sup>TM</sup> Cervical cancer
	Heptavalent combination vaccine	<i>Nimenrix</i> <sup>TM</sup> (MenACWY-TT)	<i>Synflorix</i> <sup>TM</sup> <i>Streptococcus pneumoniae</i> & <i>non-typeable Haemophilus influenzae</i>
	Hexavalent combination vaccine	<i>Simplirix</i> <sup>TM</sup> <i>Herpes simplex virus</i>	<i>Arepanrix</i> <sup>TM</sup> H1N1 Pandemic Flu
	<i>S. pneumo</i> paediatric new generation	Flu Pre-pandemic (Quebec)	<i>Hiberix</i> <sup>TM</sup> <i>Hib</i> paediatric booster



# Rotarix update

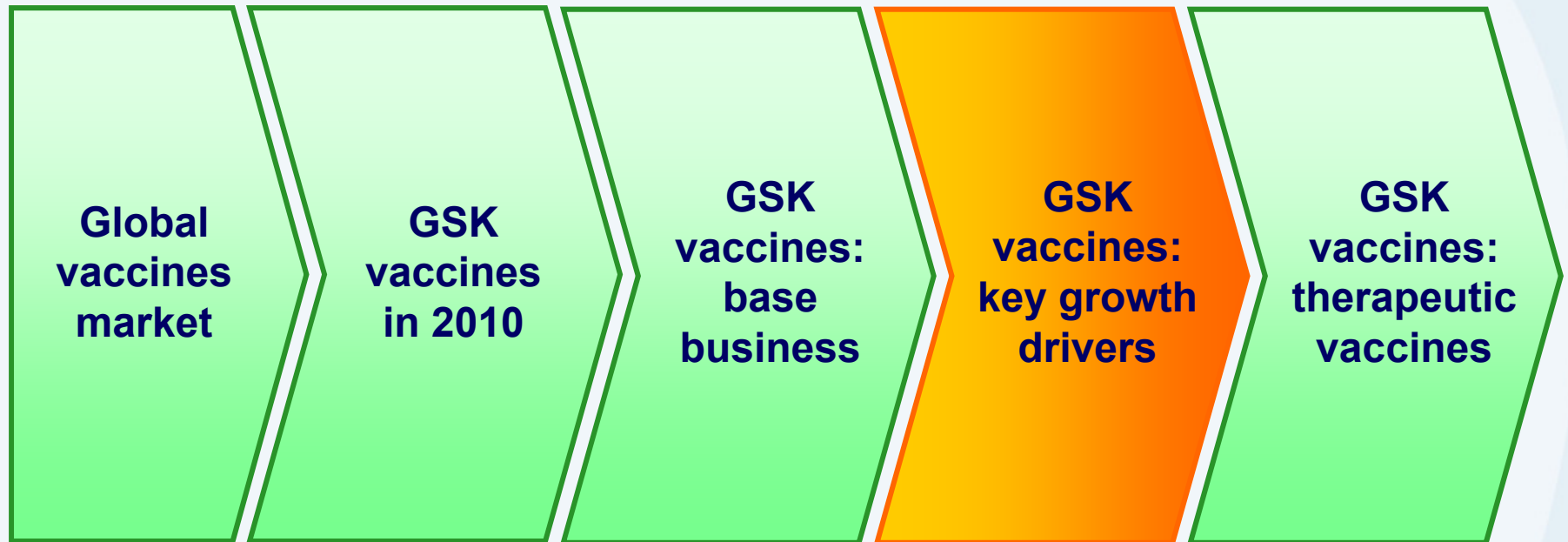
- **Most frequently used rotavirus vaccine worldwide**
  - 71 million doses distributed
  - Excellent safety & efficacy profile
  - Only rotavirus vaccine with 2 dose indication
- **March 2010: presence of PCV-1 material in *Rotarix*\***
  - PCV-1 does not multiply in humans and is not known to cause any illness in humans
  - PCV-1 found in everyday meat products and is frequently eaten
- **GSK notified regulatory authorities including FDA, EMA and WHO**
  - **FDA position**
    - “Recommend that US clinicians and public health professionals temporarily suspend the use of *Rotarix* as a precautionary measure”
  - **EMA position**
    - “Sees no safety concerns with *Rotarix* and healthcare practitioners in the EU should continue to use *Rotarix* as indicated”
  - **WHO position**
    - “WHO does not recommend any change to use of *Rotarix* vaccine”
- **US FDA advisory panel VRBPAC (7 May 2010)**
  - “The vaccines offer a clear public health benefit that far outweighs a “theoretical” risk from PCV, which does not appear to be harmful to humans” (Philip LaRussa, VRBPAC)
  - FDA will evaluate VRBPAC outcome “very expeditiously” (Karen Midthun, FDA)

# GSK response to H1N1 pandemic



- **Integrated GSK response to pandemic**
  - *Pandemrix, Arepanrix, Relenza, Actiprosect*
- **Largest global supplier of H1N1 vaccine**
  - Doses supplied to over 50 countries; approximately £1.5 bn so far
  - 50 million dose donation to WHO
- **In Europe over 42 million people have been vaccinated with H1N1 vaccines\***
  - Approximately 68% received GSK's H1N1 vaccine *Pandemrix*
- **Extensive safety experience with adjuvanted H1N1 vaccine gathered**
  - No safety signal identified (long-term follow up ongoing)
  - Positive benefit:risk profile confirmed
  - Effectiveness data by non-GSK groups to be published in 2010

# Today's agenda



**Approved in 108 countries  
including US and Japan (October 2009)**

**2009 sales £187 million  
(Q1 2010 sales £77 million +60%)**

**57% of competitive tenders won  
Over 68% by volume**

**WHO Prequalification (July 2009)  
Global access to *Cervarix* via UNICEF & GAVI**

# Cervarix<sup>®</sup>: fulfilling the promise

Significant  
new data  
presented and  
published

**Study-008**

**High efficacy against HPV-16/18 confirmed  
& significant protection beyond HPV-16/18**

**Study-010**

**Superior immune profile**

**Study-007/023**

**Continued efficacy: 8.4 yrs so far**

**All studies**

**Long-term safety**

# Synflorix™ : successful launch



**Approved in 54 countries**  
Filed in 85 countries

**Significant tender wins and market share gains**  
Q1 2010 sales £45 million

**Long-term contract signed with Brazilian government**  
€1.5 billion over 10 years

**Advance Market Commitment (AMC) for pneumococcal vaccines launched (March 2010)**  
300 million doses of *Synflorix* over 10 years



**WHO prequalification (October 2009)**  
Enables UN agency purchase

# Late-stage assets: meningitis

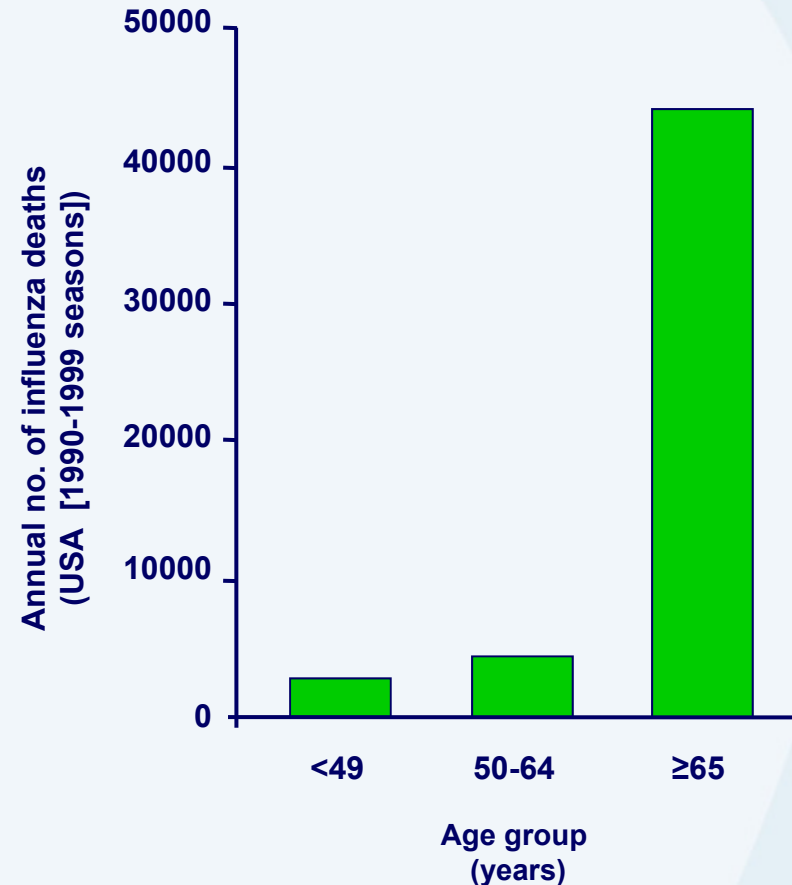
- **Meningococcal disease causes permanent disability or death**
  - Fatality rate 9-12%
- **Five serogroups (A, B, C, W135, Y) cause the majority of invasive meningococcal disease**
- **GSK developing tailored meningitis vaccines to fulfil regional and age-related needs:**
  - ***MenHibrix (HibMenCY)***
    - Protection for infants, where the need is greatest (2-24 months)
    - Filed in US
  - ***Nimenrix (MenACWY)***
    - Protection against 4 major serotypes (A, C, W, Y) in 1-55 years of age
    - Planned EU filing H2 2010

# Late-stage assets: seasonal influenza

- **Need for improved efficacy in elderly population**
- **High disease burden**
  - Approximately 90% of non-pandemic, influenza-related deaths occur among people aged  $\geq 65$  years
- **Frequent hospitalisation**
- **Exacerbation of underlying disease**

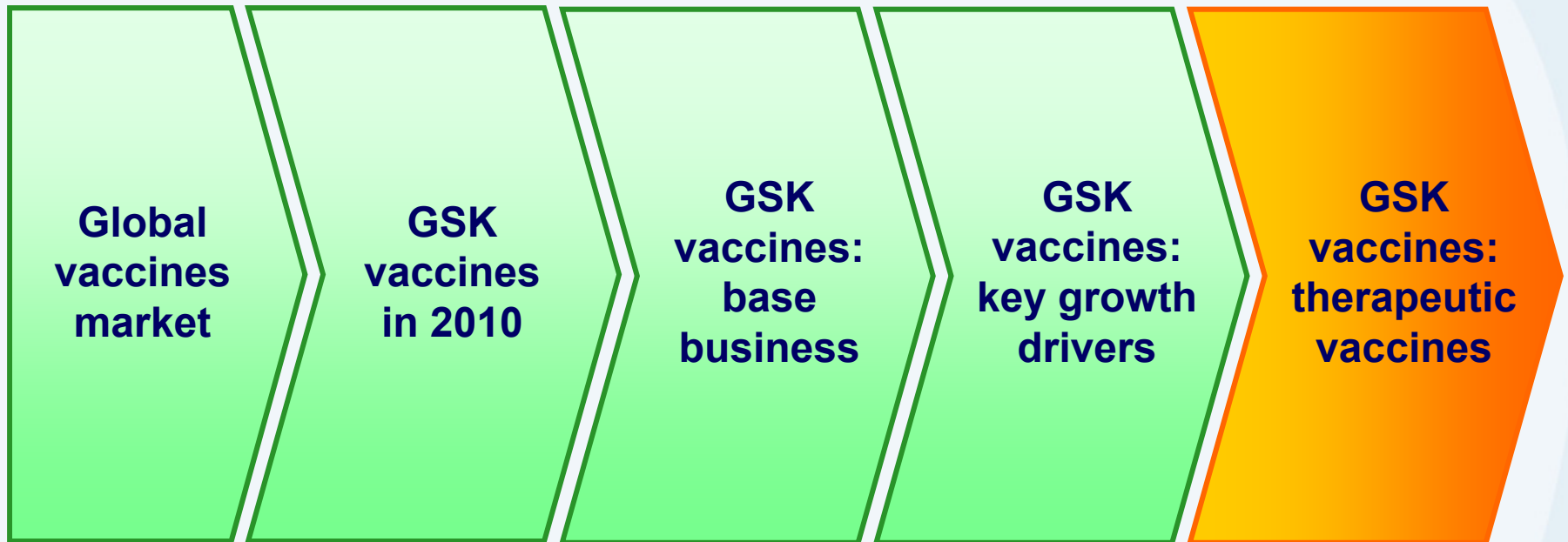
## *New generation seasonal flu vaccine*

- **Improved efficacy in the over 65s**
- **Adjuvanted**
- **Phase III ongoing (INFLUENCE-65)**
  - 43,000 patients enrolled
  - 2-year study with efficacy endpoints





# Today's agenda



# Antigen-Specific Cancer Immunotherapeutics (ASCI)

- **Novel class of compounds based on tumour antigens**
- **MAGE-A3 in Non-Small Cell Lung Cancer (NSCLC)**
  - Positive phase II data
    - 25 % reduction in the relative cancer recurrence following surgery at 44 months
    - Well-tolerated with excellent compliance
  - Ongoing phase III study (MAGRIT)
- **MAGE-A3 in Melanoma**
  - Phase III study ongoing (DERMA)
- **Collaboration with Abbott on molecular diagnostic tests**
  - MAGE-A3 in NSCLC and melanoma
- **WT1 in Acute Myelogenous Leukaemia (AML)**
  - Phase II study commenced

# Therapeutic vaccines

## ASCI

### MAGE-A3 in Phase III

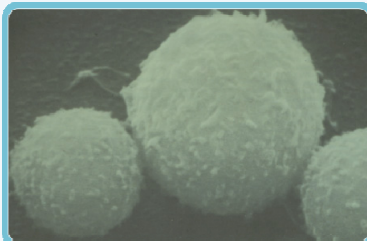
- NSCLC and melanoma

### WT1 in Phase II

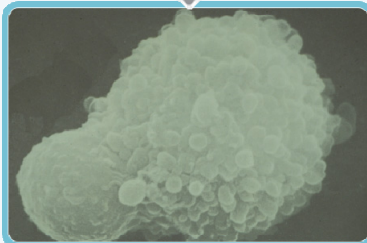
- AML

### Novel mechanism of action

- Tumour-specific
- Patient-selective



± 20 min  
(*in vitro*)

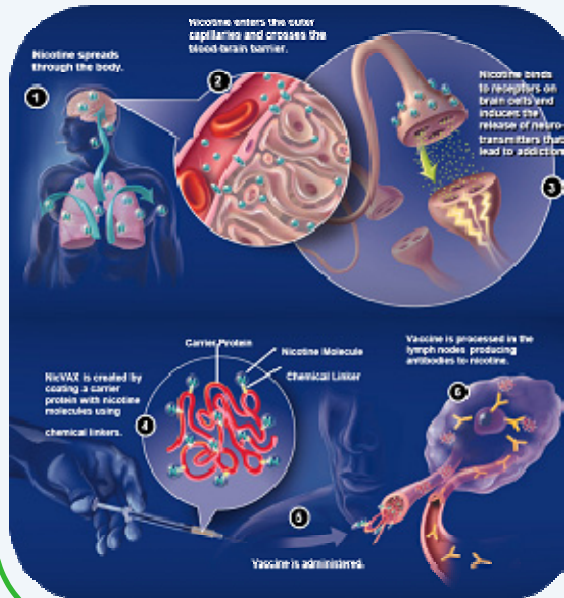


## Nicotine Addiction

### Nicotine conjugate vaccine (*NicVAX*)<sup>1</sup>

Aid to smoking cessation and  
long-term abstinence

Two Phase III studies ongoing

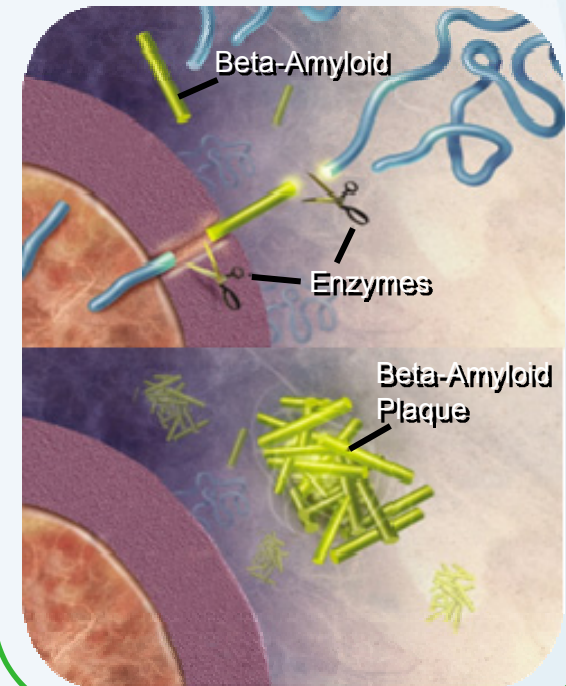


## Alzheimer's

Two candidate vaccines  
in development<sup>2</sup>

Targets beta-amyloid

- Pivotal role in plaque formation



<sup>1</sup> Licensed from Nabi Biopharmaceuticals

<sup>2</sup> Licensed from AFFIRIS

# GSK vaccines in 2010

- A world leader in vaccines
- One of the broadest portfolios and fastest growing vaccines businesses in the world
- Unique expertise in adjuvant technology
- Strong pipeline including innovative therapeutic vaccine approaches
- Global footprint: ideally positioned to capture a significant market share in all territories



**GlaxoSmithKline**