GSK VACCINES IN 2011

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Today's agenda

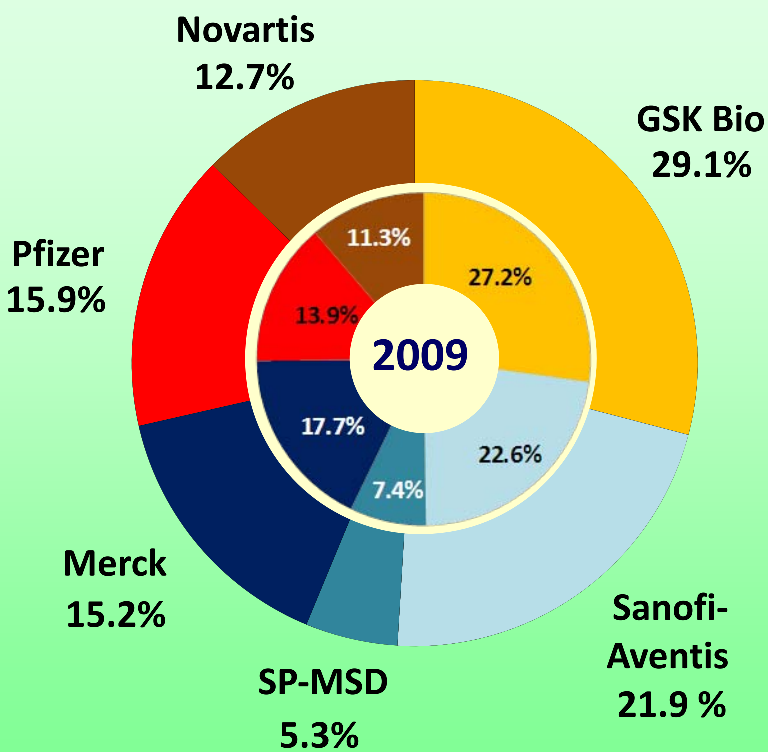
- Global vaccines market
- GSK vaccines in 2011
- GSK vaccines: key growth drivers
- GSK vaccines pipeline

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 for newer vaccines
  - HPV vaccines (*Cervarix*, *Gardasil*)
  - Pneumococcal vaccines (*Synflorix*, *Prevnar-13*)
- Operating margin comparable to pharmaceutical products
- New markets including Emerging Markets
- Heightened awareness
  - Considerable unmet medical need
- Presence of local manufacturers

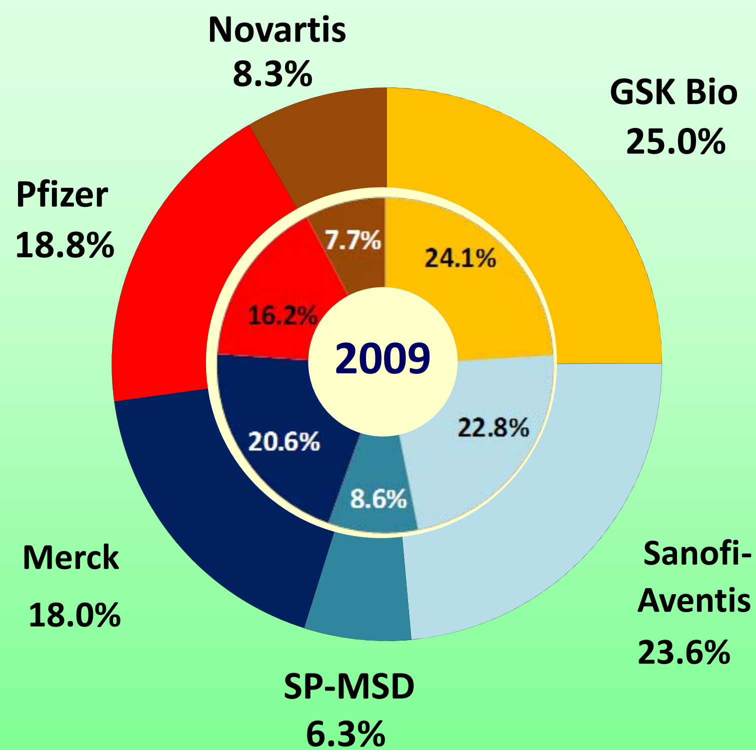
Global vaccines market 2010

2010 total sales



Total 2010 = $23,066m

2010 excluding H1N1

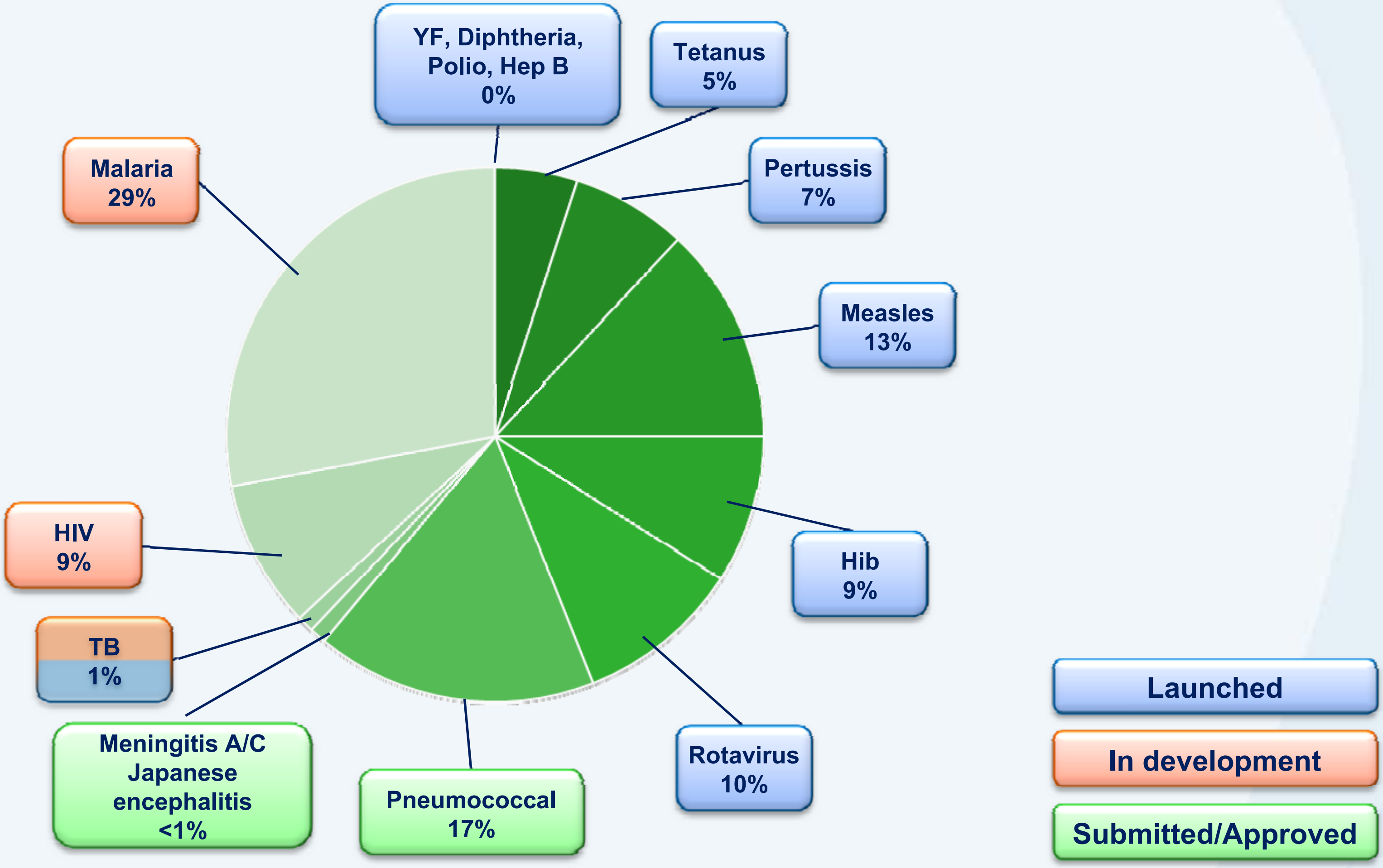


Total 2010 excl. H1N1 = $19,466m

GSK estimates from consolidated 2009 & 2010 Annual Reports (top 6 vaccine manufacturers)

Millions of children die from infectious diseases

Many of these deaths are preventable
By 2015 vaccines could reduce these deaths by 90%



Source: http://www.who.int/mediacentre/events/2006/g8summit/vaccines/en/

Today's agenda

- Global vaccines market
- GSK vaccines in 2010
- GSK vaccines: key growth drivers
- GSK vaccines: therapeutic vaccines

GSK vaccines business in 2010

2010 sales £4.3 billion (+15%)

Vaccines represent 15%
of total GSK sales

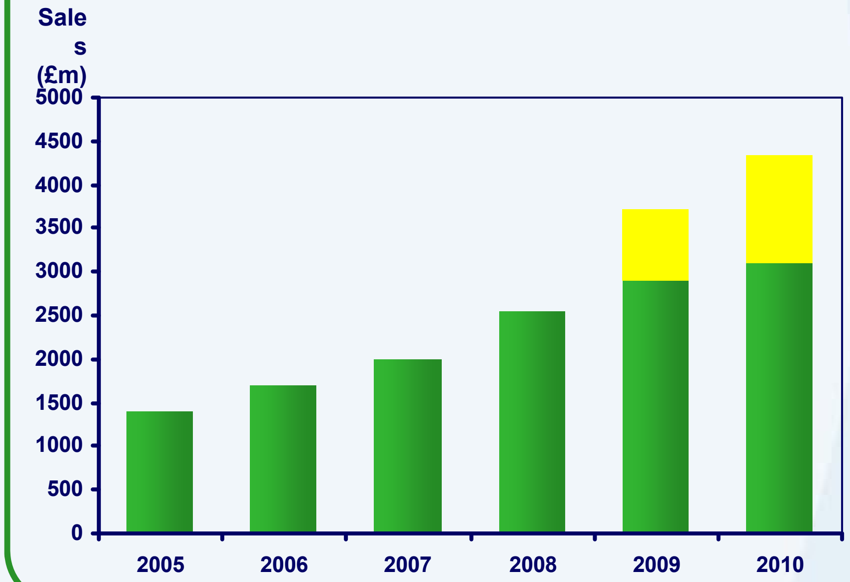
Over 30 approved vaccines and
20 in development

Distributed 1.43 billion vaccine doses
to 179 countries in 2010
Approximately 70% of doses to developing world

Over 11,000 employees worldwide,
including over 1650 scientists

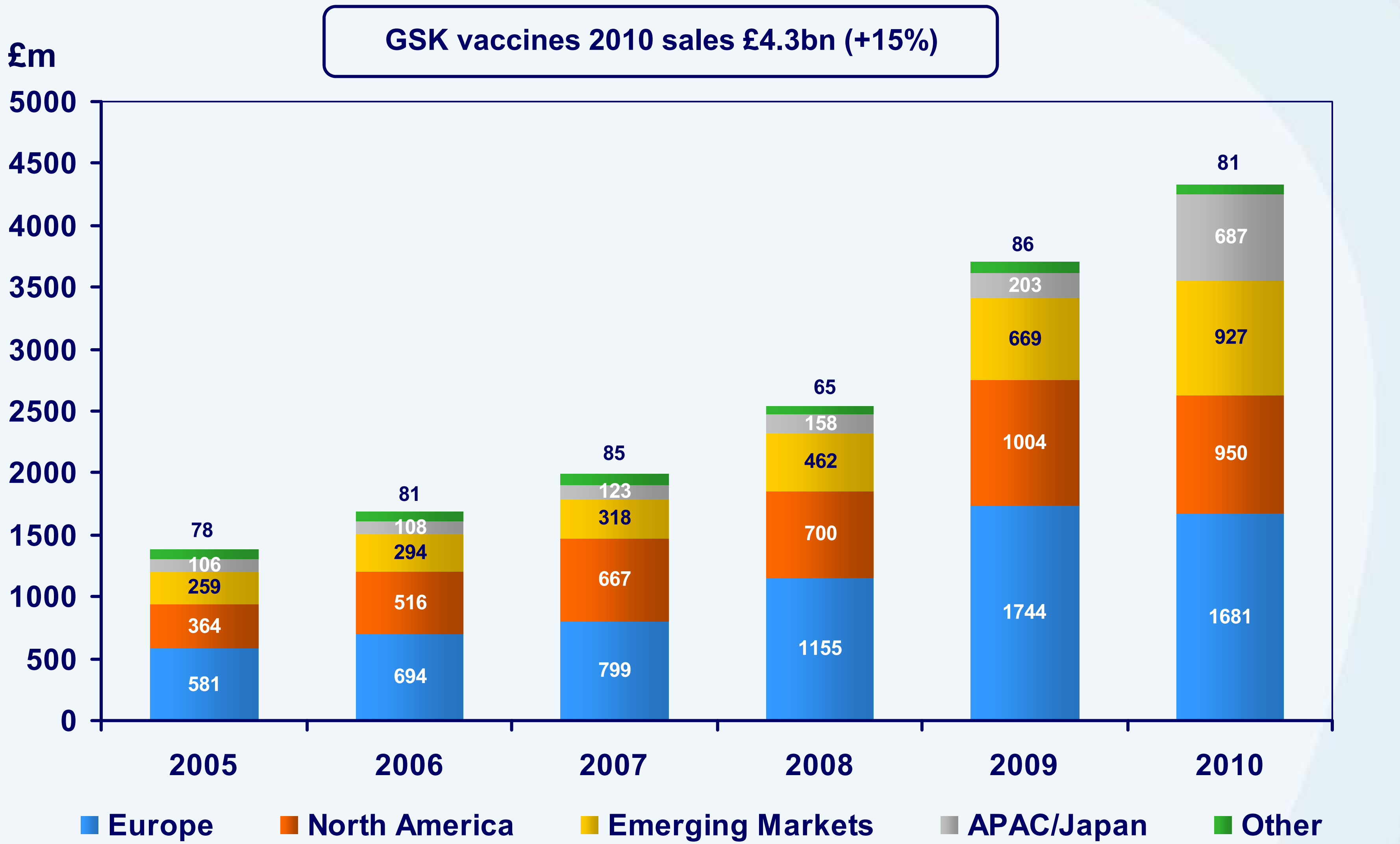
Global manufacturing network:
15 sites around the globe

+18% CAGR excl. H1N1
since 2005



Growth rate is CER

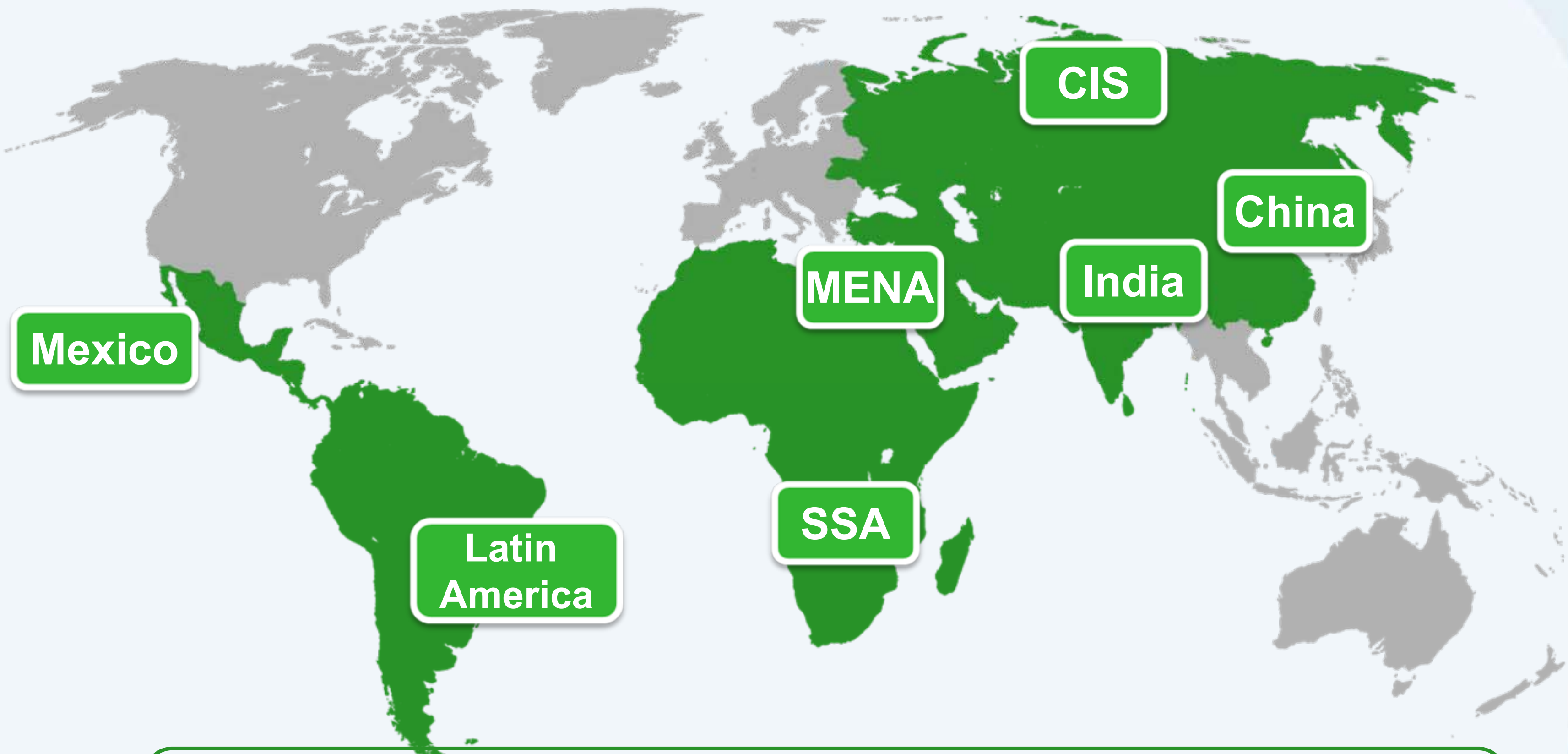
GSK vaccines: a history of growth



Note: All figures expressed at actual rates
Includes H1N1 pandemic sales

GSK "Emerging Markets" business

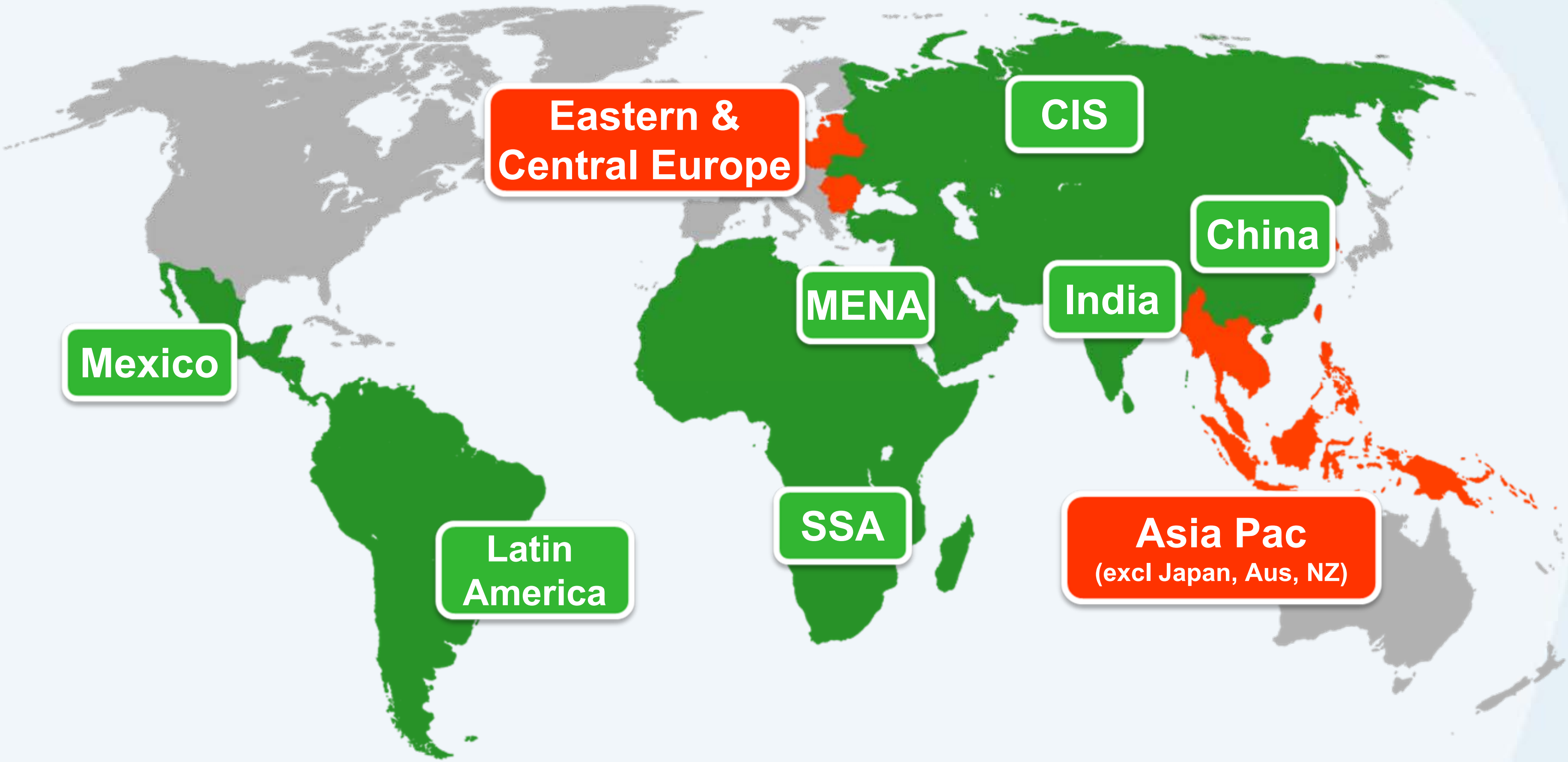
85 countries



Emerging Markets FY2010 Vaccines Sales £927mn (+38%)*
= 21% of Total GSK Vaccines Sales

*Note: GSK FY2010 sales including pandemic

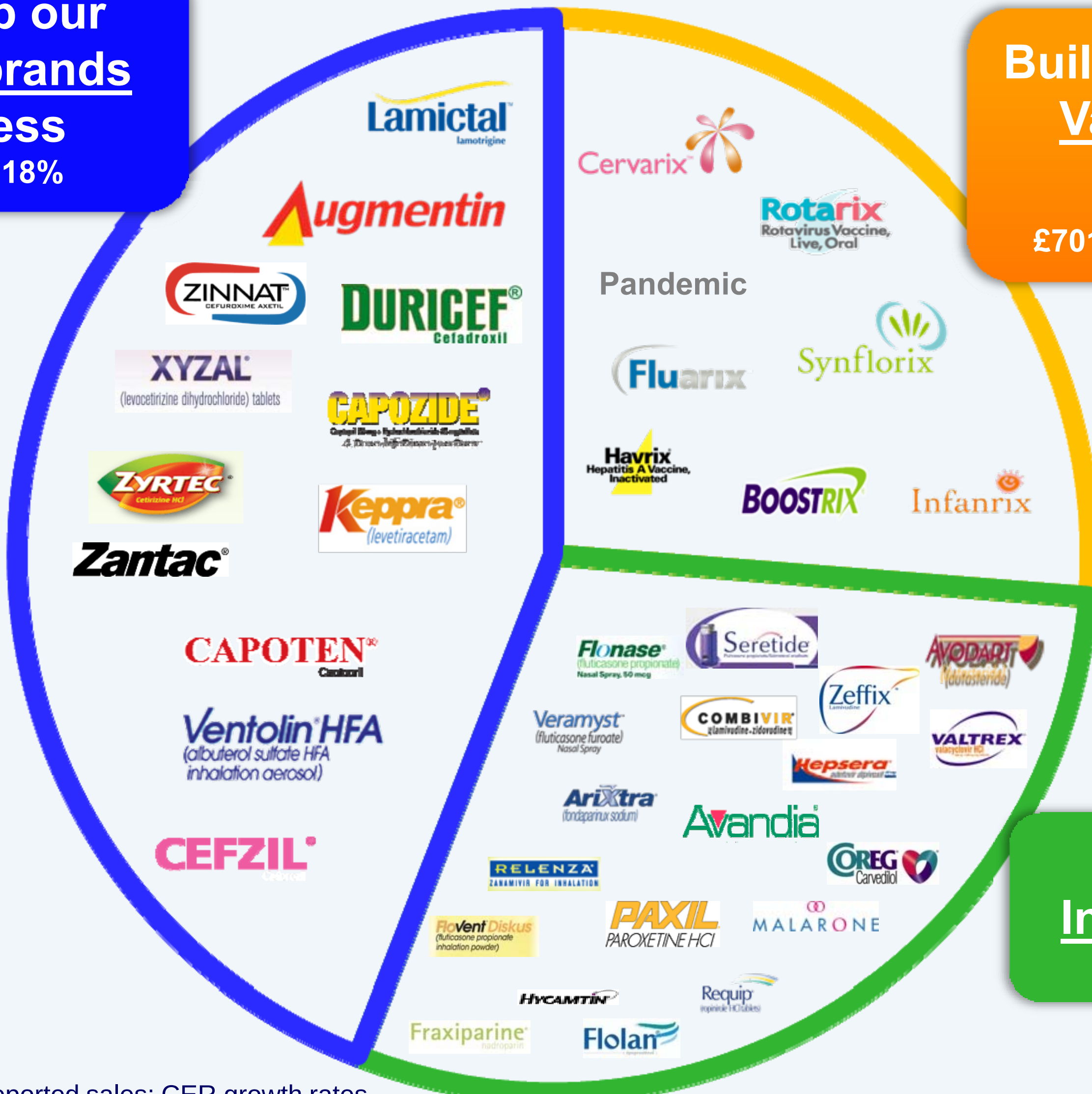
GSK's pharma presence in Emerging Markets



Emerging Markets strategy

Scale up our Classic brands business
£1.6bn +18%

FY2010 Turnover

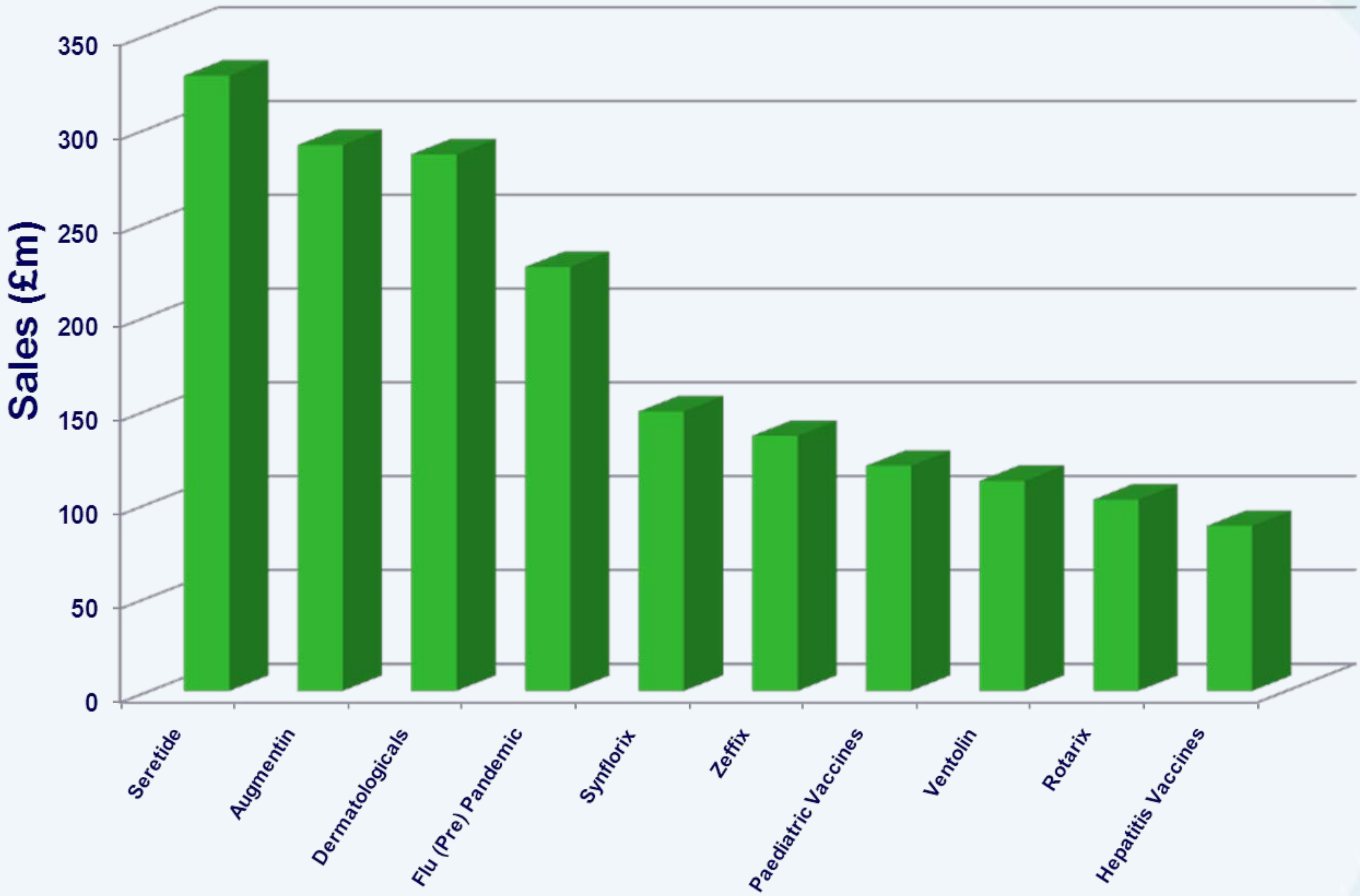


Build and capture the Vaccines market
£927m +38%
£701m +14% excl. pandemic

Drive our Innovative brands
£1.0bn +16%

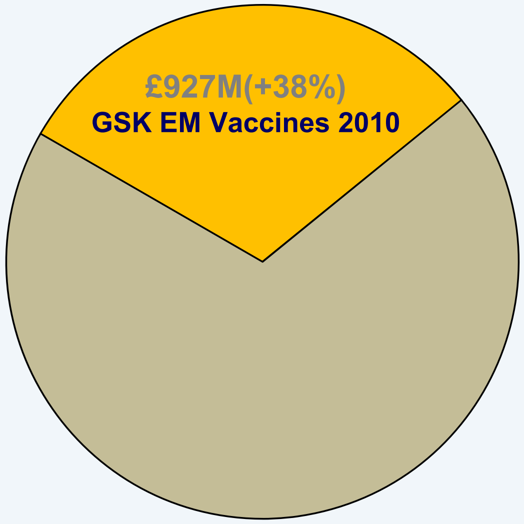
; Source: GSK FY2010 reported sales; CER growth rates

Vaccines represent 5 of Top 10 GSK EM brands



Build and capture the EM vaccines market

GSK has 38% of the market and is growing faster



Total EM Vaccines Market 2010
£2.46bn (+28%)

Significant <u>market</u> growth potential

- Growing government attention to public health agenda
- Large birth cohorts for paediatric vaccines

Significant <u>GSK</u> growth potential

- Established GSK heritage in EM
- New geographies
- Broad portfolio, well-positioned to provide for spectrum of needs
- Local partnership is critical

Source: GSK estimates for market; GSK reported sales. (2010 EM vaccines data).

GSK has the broadest vaccine portfolio across EM

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

✓ = available in EM; d = in development

Emerging markets opportunity: China & Brazil

China

£122m
+3%
(2010)

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 including *Priorix* and other paediatric vaccines

GSKNB
WALVAX沃森

Brazil

£337m
>100%
(2010)

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

Long term governmental contracts

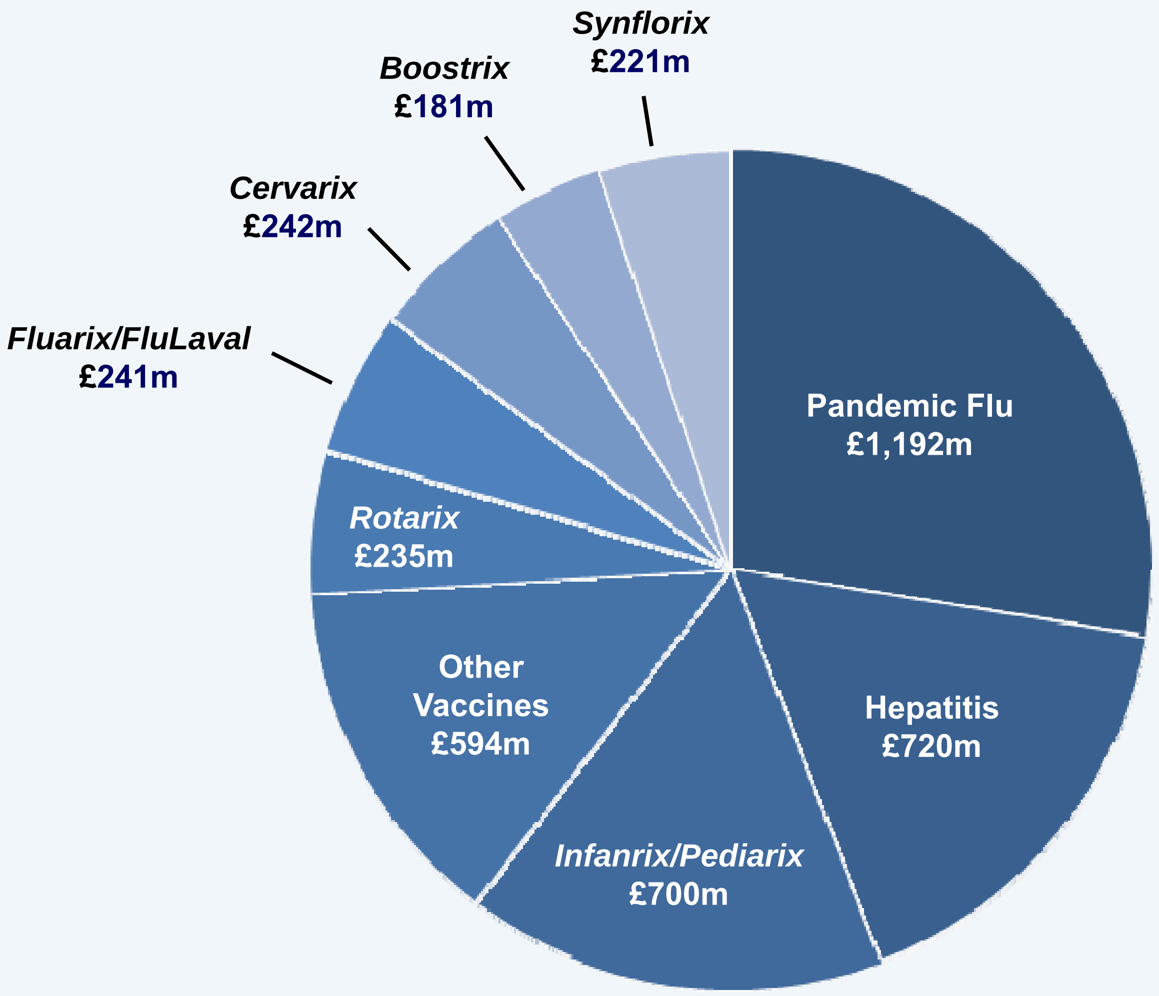
Technology transfer agreements
- Oral polio vaccine (1980's)
- *Hiberix* (1998)
- *Priorix* (2003)
- *Rotarix* (2008)
  - Included in National Immunization Programme
- *Synflorix* (2009)
  - Inclusion in National Immunization Programme

FIOCRUZ

Today's agenda

- **Global vaccines market**
- **GSK vaccines in 2010**
- **GSK vaccines: key growth drivers**
- **GSK vaccines pipeline**

GSK key vaccines: 2010 sales



2010 sales: £4.3 billion (+15%)

GSK Vaccines: base business

- Strong heritage in paediatric and hepatitis vaccines including several world firsts
- Significant sales contribution from
  - *Infanrix* family
    - £700m; +8% (2010)
  - Hepatitis
    - £720m; +7% (2010)
  - *Boostrix*
    - £181m; +29% (2010)
- Continuing innovation
  - Heptavalent combination vaccine (phase II)

Heptavalent combination vaccine: *Neisseria* meningitis C, *Haemophilus influenzae* type b, diphtheria, Hepatitis B, tetanus, pertussis and poliomyelitis disease prophylaxis

Influenza: seasonal & pandemic

- Seasonal influenza sales of £241 million in 2010
  - £40 million in Emerging Markets
- Largest global supplier of H1N1 pandemic vaccine
  - Doses supplied to over 60 countries
  - Approximately £2.0 billion sales
    - £883 million (2009)
    - £1,192 million (2010)
  - 60 million dose donation to WHO
- In Europe over 30 million doses of *Pandemrix* administered[1]
  - *Pandemrix*: approximately 80% of European doses administered

[1] 22nd pandemic pharmacovigilance weekly update (EMA/527985/2010) 19 August 2010

Synflorix: successful launch

Synflorix

Approved in 95 countries
Filed in additional 19 countries

Significant tender wins and market share gains
2010 sales £221 million

Strongest GSK launch in EM in a decade
2010 EM sales £149 million

S. pneumoniae **causes 700,000 - 1 million deaths annually**
Ten countries account for 66% of pneumococcal cases worldwide

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

Advance Market Commitment (AMC) launched
300 million doses of Synflorix *over 10 years*

AMC ADVANCE MARKET COMMITMENTS for vaccines

Rotarix in 2010: returning to growth

Approved in 121 countries
Filed in Japan (November 2009)

2010 sales £235 million
2010 EM sales £102 million

Key national tender wins
Significant private market share in EM

Disease burden in EM is significant
600,000 children die from RVGE & 2 million are hospitalised annually
Over 80% of deaths due to RVGE occur in developing countries

WHO prequalification (June 2009)

RVGE: rotavirus gastroenteritis

Cervarix in 2010: future opportunities

Approved in 112 countries
Including US and Japan

2010 sales £242 million (+26%)
Japan 2010 sales £57 million (>100%)

Improved EU & International label
Includes cross-protection

Over half of competitive tenders won
Over two-thirds by volume

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

Improving access to *Cervarix*
Tiered pricing

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GSK vaccines: a rich pipeline

Phase I

- **HIV** Prophylaxis
- **Pandemic influenza** H5N1 cell-culture
- **PRAME ASCI** Metastatic melanoma
- **PRAME ASCI** Non-Small Cell Lung Cancer
- **NY-ESO-1 ASCI** Metastatic melanoma

Phase II

- **Tuberculosis**
- **MMR**
- **WT1 ASCI** Acute myelogenous leukaemia
- **Heptavalent combination vaccine**
- **HIV** Immunotherapy
- ***S. pneumo* paediatric** New generation
- **Alzheimer's disease[2]**

Phase III

- ***Mosquirix™*** Malaria
- **Seasonal influenza** Qaudrivalent
- **MAGE-A3 ASCI** Non-Small Cell Lung Cancer
- **MAGE-A3 ASCI** Melanoma
- ***Herpes zoster***
- **Flu Pre-pandemic** Quebec
- ***NicVAX™*[1]** Smoking cessation

Submitted

- ***MenHibrix™*** HibMenCY-TT
- ***Nimenrix™*** MenACWY-TT

Approved

- ***Pumarix™*** H5N1 pandemic influenza (Quebec)

[1] Nabi Biopharmaceuticals
[2] AFFiRiS

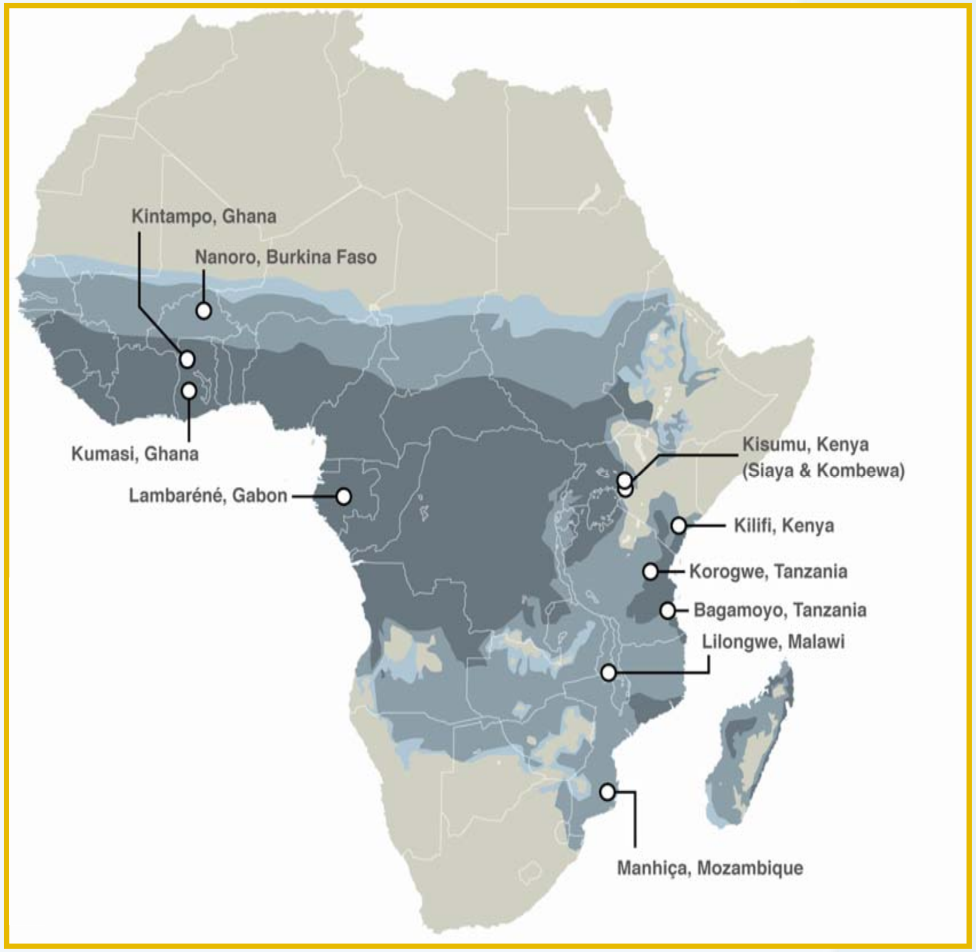
Late-stage assets: meningitis

- **Meningococcal disease causes permanent disability or death**
  - Fatality rate 9-12%[1]
- **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:**
  - ***Nimenrix* (MenACWY)**
    - Protection against 4 major serotypes (A, C, W, Y) from one year of age
    - Filed in EU (March 2011)
    - International submissions planned
  - ***MenHibrix* (HibMenCY)**
    - Protection for infants, where the need is greatest (2-24 months)
    - Filed in US (August 2009)
    - Complete Response Letter received (June 2010)

[1]Khatami & Pollard *Expert Rev. Vaccines* 2010; 9, 285–298

Late-stage assets: *Mosquirix* (RTS,S)

- **Significant burden of disease**
  - Malaria kills almost 900,000 people every year[1]
    - Many in sub-Saharan Africa
    - Majority are children under the age of five
- **Phase III trials underway**
  - 11 trial sites across 7 African countries
  - Enrolment complete (15,461)
    - 8,923 children (5-17 months)
    - 6,538 infants (6-12 weeks)



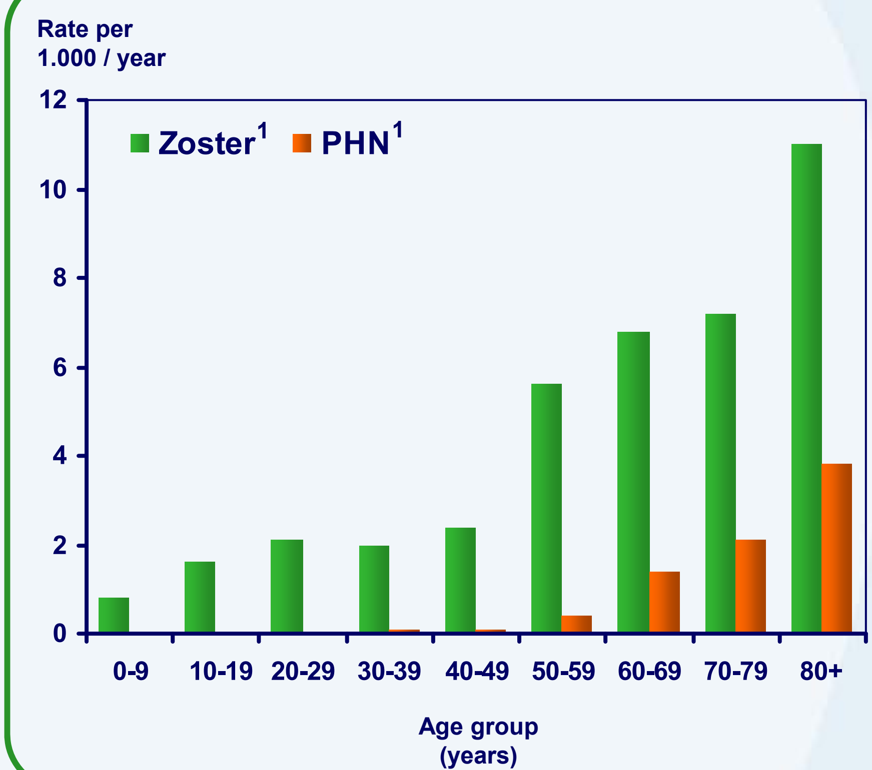
[1]World Health Organization (WHO) World Malaria Report, 2009

Late-stage assets: *Herpes zoster*

- ***Herpes zoster (HZ) & Post-herpetic neuralgia (PHN)***
  - After initial varicella zoster infection (chickenpox), VZV DNA remains latent in nerve cells
  - May reactivate later in life to cause HZ (shingles)
  - 1 in 4 will suffer from shingles (lifetime)[2]
  - 1 in 5 shingles patients develop chronic pain (PHN)[3]
- Risk factors
  - Age ≥ 50 years
  - Impaired cellular immunity

GSK Herpes zoster vaccine candidate

- Adjuvanted sub-unit vaccine
- Phase III commenced August 2010



[1]Hope-Simpson *J R Coll Gen Pract* 1975; 25: 571-575; [2]Bowsher et al *Eur J Pain* 1999; 3: 335-342; [3]Scott et al *J Med Virol* 2003; 70: S24-30.

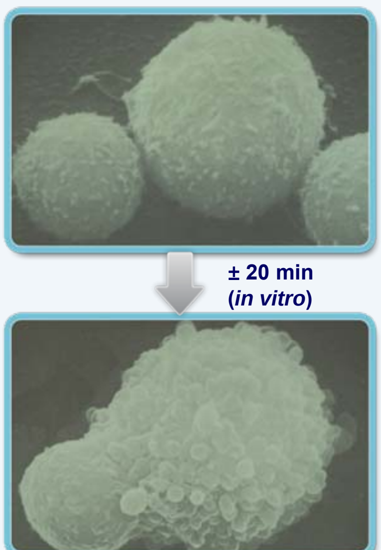
Therapeutic vaccines

ASCI

Four ASCIs in development
- MAGE-A3, WT1, PRAME & NY-ESO-1

Three tumour types
- NSCLC, melanoma & leukaemia

Novel mechanism of action
- Tumour-specific
- Patient-selective

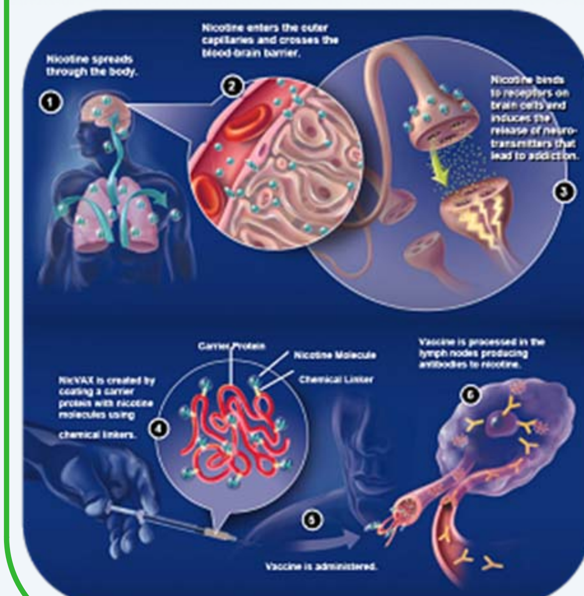


Nicotine Addiction

Nicotine conjugate vaccine (*NicVAX*)[1]

Aid to smoking cessation and long-term abstinence

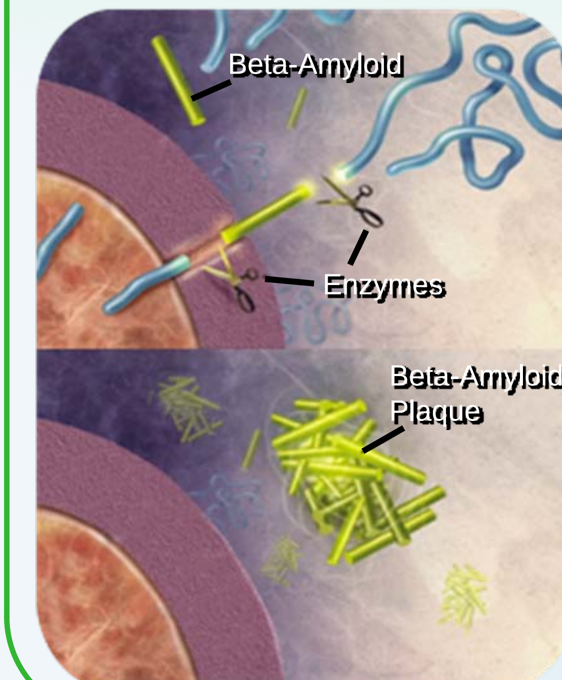
Two Phase III studies ongoing
- Fully recruited



Alzheimer's

Candidate vaccines in development[2]

Targets beta-amyloid
- Pivotal role in plaque formation



[1] Nabi Biopharmaceuticals
[2] AFFiRiS

GSK vaccines in 2011

- A world leader in vaccines
- One of the broadest portfolios and fastest growing vaccines businesses in the world
- Strong pipeline including innovative therapeutic vaccine approaches
- Flexibility of GSK vaccines business model
  - Partnerships (JVs, technology transfer)
  - Pricing (Tiered pricing, Innovative funding mechanisms)
- Global footprint: ideally positioned to capture a significant market share in all territories including Emerging Markets

gsk

GlaxoSmithKline