GSK VACCINES IN 2011

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Senior Vice President
Global Vaccines Centre of Excellence
GSK Biologicals
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

- Novartis 12.7%
- Pfizer 15.9%
- Merck 15.2%
- Sanofi-Aventis 21.9%
- SP-MSD 5.3%
- GSK Bio 29.1%

Total 2010 = $23,066m

2010 excluding H1N1

- Novartis 8.3%
- Pfizer 18.8%
- Merck 18.0%
- Sanofi-Aventis 23.6%
- SP-MSD 6.3%
- GSK Bio 25.0%

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

Growth rate is CER

+18% CAGR excl. H1N1 since 2005

Distributed 1.43 billion vaccine doses to 179 countries in 2010
Approximately 70% of doses to developing world
GSK vaccines: a history of growth

GSK vaccines 2010 sales £4.3bn (+15%)

Note: All figures expressed at actual rates
Includes H1N1 pandemic sales
GSK “Emerging Markets” business

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

- Mexico
- Latin America
- SSA
- MENA
- CIS
- China
- India
- Eastern & Central Europe
- Asia Pac (excl Japan, Aus, NZ)
Emerging Markets strategy

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

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

Drive our Innovative brands
£1.0bn +16%

FY2010 Turnover

; 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%)
- **GSK EM Vaccines 2010**
  - £927M (+38%)

**Significant market growth potential**
- Growing government attention to public health agenda
- Large birth cohorts for paediatric vaccines

**Significant GSK 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

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✔ = available in EM; d = in development
Emerging markets opportunity: China & Brazil

**China**

**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

**Brazil**

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

**Long term governmental contracts**

**Technology transfer agreements**
- Oral polio vaccine (1980’s)
  - Included in National Immunization Programme
- *Synflorix* (2009)
  - Inclusion in National Immunization Programme

£122m +3% (2010)

£337m >100% (2010)
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%)

- Rotarix: £241m
- Fluarix/FluLaval: £235m
- Cervarix: £242m
- Synflorix: £221m
- Boostrix: £181m
- Pandemic Flu: £1,192m
- Infanrix/Pediarix: £700m
- Infanrix/Pediarix: £700m
- Other Vaccines: £594m
- Hepatitis: £720m
- Other Vaccines: £594m

17
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
Significant tender wins and market share gains
2010 sales £221 million

Approved in 95 countries
Filed in additional 19 countries

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
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*
Today’s agenda

Global vaccines market

GSK vaccines in 2010

GSK vaccines: key growth drivers

GSK vaccines pipeline
### GSK vaccines: a rich pipeline

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<th>Phase I</th>
<th>Phase II</th>
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1 Nabi Biopharmaceuticals
2 AFFiRiS
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)

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\(^1\) 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 $\geq$ 50 years
  - Impaired cellular immunity

**GSK Herpes zoster vaccine candidate**
- Adjuvanted sub-unit vaccine
- Phase III commenced August 2010

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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*)
Aid to smoking cessation and long-term abstinence
Two Phase III studies ongoing
- Fully recruited

Alzheimer’s

Candidate vaccines in development
- Targets beta-amyloid
  - Pivotal role in plaque formation

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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