GSK Vaccines meet the management

29 November 2016

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Agenda

Luc Debruyne

President
GSK Vaccines

Thomas Breuer

Chief Medical Officer
GSK Vaccines

Emmanuel Hanon

Head of R&D
GSK Vaccines

John McGrath

Head of Global Industrial Operations
GSK Vaccines

Q&A

Luc Debruyne

President, GSK Vaccines

Luc was appointed President, Global Vaccines in 2013. Following the successful integration of the Novartis vaccines business acquired in early 2015, GSK Vaccines delivers today a broad portfolio of more than 30 paediatric, adolescent, adult/travellers and elderly vaccines to 90% of the world's countries. Luc's ambition for the business is to lead the industry in improving health globally, continuously delivering better vaccines and protecting more people while running our business sustainably. He is a member of the Corporate Executive Team.

Luc joined GSK in 1991. He spent two years in the UK as a commercial strategy director in R&D, before becoming head of GSK's European Commercial Centre of Excellence in 2005. In 2006, Luc became the General Manager for GSK in the Netherlands and then in 2010 Senior Vice President and General Manager in Italy, while also managing the European Established Products Business Unit. In 2012, he was appointed Senior Vice President, Pharma Europe, prior to assuming his current role.

Luc is a member of the Vaccines CEO Roundtable convened by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and a member of the Management Committee of the Belgian Federation of Enterprises. He has previously co-chaired the Executive Committee of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and has been a member of the Board of Italy's Farmindustria and its equivalent in The Netherlands, NEFARMA. He also served on the Committee for international investment of CONFINDUSTRIA, Italy and was a member of ASPEN.

Thomas Breuer

Chief Medical Officer, GSK Vaccines

Thomas Breuer is GSK Vaccines Chief Medical Officer. He leads the global medical affairs organisation, safety and pharmacovigilance, and patient access functions such as health economics. He is a member of the management team of GSK Vaccines.

From 2007 to 2015 Thomas ran the Vaccines Development Organisation and has been instrumental in the development and licensure of many of GSK's vaccines. Before joining the company in 2001, Thomas had a career in internal medicine and public health. After six years in patient care he worked at the US Centers for Disease Control (CDC) in Atlanta, GA, before joining the German Public Health Institute as Head of Infectious Disease Epidemiology in Berlin.

Thomas has a doctorate in medicine from the University of Cologne, Germany. He is board certified in internal medicine and has a Master of Science degree in epidemiology from the University of Texas.

Emmanuel Hanon

Head of Research & Development, GSK Vaccines

Emmanuel leads our vaccines research and development organisation, covering discovery, early and late-stage development, regulatory and medical affairs activities. He is based in Rixensart, Belgium.

Emmanuel joined GSK Vaccines in 2001 taking roles of increasing responsibility in Immunology and Human Cell mediated immunity before leading the viral vaccines programme in R&D.

After heading the Elderly vaccines franchise, playing a critical role in the development of our flu pre-pandemic and pandemic strategy, he was appointed Senior Vice President - Vaccine Discovery and Development in August 2011.

Prior to joining GSK, Emmanuel obtained a PhD at University of Liège in the field of Immunology and herpes virology and occupied a post-doctorate position in the field of retrovirology at Imperial College in the UK.

John McGrath

Head of Global Industrial Operations, GSK Vaccines

John McGrath has been involved with the biologics industry for over twenty five years since graduating from Dublin City University in Ireland.

In that time he has held various technical and management positions in Ireland, the UK, the US, Switzerland and Belgium.

His experience spans manufacturing, process engineering, validation, quality assurance, general management and operations.

John holds a BSc from Dublin City University and an MBA from Babson College in the United States.

Strategic overview

Luc Debruyne
President, GSK Vaccines

Cautionary statement regarding forward-looking statements

This presentation contains statements that are, or may be deemed to be, “forward-looking statements”. Forward-looking statements give the Group’s current expectations or forecasts of future events. An investor can identify these statements by the fact that they do not relate strictly to historical or current facts. They use words such as ‘anticipate’, ‘estimate’, ‘expect’, ‘intend’, ‘will’, ‘project’, ‘plan’, ‘believe’, ‘target’ and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, the outcome of contingencies such as legal proceedings and financial results.

Other than in accordance with its legal or regulatory obligations (including under the UK Listing Rules and the EU Market Abuse Regulation), the Group undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. Investors should, however, consult any additional disclosures that the Group may make in any documents which it publishes and/or files with the US Securities and Exchange Commission (SEC). All investors, wherever located, should take note of these disclosures. Accordingly, no assurance can be given that any particular expectation will be met, and investors are cautioned not to place undue reliance on the forward-looking statements.

All expectations and targets regarding future performance should be read together with the “Assumptions related to 2016-2020 outlook” on page 35 of the Group’s third quarter earnings release dated 26 October 2016. Forward-looking statements are subject to assumptions, inherent risks and uncertainties, many of which relate to factors that are beyond the Group’s control or precise estimate. The Group cautions investors that a number of important factors, including those in this document, could cause actual results to differ materially from those expressed or implied in any forward-looking statement. Such factors include, but are not limited to, those discussed under Item 3.D ‘Risk factors’ in the Group’s Annual Report on Form 20-F for 2015 and those discussed in Part 2 of the Circular to Shareholders and Notice of General Meeting furnished to the SEC on Form 6-K on 24 November 2014. Any forward-looking statements made by or on behalf of the Group speak only as of the date they are made and are based upon the knowledge and information available to the Group on the date of this presentation.

A number of adjusted measures are used to report the performance of our business. These measures are defined in our third quarter earnings release dated 26 October 2016 and Annual Report on Form 20-F for 2015. The earnings release also contains reconciliations to the equivalent IFRS numbers.

The value of vaccination

Widely recognised as one of the best investments in healthcare

Tremendous progress for global health…

~3m
deaths prevented annually:
~5 per minute

…but still underserved populations

~22m
infants still missing basic vaccines

Target populations are growing…

~1bn
60+ year olds by 2020

…and major diseases remain without vaccines

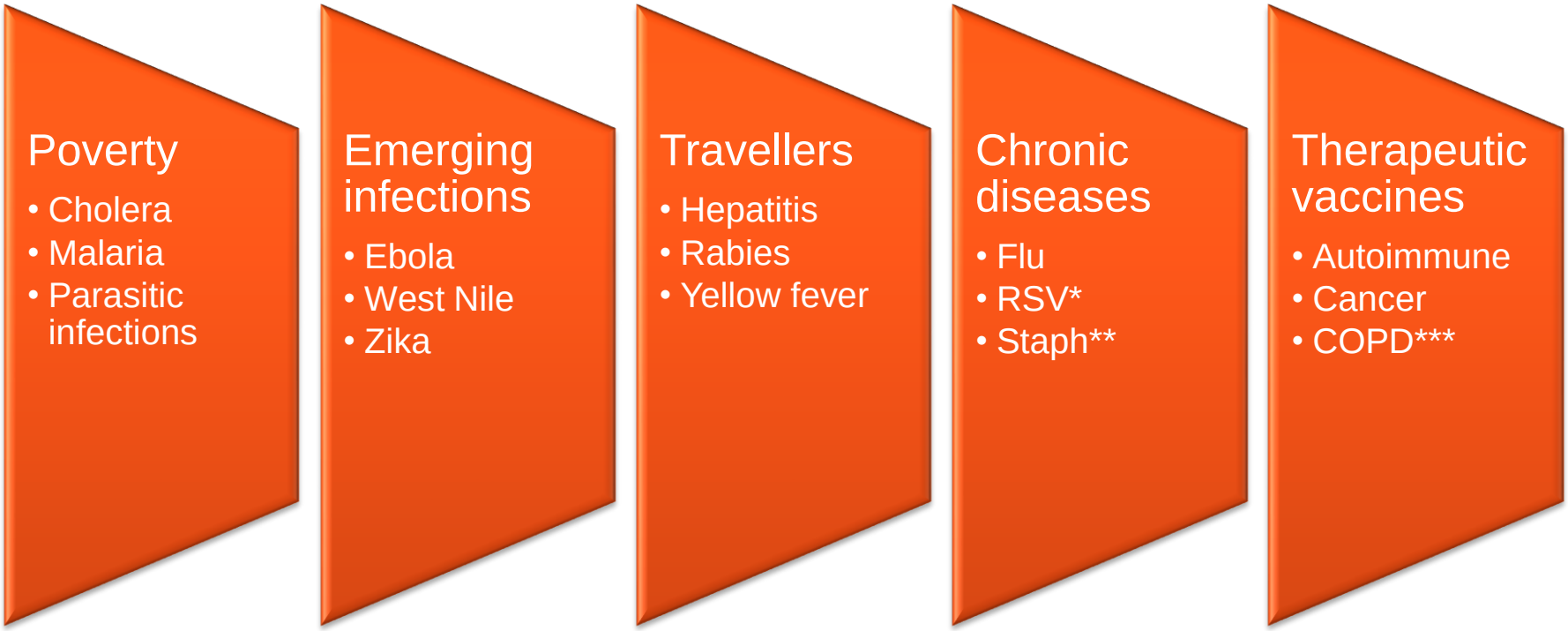
- RSV
- Group B Strep
- TB
- HIV
- & many more…

Source: UN, WHO, CDC.

Vaccines benefit all phases of life

Multiple drivers of the need for vaccines

Examples of industry wide focus areas, including vaccines under development



*RSV: Respiratory Syncytial Virus
** Staph: Staphylococcus infection
***COPD: Chronic Obstructive Pulmonary Disease

Vaccines is an attractive business, with barriers to entry

Growing market: ~£18bn in 2015[1] expected to grow at 5%[2]

Pharma-like operating margins

Long product lifecycles, no patent cliff

Few global players

Large capital investment

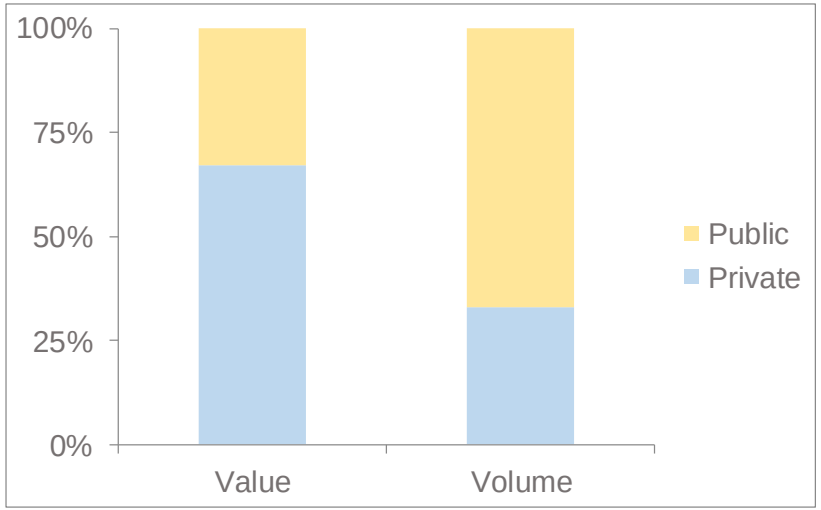
Complex manufacturing & quality control

Depth of expertise across value chain

[1] Market data from Evaluate Pharma: $27bn, assuming FX rate of $1.53 per GBP
[2] Expected CAGR from Evaluate Pharma: 2015-2022

Value and volume based business model

Two distinct markets



‘Quarterly’ volatility the norm

Tenders
- Wins
- Timing
- Funding
- Pricing

Government stockpiles
- Replenishments
- Withdrawals

Seasonality
- Back to school
- Flu season
- Outbreaks

Supply
- GSK
- Competitors

Source: GSK internal data, using GSK 2015 full year sales. Excludes legacy Novartis brands

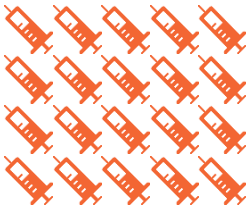
GSK Vaccines is an ambitious global leader

Helping to improve health around the world

Broadest portfolio in the industry

39
vaccines approved, covering every demographic

Helping to protect more people



~2 million
doses per day

Continuously delivering new and improved vaccines

15
in development, including Shingrix™ candidate vaccine, Men ABCWY, RSV, GBS, COPD, as well as novel proprietary adjuvant systems

Strategy to deliver sustainable financial performance

2020 vision
Targeting strong sales growth and margin expansion*

Shingrix is an investigational candidate vaccine for shingles that has been submitted for approval to the FDA and other authorities. The name 'Shingrix' has not yet been approved for use by any regulatory authority. * Growth expectations were communicated at the investor event in May 2015. This includes the expected CAGR to 2020, using 2015 as the base year. All expectations and targets regarding future performance should be read together with the "Assumptions related to 2016-2020 outlook" on page 35 of the Group's third quarter earnings release dated 26 October 2016. All financial figures at CER.

The Novartis transaction complemented our strengths

Acquired portfolio

Including meningitis

Innovation

Pipeline assets and platform technologies

Supply chain

Ownership of diphtheria & tetanus antigens

People

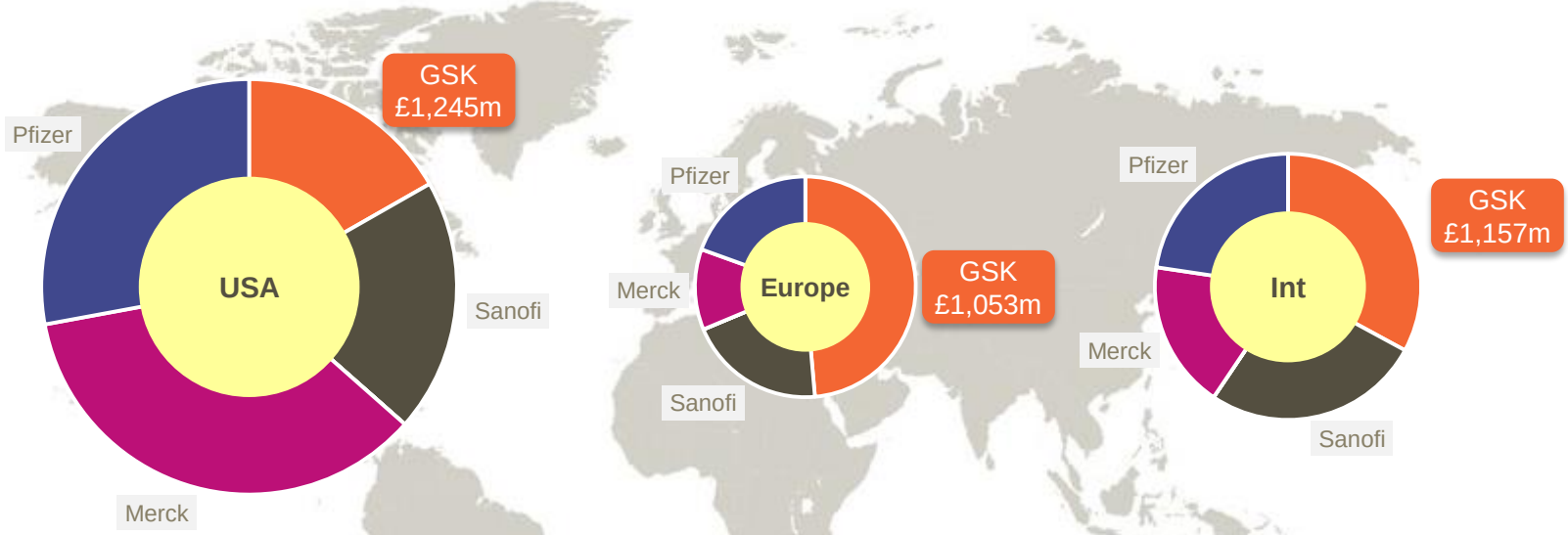
Network of highly skilled experts in R&D, manufacturing & quality

US

Helping to unlock US potential (e.g. Rockville)

GSK is well positioned in US, Europe and International

2016 vaccines sales for top four companies: September YTD



50-60% of global market

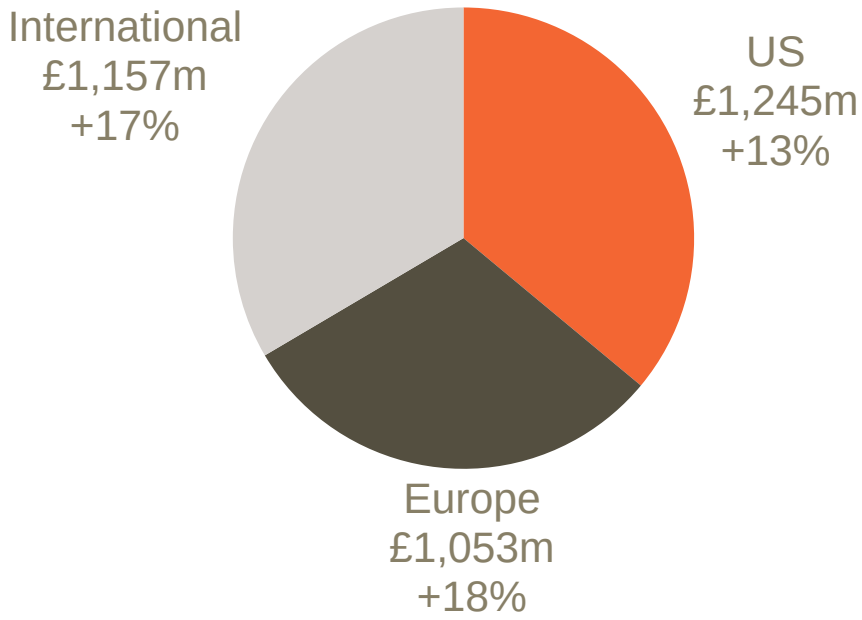
15-20% of global market

25-30% of global market

Source: Company reports and GSK estimates

Strong growth for GSK in US, Europe and International

9 month sales to September 2016

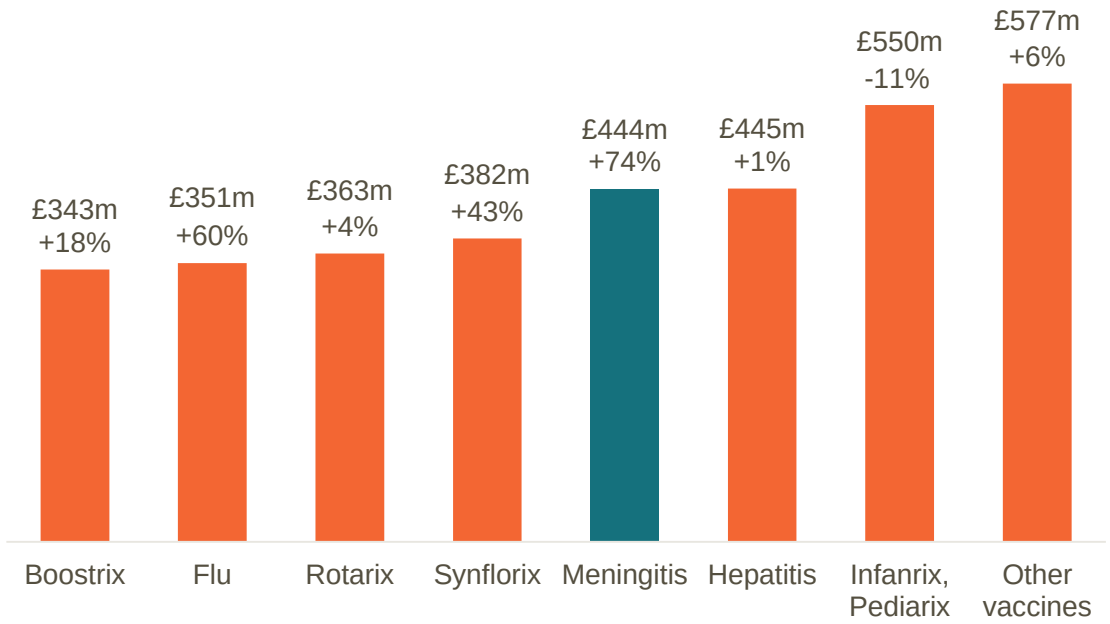


2016 YTD: £3.5bn
+16% CER pro-forma

All growth rates are at CER and pro-forma: i.e. adjusted for the Novartis transaction.

Strong growth across most franchises

9 month sales to September 2016



2016 YTD: £3.5bn
+16% CER pro-forma

All growth rates are at CER and pro-forma: i.e. adjusted for the Novartis transaction.
"Other vaccines" includes Cervarix, Priorix, Priorix Tetra, Varilrix, Rabipur and others.

On track to deliver vaccines sales growth targets*

Expected CAGR 2016-20*

Expected growth drivers

~1/3
of growth from: Marketed portfolio

~1/3
of growth from: Meningitis portfolio

~1/3
of growth from: Shingrix candidate vaccine

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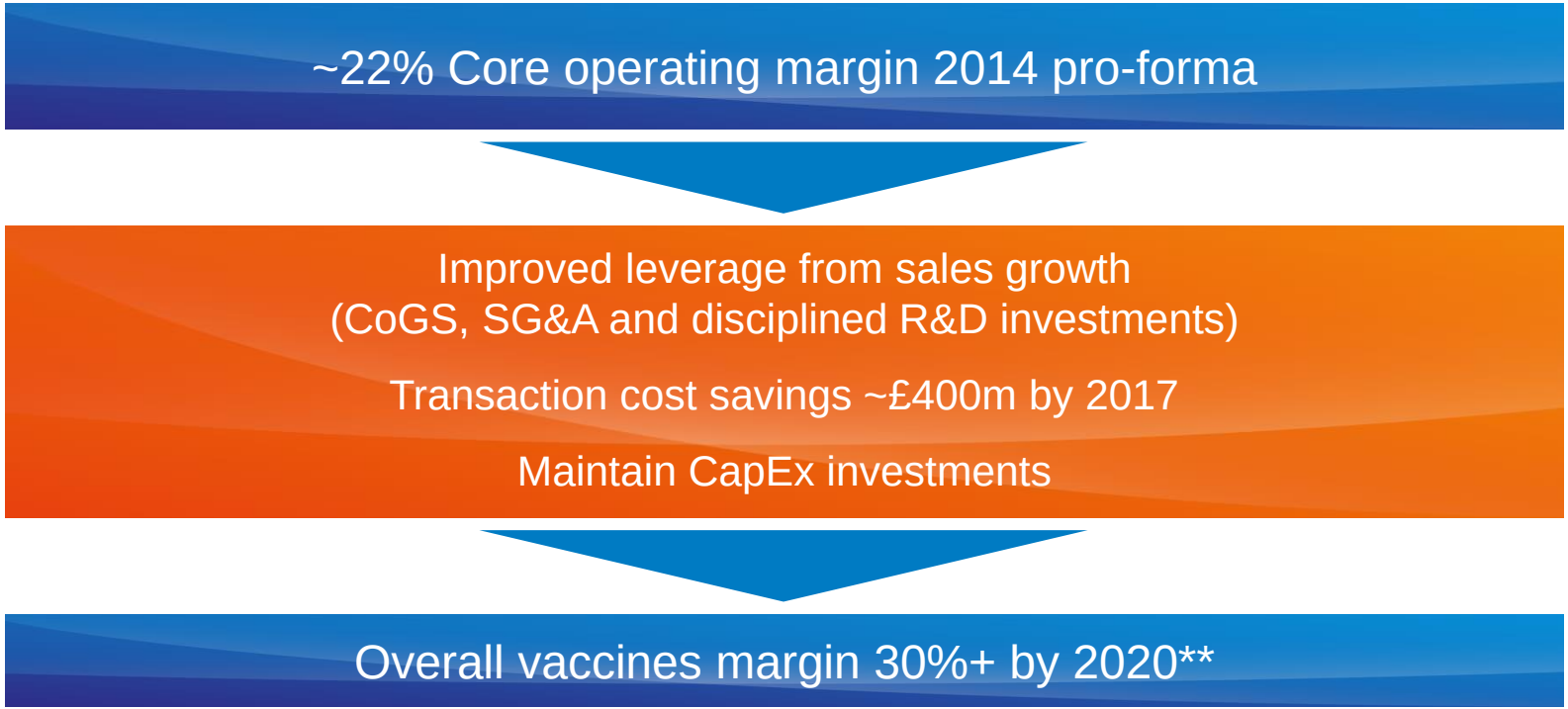
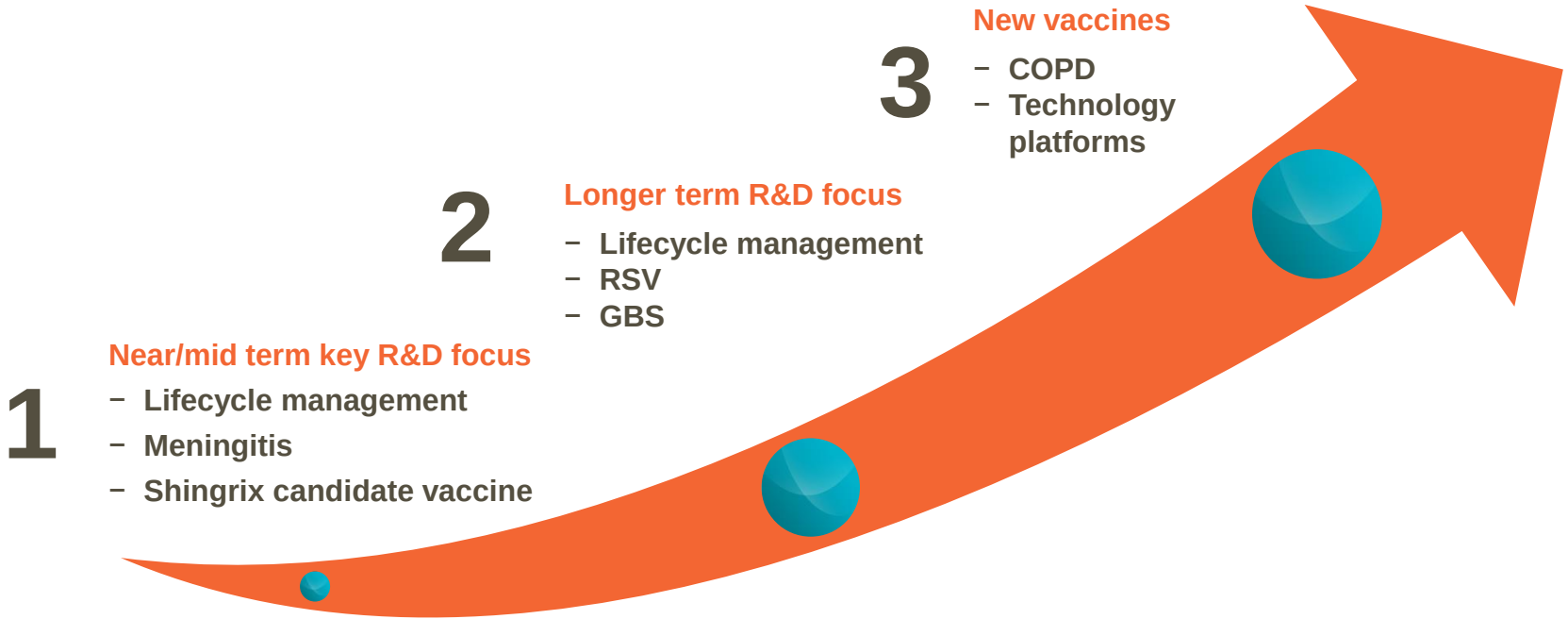
On track to deliver improved margin expectations*



*Core results are defined in the third quarter results dated 26 October 2016. ** Growth expectations were communicated at the investor event in May 2015. This includes the expected CAGR to 2020, using 2015 as the base year. All expectations and targets regarding future performance should be read together with the with the "Assumptions related to 2016-2020 outlook" on page 35 of the Group's third quarter earnings release dated 26 October 2016. All sales growth rates at CER.

Innovative R&D programmes aim to deliver sustainable growth to 2020 and beyond

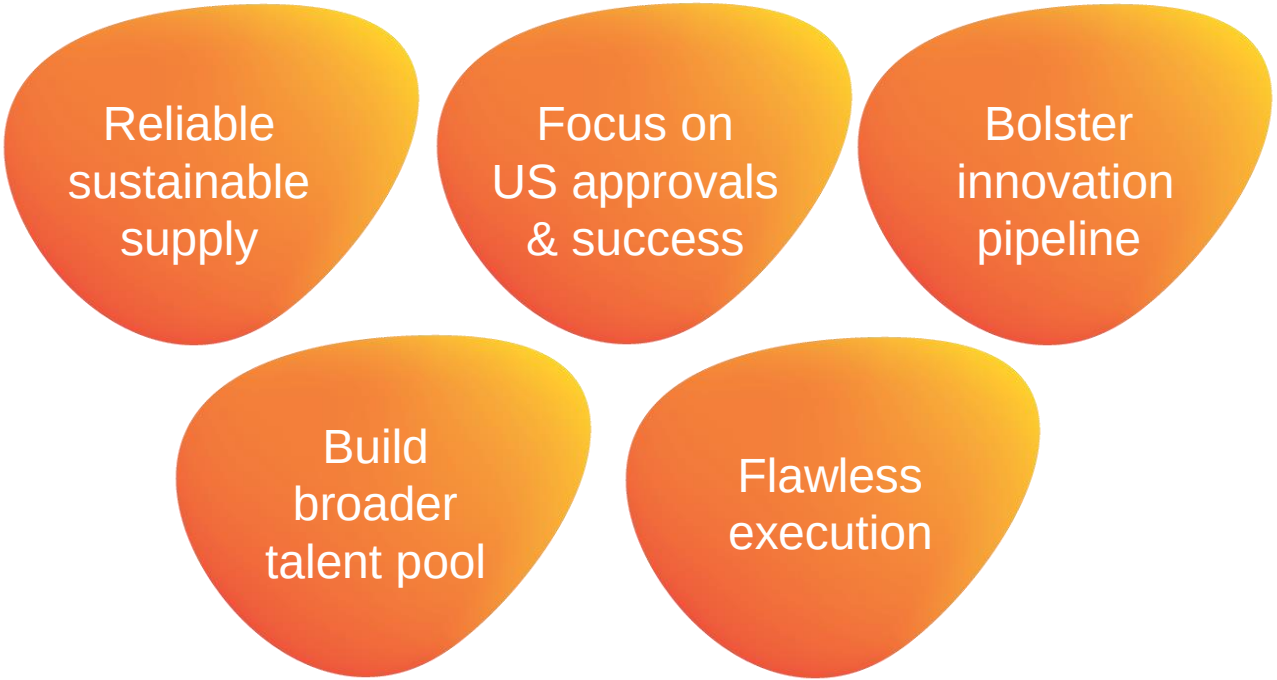


GBS=Group B Streptococcus

Shingrix is an investigational candidate vaccine for shingles that has been submitted for approval to the FDA and other authorities. The name 'Shingrix' has not yet been approved for use by any regulatory authority.

Positioned to be global leader for a very long time

Strategic focus



Portfolio strength & growth drivers

Thomas Breuer
Chief Medical Officer, GSK Vaccines

GSK's strong vaccines portfolio

Paediatric

- Diphtheria
- Haemophilus influenzae type b (Hib)
- Hepatitis A
- Hepatitis B
- Influenza (flu)
- Measles
- Meningococcal (A, B, C, W, Y)
- Mumps
- Pertussis
- Pneumococcal
- Poliomyelitis
- Rotavirus
- Rubella
- Tetanus
- Typhoid fever
- Varicella

Adolescent, adult and travel

- Cervical cancer (HPV)
- Diphtheria
- Haemophilus influenzae type b (Hib)
- Hepatitis A
- Hepatitis B
- Influenza (pre-pandemic flu)
- Influenza (seasonal flu)
- Measles
- Meningococcal (A, B, C, W, Y)
- Mumps
- Pertussis
- Poliomyelitis
- Rabies
- Rubella
- Tetanus
- Tick-borne encephalitis
- Typhoid fever
- Varicella

Older adult

- Diphtheria
- Hepatitis A
- Hepatitis B
- Influenza (pre-pandemic flu)
- Influenza (seasonal flu)
- Pertussis
- Tetanus
- Shingles*

* Under regulatory review

GSK's strong vaccines portfolio

Maternal**

- Diphtheria
- Influenza (flu)
- Pertussis
- Poliomyelitis
- Tetanus

Paediatric

- Diphtheria
- Haemophilus influenzae type b (Hib)
- Hepatitis A
- Hepatitis B
- Influenza (flu)
- Measles
- Meningococcal (A, B, C, W, Y)
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Adolescent, adult and travel

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Older adult

- Diphtheria
- Hepatitis A
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- Influenza (seasonal flu)
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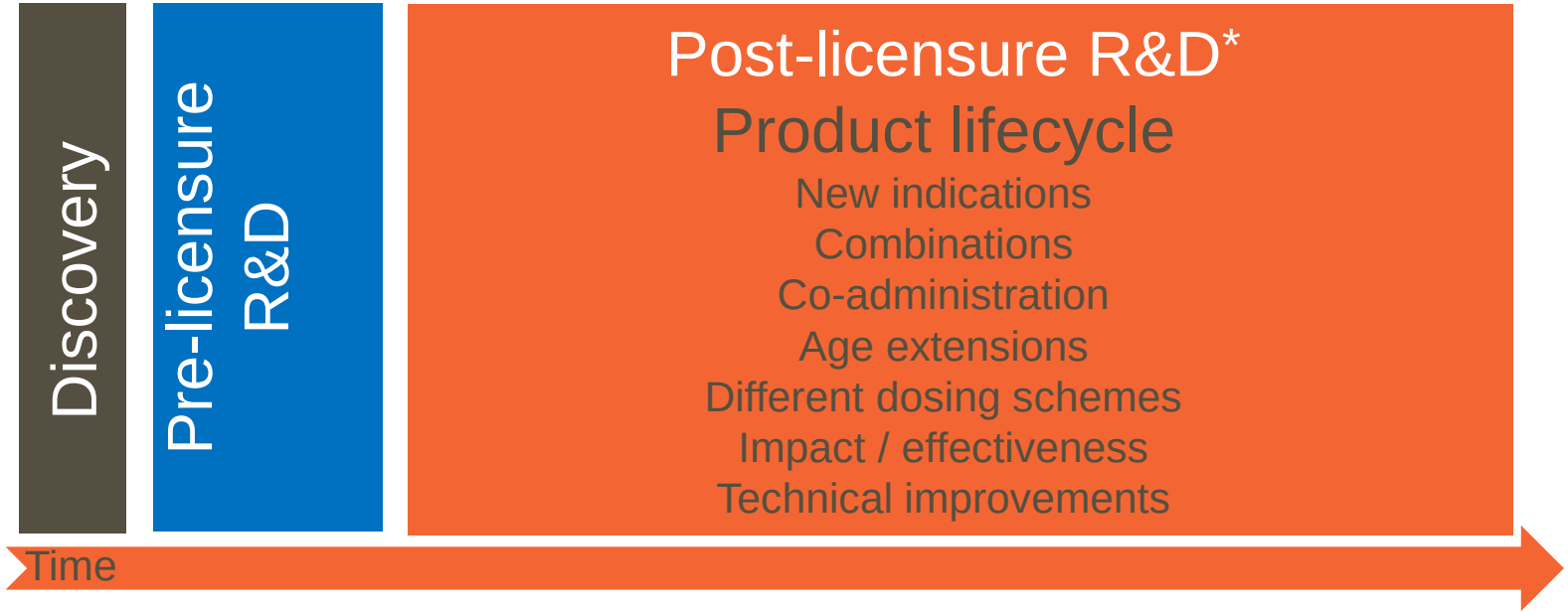
- Tetanus
- Shingles*

* Under regulatory review

** GSK's vaccines do not currently have approved indications for maternal immunisation. GSK recently received EMA approval for updated Boostrix and Boostrix Polio labels with human prospective safety data in pregnant women. Maternal immunization is recommended by WHO and implemented in many countries including US and Europe

Vaccine product lifecycle is a lifelong endeavor

No patent cliff – no generics – each vaccine a unique entity



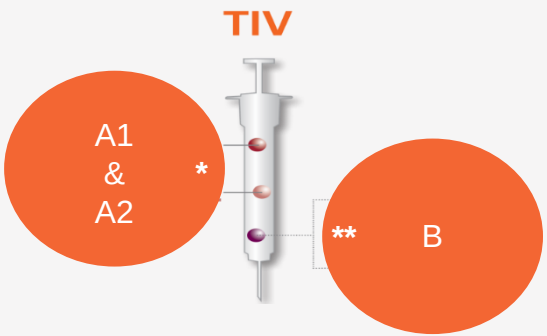
* schematic

Flu vaccines: from trivalent to quadrivalent

Lifecycle example

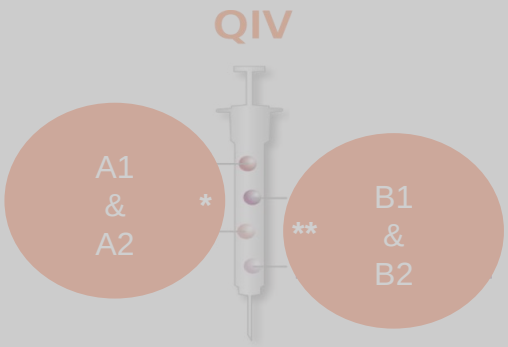
Trivalent (TIV) licensed in 1998

3 strains



Quadrivalent (QIV) licensed in 2012

4 strains



* e.g. A/H1N1, A/H3N2 - ** e.g. B/Victoria, B/ Yamagata

Flu vaccines: from trivalent to quadrivalent

Lifecycle example

Trivalent (TIV) licensed in 1998

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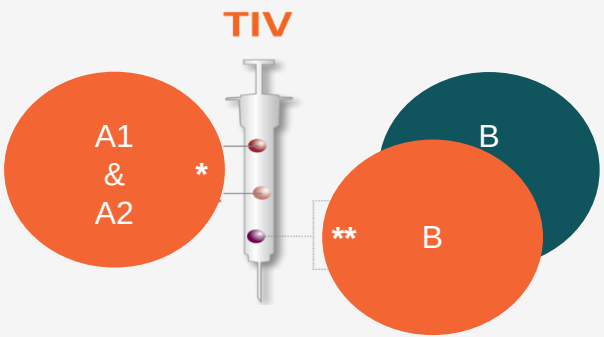

Quadrivalent (QIV) licensed in 2012

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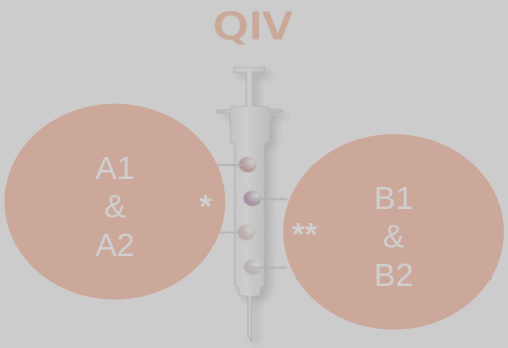
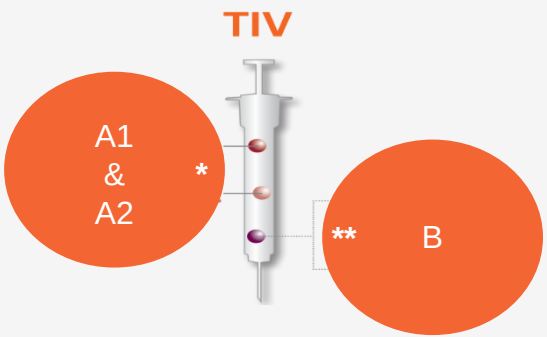


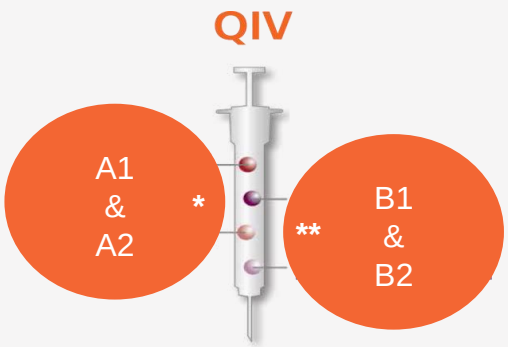
* e.g. A/H1N1, A/H3N2 - ** e.g. B/Victoria, B/ Yamagata

Flu vaccines: from trivalent to quadrivalent

Lifecycle example

Trivalent (TIV) licensed in 1998	**Quadrivalent (QIV)** licensed in 2012
3 strains	**4 strains**





Competitive differentiation → total revenue increase 2012-2015: 46%***

* e.g. A/H1N1, A/H3N2 - ** e.g. B/Victoria, B/ Yamagata - *** at constant exchange rates -

Rotarix: continuous label & technical improvements since initial licensure (2004)

Lifecycle example

gsk

Impact data*

Thermostability data

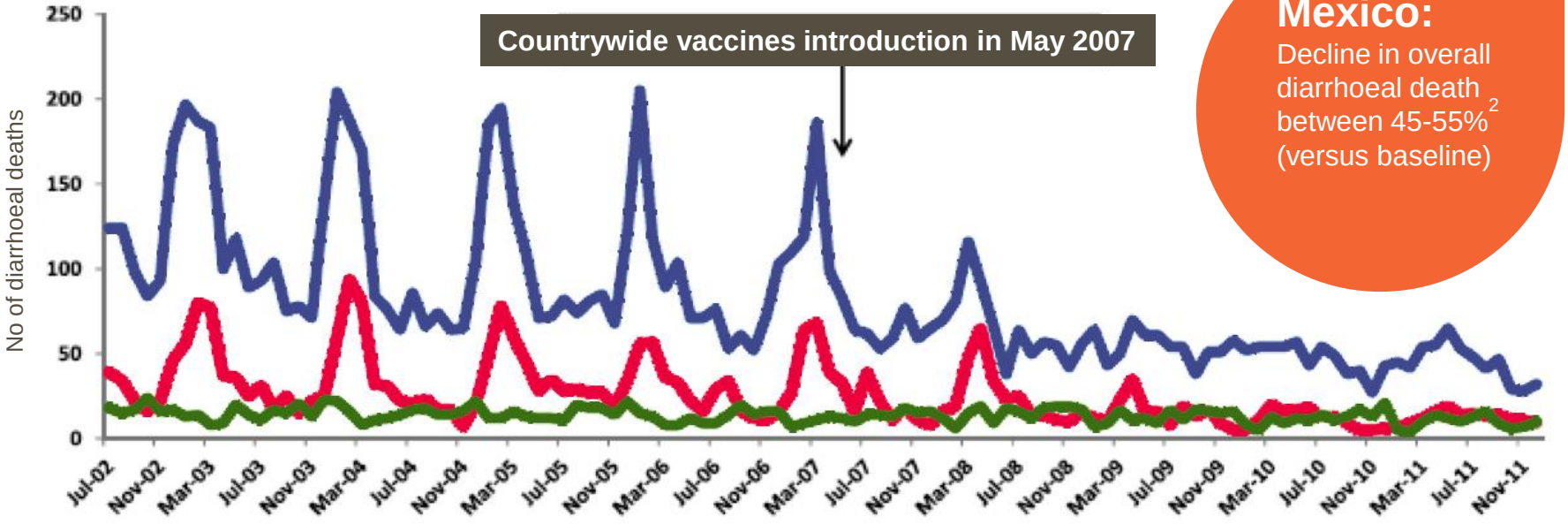
Rotarix co-administration

Lowering cost of goods**

Rotarix growth since 2009: CAGR ~ 15%***

* Morbidity/Mortality, Health budget - ** e.g. fully liquid presentation, “blow fill” tube - *** at constant exchange rates

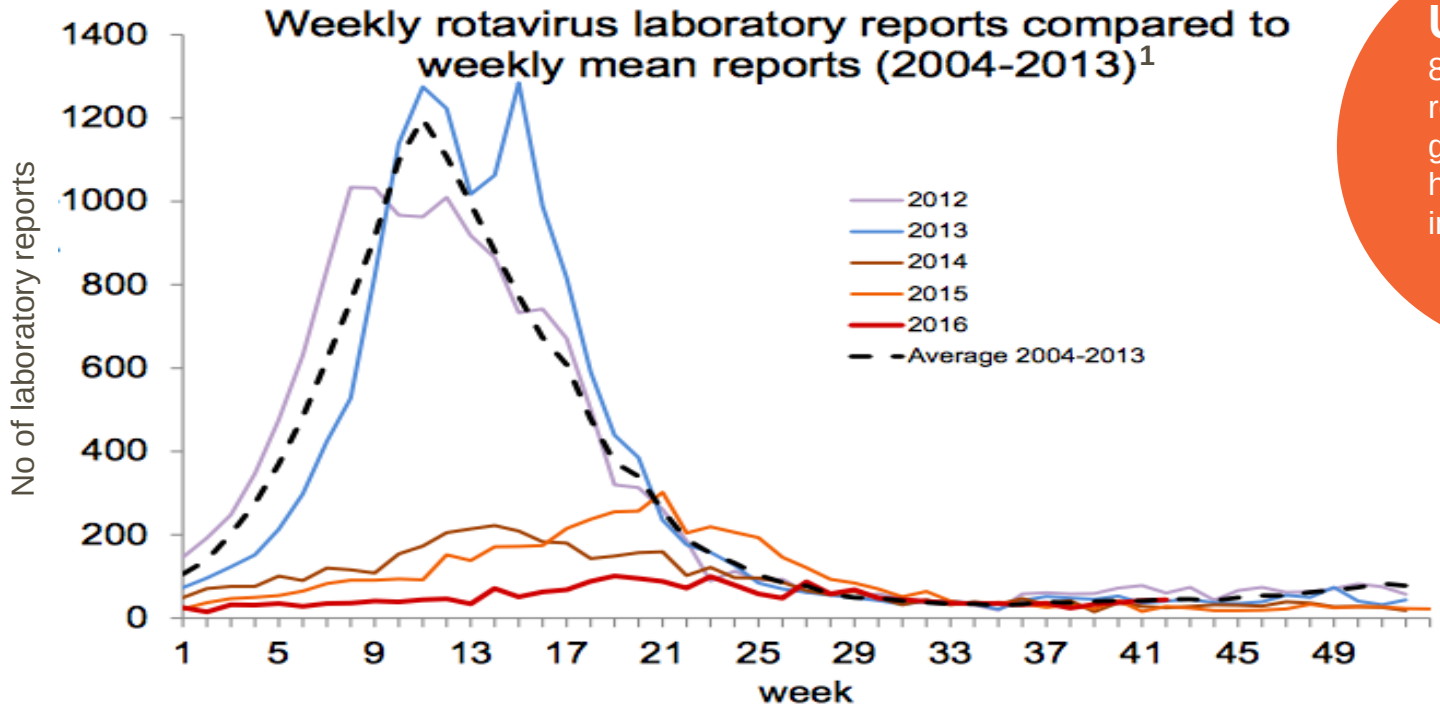
Rotarix: impact on the number of diarrhoea-related deaths in Mexico[1]



Mexico:
Decline in overall diarrhoeal death between 45-55%[2] (versus baseline)

[1] Among children aged <5 years in Mexico according to age group
[2] Gastañaduy PA, et al. Pediatrics. 2013;131:e1115-20.

Rotarix: introduction of Universal Mass Vaccination in infants in UK (2013)

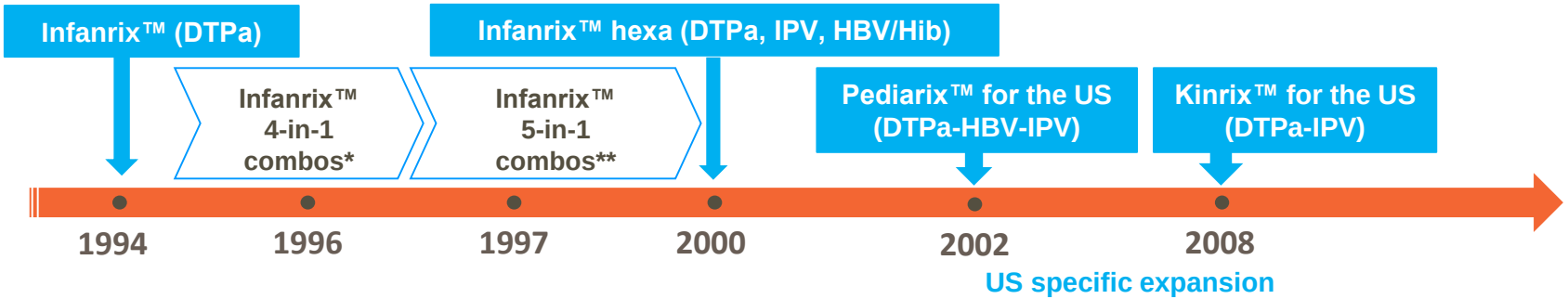


UK:
80% reduction in rotavirus gastroenteritis hospitalisations in infants[2]

(1)Public Health England. Norovirus and rotavirus: summary of surveillance. Available at :https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/544894/Norovirus_update_2016_weeks_26_30.pdf [accessed Nov 2016]. (2) Public Health England. Successful start to rotavirus vaccination programme. Available at: https://www.gov.uk/government/news/successful-start-to-rotavirus-vaccination-programme [accessed Nov 2016].

Infanrix (DTPa) franchise: expanded combinations and indications (from 3-in-1 to 6-in-1)

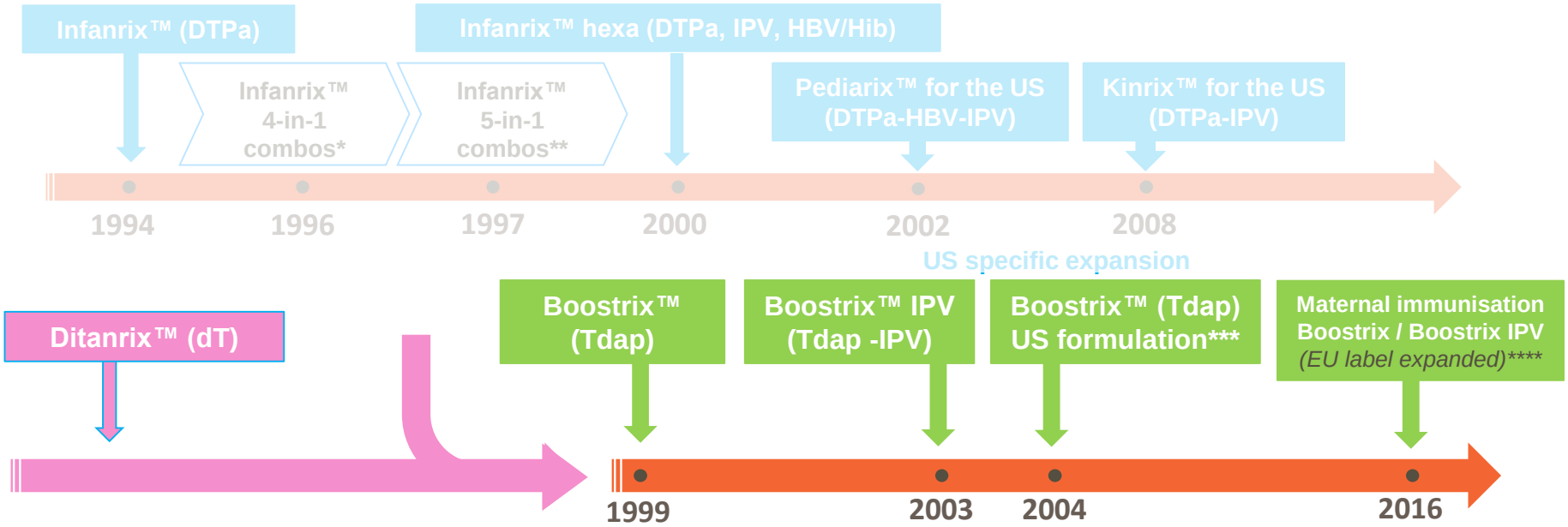
Lifecycle example



*Infanrix™ Hib, Infanrix™ IPV, Infanrix™ HBV - ** Infanrix™ IPV-Hib, Infanrix™ –HBV-IPV

Infanrix (DTPa) franchise: expanded combinations and indications (adding vaccines aimed for boosting)

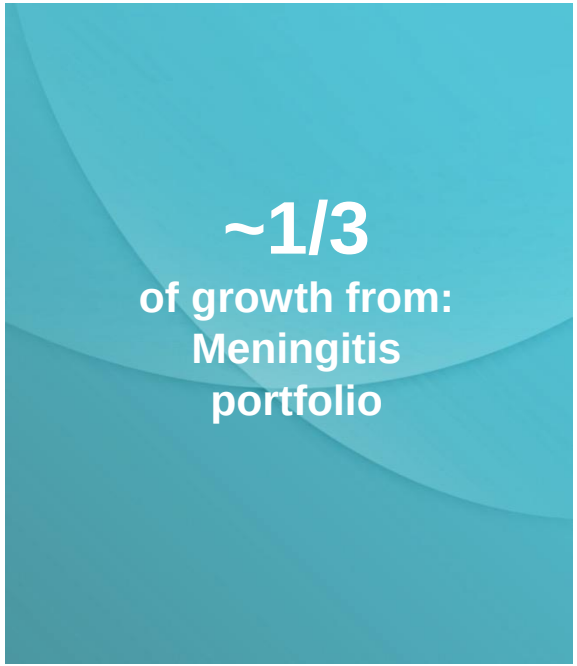
Lifecycle example

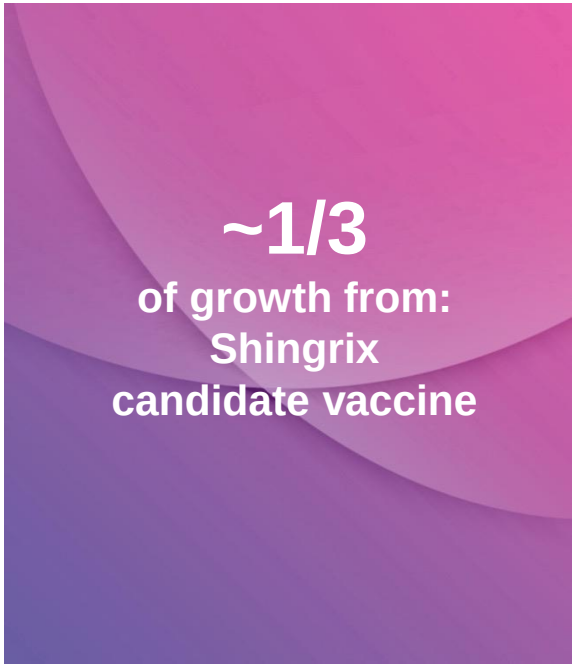


DTPa franchise (including Infanrix™ & Boostrix™ family) 10 year CAGR: ~9%***

*Infanrix™ Hib, Infanrix™ IPV, Infanrix™ HBV - ** Infanrix™ IPV-Hib, Infanrix™ –HBV-IPV - ***Different alum content **** GSK's vaccines do not currently have approved indications for maternal immunisation. GSK recently received EMA approval for updated Boostrix and Boostrix Polio labels with human prospective safety data in pregnant women. Maternal immunization is recommended by WHO and implemented in many countries including US and Europe - *****at constant exchange rates

GSK Vaccines sales growth ambition by 2020





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Meningococcal meningitis

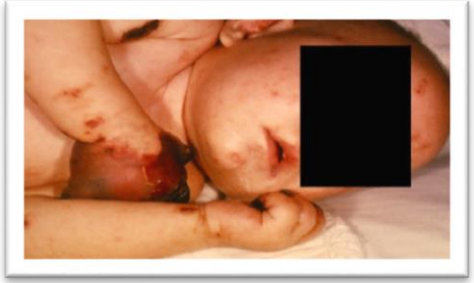
Meningococcal disease: uncommon, however progresses rapidly with unpredictable outcome

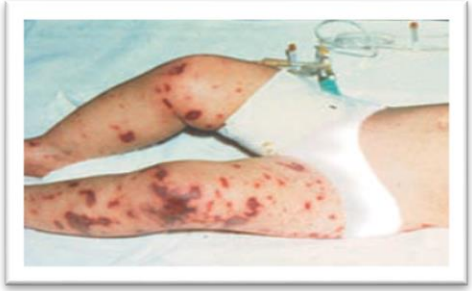
Incidence and diagnosis

Meningococcal disease incidence peaks in infants and adolescents
Early signs and symptoms often resemble those of common viral illnesses[1]

Significant morbidity and mortality

Despite appropriate medical treatment:
- ~5–10% of cases are fatal[2]
- Up to 20% of survivors of invasive meningococcal disease (all serogroups) have sequelae[2] , including limb amputations, seizures and hearing loss[3]





Top image: Courtesy of Centers for Disease Control and Prevention and Dr Gust. Bottom image: Courtesy of Meningitis Research Foundation UK. Available at www.meningitis.org.

*Case-control study (246 cases recruited) in UK (May 2008 to September 2010). Subjects aged 1 month to 13 years at disease

1. Thompson MJ *et al. Lancet* 2006;367:397–403; 2. Meningococcal meningitis factsheet No 141. World Health Organization website. http://www.who.int/mediacentre/factsheets/fs141/en/# , Updated November 2015 (Accessed August 2016); 3. Viner RM *et al*. *Lancet Neurol* 2012;11:774–783.

Broad meningitis vaccines portfolio*, including candidate pentavalent

Menveo™

- MenACWY tetravalent vaccine
- Approved in 64 countries
  - US & EU (2010)
- **Lifecycle management**
  - Fully liquid formulation
  - Booster indication in US

Bexsero™

- MenB vaccine
- Approved in 38 countries
  - EU from > 2 months onwards (2013)
  - US for adolescents (2015)
- **Lifecycle management**
  - Infant indication in US
  - Impact on meningococcal carriage (> 40,000 subjects)

MenABCWY**

- Candidate pentavalent combination vaccine
- Currently in phase II, data expected ~2017

* Meningitis portfolio: Menjugate (MenC vaccine), Bexsero (MenB vaccine), Menveo (MenACWY vaccine) ** Candidate vaccine

UK infant effectiveness data major milestone for Bexsero

First country to start a public UMV program

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Health

Meningitis B vaccinations start across UK for all newborns

By James Gallagher
Health editor, BBC News website

1 September 2015 | Health | Share

83% effectiveness, cases halved, >600k infants vaccinated

PRESS RELEASE

Issued: 5 September 2016

'Real world' data shows 83 percent effectiveness for Bexsero® in infants in first year of UK national meningitis B immunisation programme

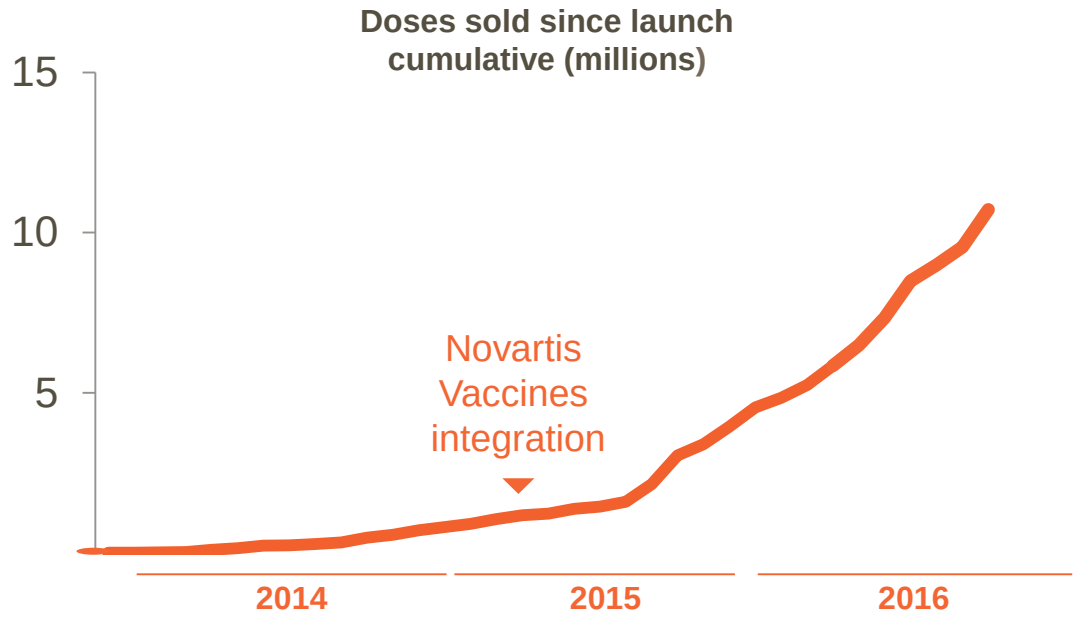
- Cases of meningitis B halved after ten months

Preliminary data from the world's first national meningitis B immunisation programme with Bexsero[1], launched one year ago in the UK, shows the estimated effectiveness of the vaccine at 83 percent against any meningitis B strain and 94 percent against vaccine preventable strains, for all children receiving the first two of three recommended doses [2]. Reported cases of the disease have dropped 50 percent in the vaccine-eligible population in the first ten months of the programme, compared to the average number of cases over the last four years. These data were presented today by Public Health England (PHE) at the International Pathogenic Neisseria Conference (IPNC) in Manchester, UK.

Uptake of the vaccine in the UK national immunisation programme is high. In more than 600,000 infants aged 0-1 year old, eligible for the vaccine, more than 90 percent received two doses.

Excellent execution of Bexsero's launch

Strong performance globally



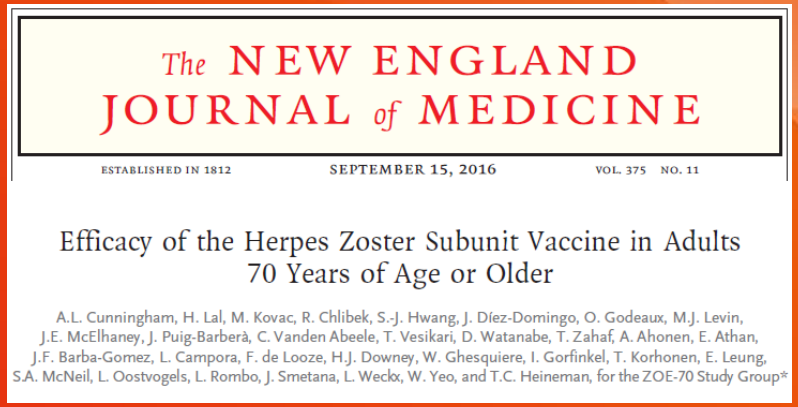
Cumulative volume >10 million in 2 years

Investing to expand capacity to capture market growth over time

Source: GSK internal data

GSK shingles candidate vaccine

In regulatory approval process

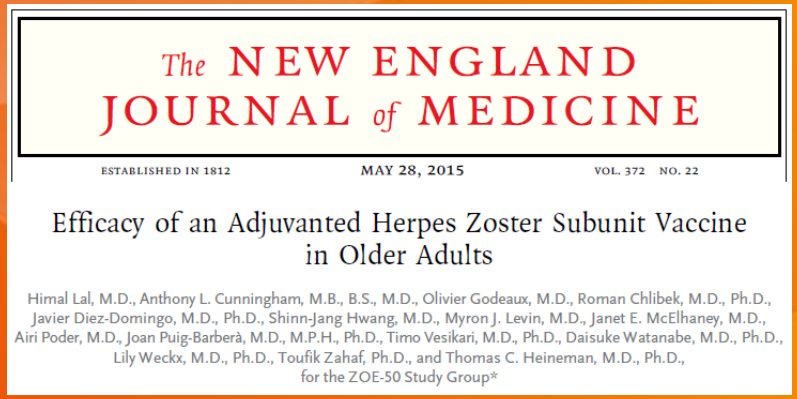


The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 15, 2016 VOL. 375 NO. 11

Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older

A.L. Cunningham, H. Lal, M. Kovac, R. Chlibek, S.-J. Hwang, J. Díez-Domingo, O. Godeaux, M.J. Levin, J.E. McElhaney, J. Puig-Barberà, C. Vanden Abeele, T. Vesikari, D. Watanabe, T. Zahaf, A. Ahonen, E. Athan, J.F. Barba-Gomez, L. Campora, F. de Looze, H.J. Downey, W. Ghesquiere, I. Gorfinkel, T. Korhonen, E. Leung, S.A. McNeil, L. Oostvogels, L. Rombo, J. Smetana, L. Weckx, W. Yeo, and T.C. Heineman, for the ZOE-70 Study Group*



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 28, 2015 VOL. 372 NO. 22

Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults

Himal Lal, M.D., Anthony L. Cunningham, M.B., B.S., M.D., Olivier Godeaux, M.D., Roman Chlibek, M.D., Ph.D., Javier Diez-Domingo, M.D., Ph.D., Shinn-Jang Hwang, M.D., Myron J. Levin, M.D., Janet E. McElhaney, M.D., Airi Poder, M.D., Joan Puig-Barberà, M.D., M.P.H., Ph.D., Timo Vesikari, M.D., Ph.D., Daisuke Watanabe, M.D., Ph.D., Lily Weckx, M.D., Ph.D., Toufik Zahaf, Ph.D., and Thomas C. Heineman, M.D., Ph.D., for the ZOE-50 Study Group*

Epidemiology of shingles/herpes zoster (HZ) in the US

~1m
cases in the US annually[1]

32%
estimated lifetime risk of zoster[1]

50%
of persons living over age 85 years are likely to develop zoster[1]

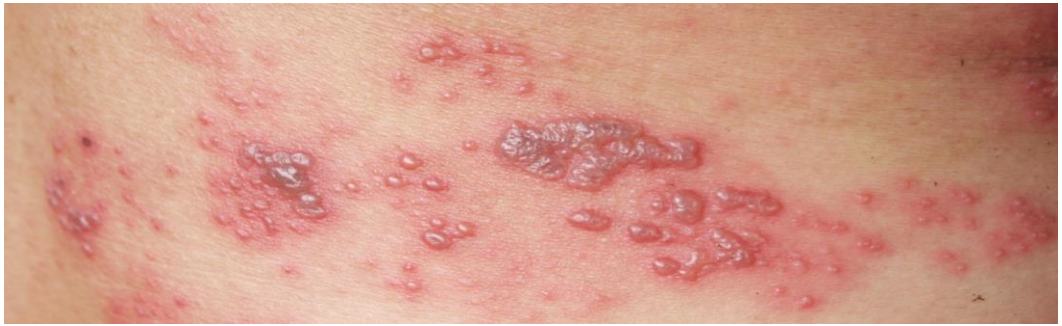
The most important risk factors

Increasing age

Immunosuppression

Feared complication

Postherpetic neuralgia



1. CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 13th ed. 2015

Shingrix candidate vaccine developed to differentiate

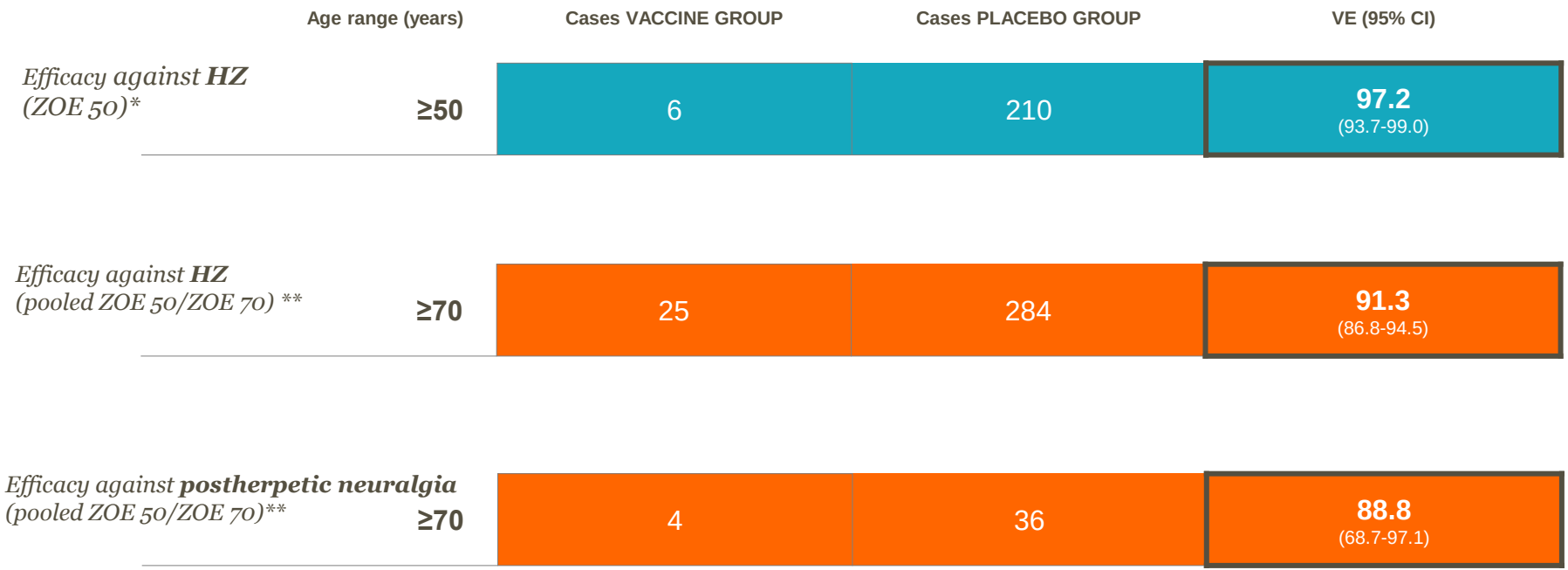
Ambition at the outset:

- **Sub-unit vaccine (non-live)**
- **High efficacy in 50+, including older subgroups**
- **Sustained efficacy over time**
- **Applicable to immunocompromised individuals**
- **Refrigerator stable**

Shingrix is an investigational candidate vaccine for shingles that has been submitted for approval to the FDA and other authorities. The name 'Shingrix' has not yet been approved for use by any regulatory authority.

Two dose vaccine: strong efficacy across different age groups

ZOE-50 / pooled ZOE-50 / ZOE-70 results



* Lal H, M.D., Anthony L. Cunningham AL, Godeaux O, et al. Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults. N Engl J Med 2015; 372:2087-2096

** Cunningham AL, Lal H, Kovac M, et al. Efficacy of the herpes zoster subunit vaccine in adults ≥70 years of age. *NEJM* 2016;375:1019-1032

High and sustained efficacy over 4 years

Pooled ZOE-50 and ZOE-70 results

Time post-vaccination*	HZ/Vaccine group n=8,250 HZ cases	Placebo group n=8,346 HZ cases	VE (95% CI)†
Year 1	2	83	**97.6** (90.9-99.8)
Year 2	7	87	**92.0** (82.8-96.9)
Year 3	9	58	**84.7** (69.0-93.4)
Year 4	7	56	**87.9** (73.3-95.4)

Cunningham AL, Lal H, Kovac M, et al. Efficacy of the herpes zoster subunit vaccine in adults ≥70 years of age. NEJM 2016;375:1019-1032

*Year 1: from 30 days to 395 days after the second vaccination. Year 2: from >395 days to 760 days after the second vaccination. Year 3: from >760 days to 1,125 days after the second vaccination. Year 4: from >1,125 days after the second vaccination to the last contact date.

Safety and reactogenicity profile

*ZOE-50/70 results**

Safety:

No imbalance between vaccine and placebo group for:

- Serious Adverse Events
- Potentially Immune mediated Diseases
- Deaths

Reactogenicity:

- Local and systemic reactions were common, however majority were of

- mild to moderate intensity and of short duration

Second-dose compliance:

High: ~95%

* Herpes zoster subunit vaccine – GSKs shingles candidate vaccine

Ref: 1. Lal H, Cunningham A, Godeaux O, et al. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. NEJM 2015;372:2087-96. Ref: 2. Cunningham AL, Lal H, Kovac M, et al. Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age and Older. NEJM 2016;375:1019-32

Key milestones on track

Filing completed in US, Canada and Europe

US, Canada, EU **filings**

Japan **filing**

Additional co-administration data

Revaccination of people previously vaccinated with Zostavax*

Phase III efficacy study in immuno-compromised

* Zostavax is a trademark of Merck & Co

Shingrix candidate vaccine: the opportunity…

Globally only a small proportion of the older adult population has received a shingles vaccine

Redefine and expand the market

New standard of prevention	Potential revaccination opportunity*	Increase immunisation rates	Geographic expansion	New cohorts
91%-97% efficacy across identified age groups Sustained efficacy	Data in 2017	~30% in US (current)	US, Canada, EU filed Japan filing 2017	Immuno-compromised Expand age recommendations over time

* of Zostavax recipients. Zostavax is a trademark of Merck & Co.

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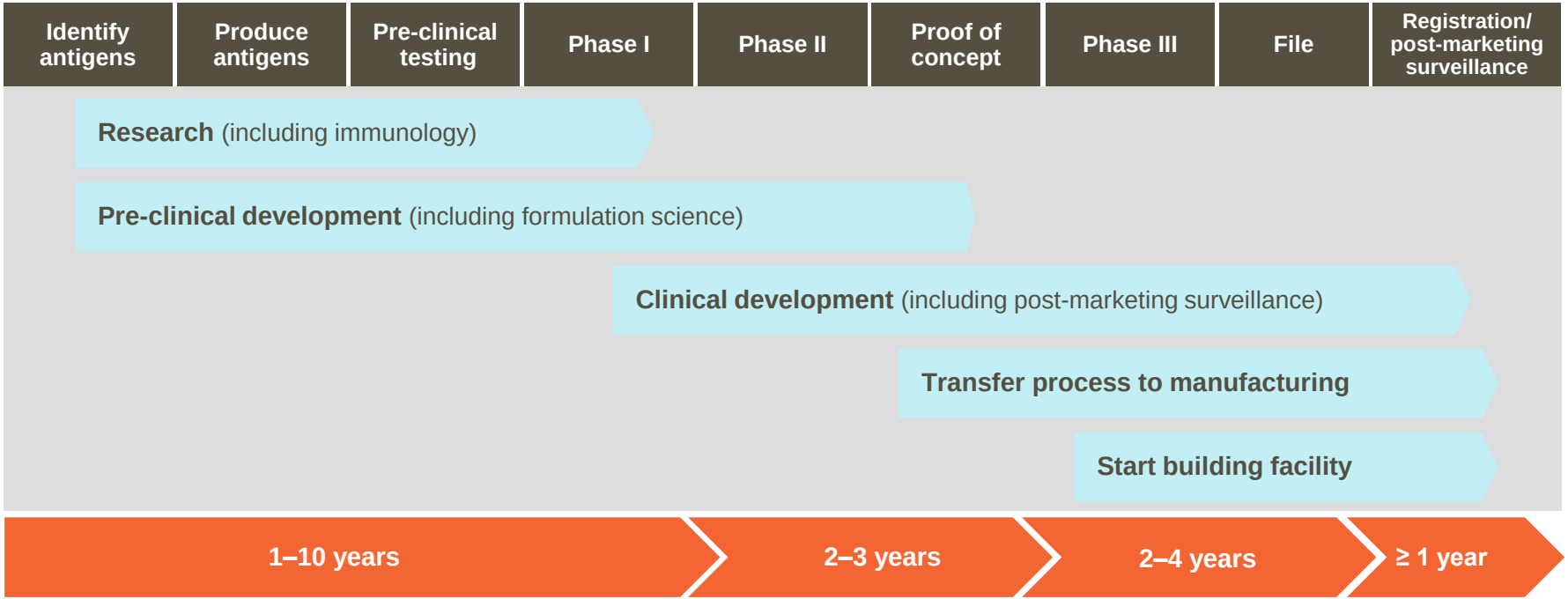
Research & Development

Emmanuel (Manu) Hanon
Head of R&D, GSK Vaccines

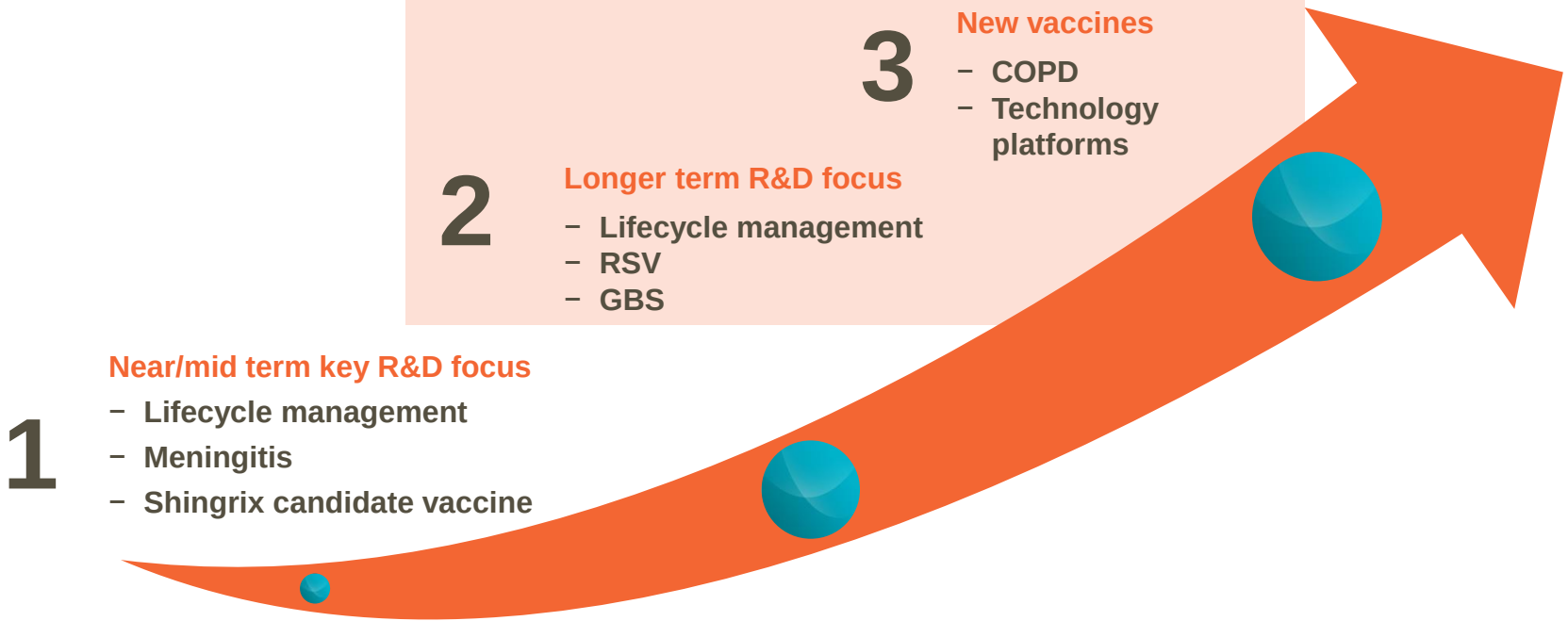
R&D organisation

Vaccines R&D timelines (illustrative)



1. Figure adapted from GSK. How we discover new vaccines. Available at: http://www.gsk.com/en-gb/research/how-we-discover-new-products/how-we-discover-new-vaccines/. Accessed May 2016; 2. Stergiopoulos S, et al. Characterizing the cost of non-clinical development activity. 5 June 2013. Available at: http://www.contractpharma.com/issues/2013-06/view_features/characterizing-the-cost-of-non-clinical-development-activity. Accessed May 2016; 3. U.S. Department of Health and Human Services. Examination of clinical trial costs and barriers for drug development. 25 July 2014. Available at: https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development. Accessed May 2016.

Innovative R&D programmes aim to deliver sustainable growth to 2020 and beyond



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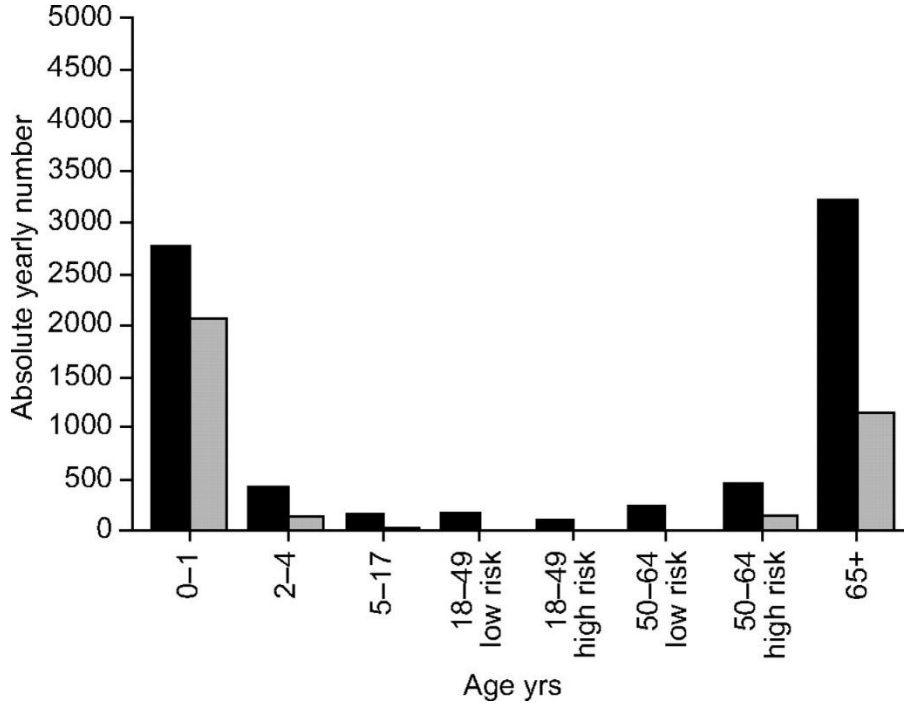
Respiratory Syncytial Virus (RSV)

RSV-associated hospitalisation burden significantly impacts infants and the elderly

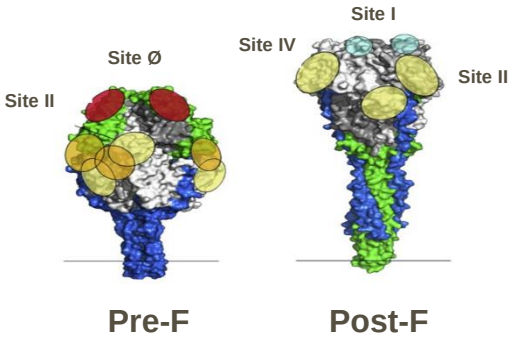


A. G. S. C. Jansen et al. Eur Respir J 2007;30:1158-1166

Respiratory syncytial virus-associated hospitalisation burden in the Netherlands.
■: versus summer baseline period; ■: versus peri-seasonal baseline period.

Novel RSV candidate vaccine approaches

The inclusion of RSV F (fusion) protein in the composition of an RSV vaccine is critical



Graham B et al., Current Opinion in Immunology 35; 30-38, 2015

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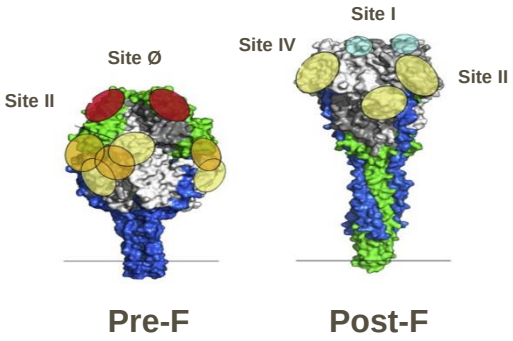
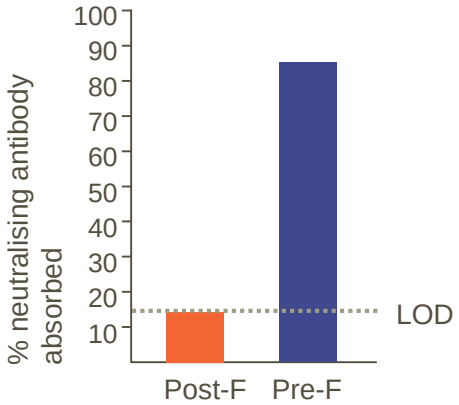
GSK Pre-F approach differs from competitor Post-F which recently did not meet end points



Graham B et al., Current Opinion in Immunology 35; 30-38, 2015

Absorption with Pre-F but not Post-F depletes neutralising IgG from convalescent serum



GSK preclinical data, unpublished

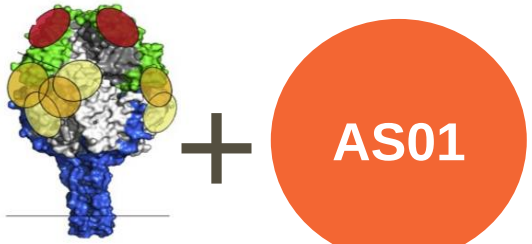
LOD = Limit of detection
IgG = Immunoglobulin G

Novel RSV candidate vaccine for the elderly

The inclusion of RSV F (fusion) protein in the composition of an RSV vaccine is critical

GSK Pre-F approach differs from competitor Post-F which recently did not meet end points

AS01 adjuvant system has been shown to be highly efficient in the elderly



Pre-F

Novel RSV candidate vaccine for the elderly

The inclusion of RSV F (fusion) protein in the composition of an RSV vaccine is critical

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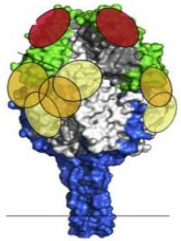
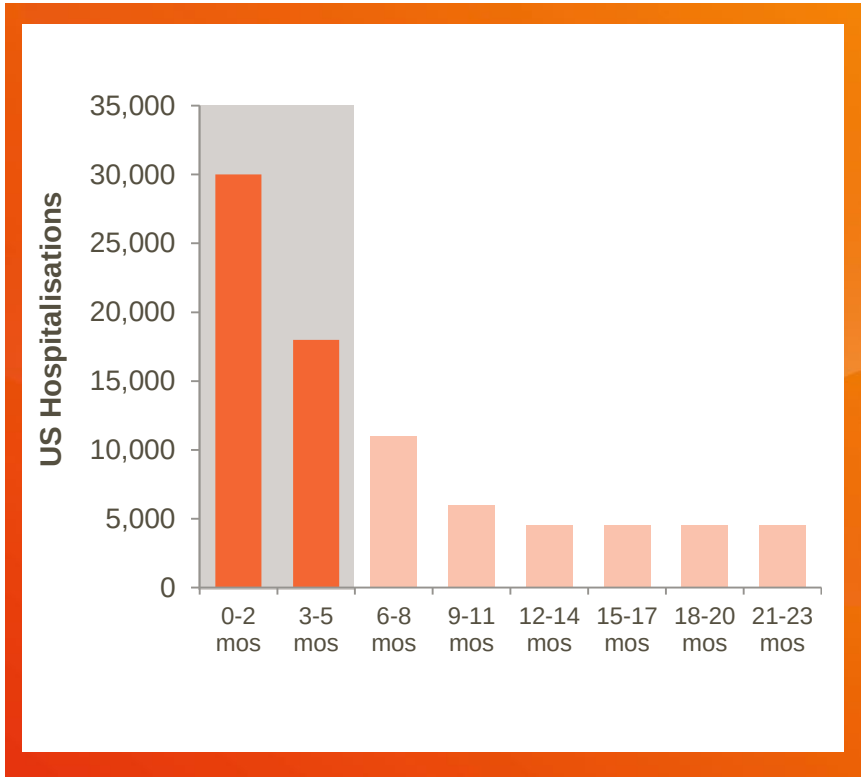


Pre-F + AS01

Elderly candidate with AS01

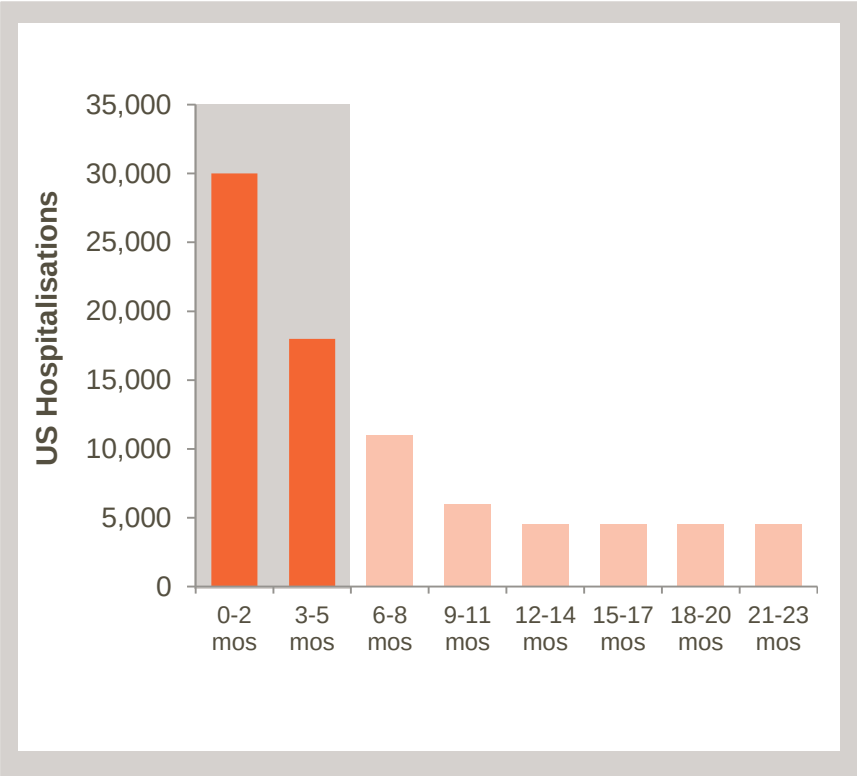
Expected to enter late stage development in 2020

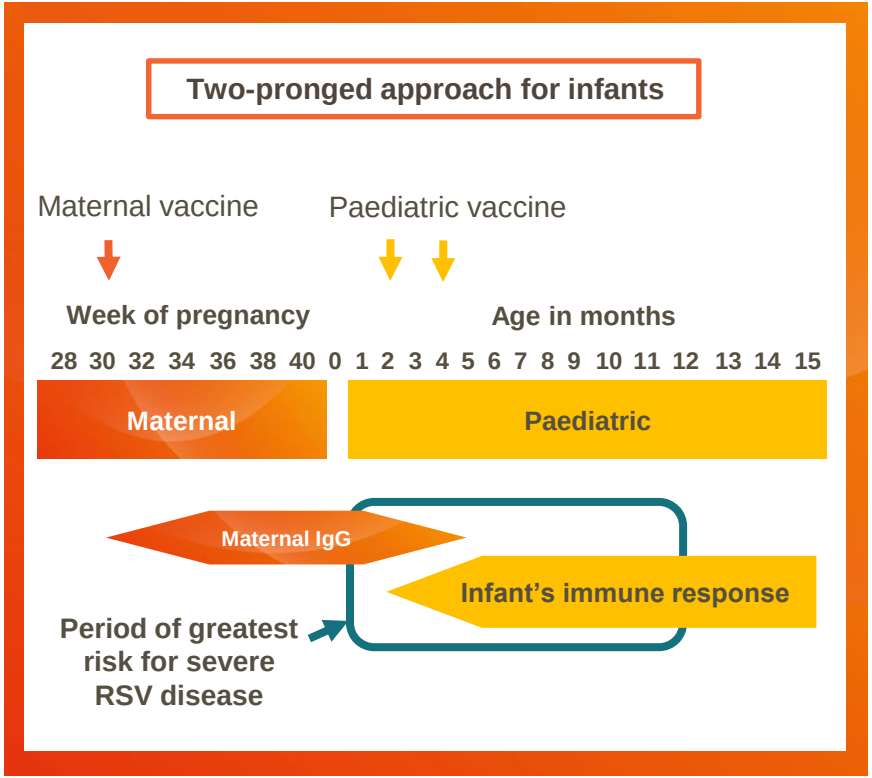
Period of most severe RSV cases for young infants occurs from birth to 12 months



Paramore, Pharmacoeconomics 22:274-285, 2004

Period of most severe RSV cases for young infants occurs from birth to 12 months

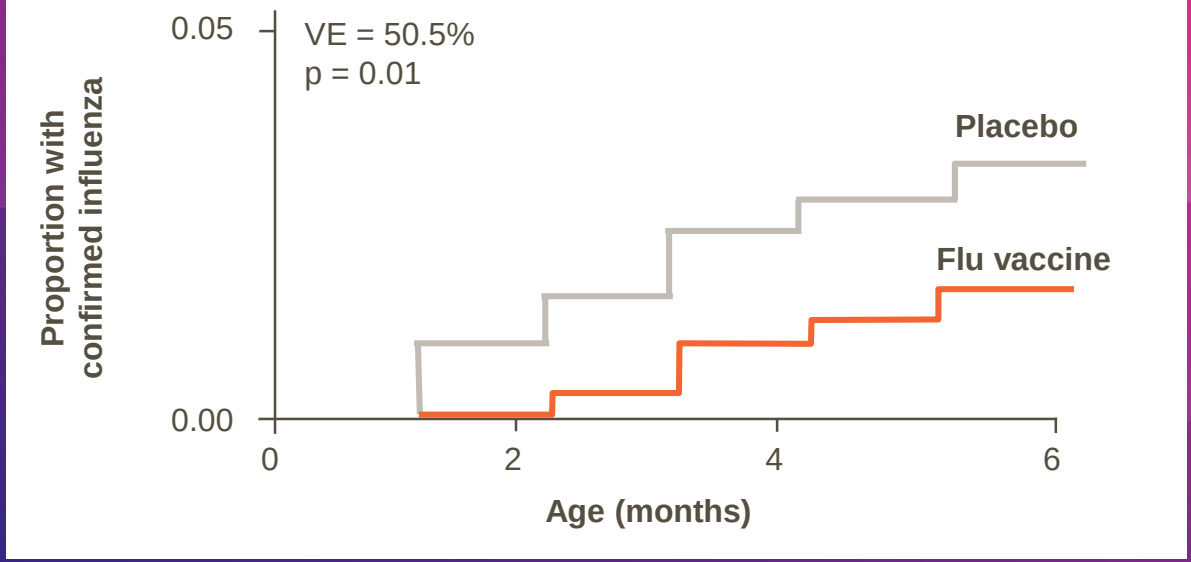




Paramore, Pharmacoeconomics 22:274-285, 2004

Maternal immunisation strategy to help prevent diseases that afflict very young infants

Infants protected by maternal flu vaccination



GSK's flu vaccines do not have approved indications for maternal immunization
VE = Vaccine efficacy
Source: N Engl J Med. 2014 Sep 4;371(10):918-31

Novel RSV candidate vaccine approaches

The inclusion of RSV F (fusion) protein in the composition of an RSV vaccine is critical

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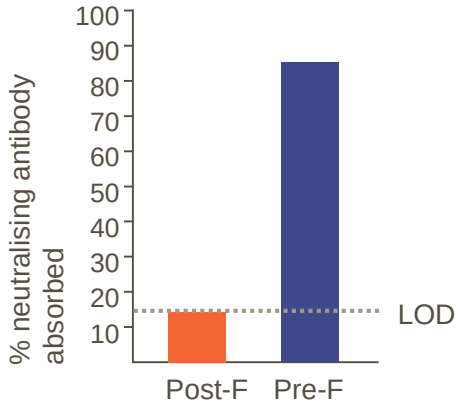


GSK preclinical data, unpublished

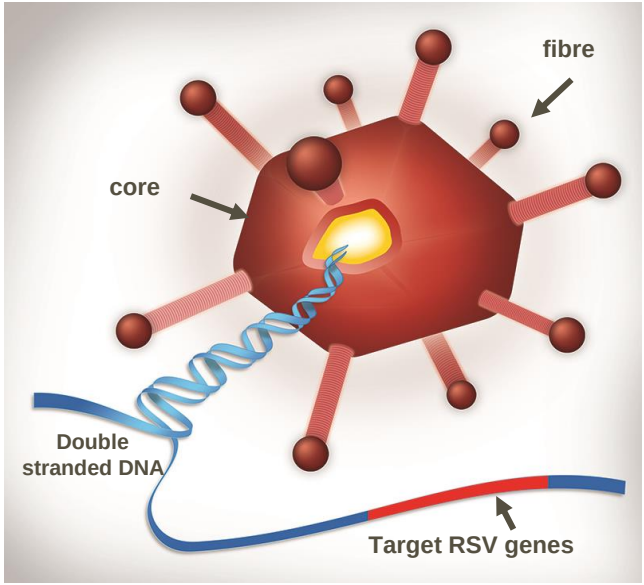
Maternal
Expect Phase III start: 2019

A different novel approach for paediatric

Genetically engineered recombinant CHAd155

Same vector used in Ebola vaccine (Okairos transaction)

Non-alum composition



Paediatric
Expect Phase III start: post 2020

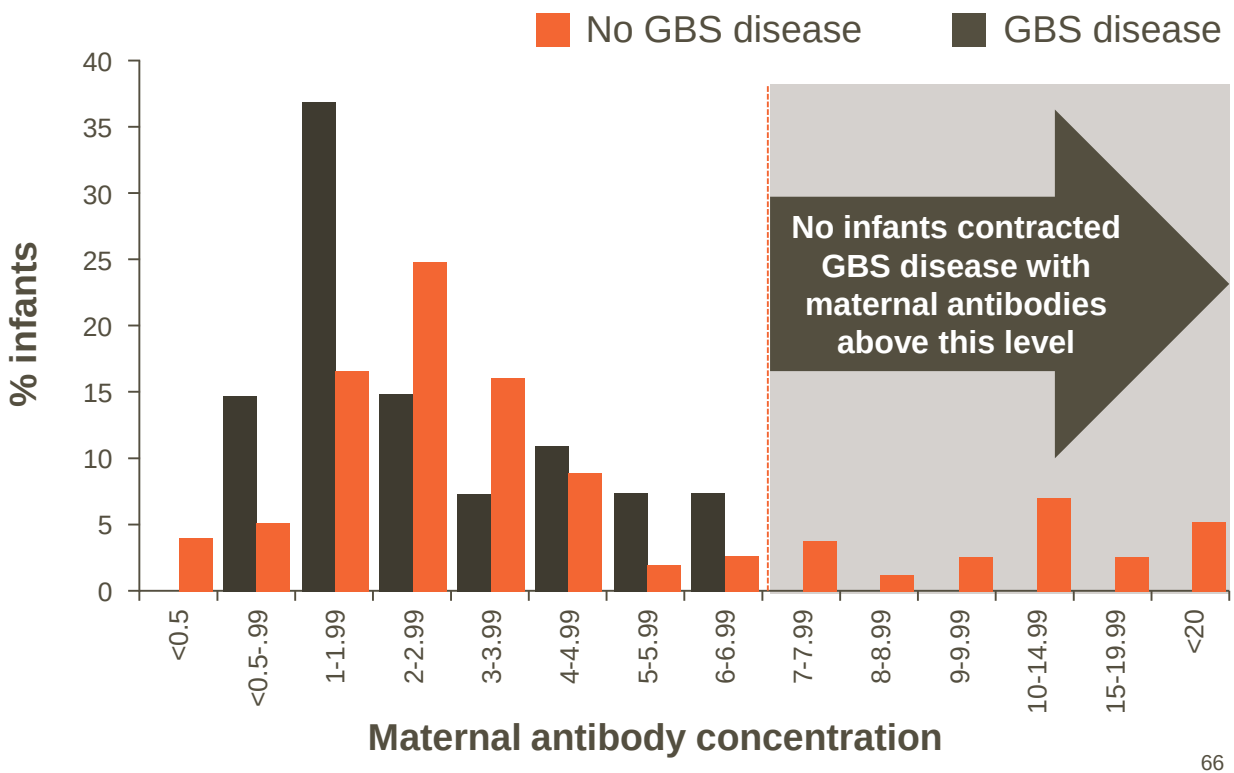
Group B Streptococcus (GBS)

Maternal immunisation for GBS

The leading cause of pneumonia, meningitis and sepsis in neonates

1 in 2,500 of babies develop GBS disease despite antibiotic prophylaxis of colonised mothers

No vaccine is available

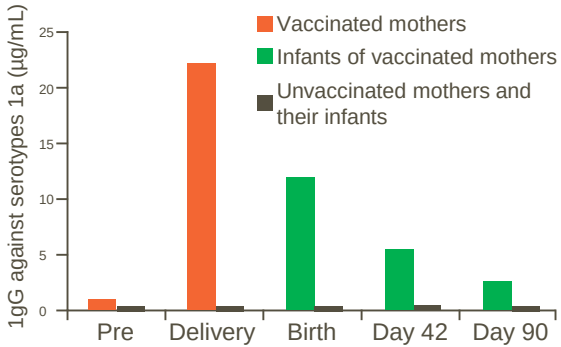


Gibbs, Obstet Gynecol, 104;1062-1075, 2004

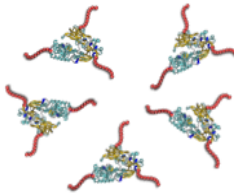
Lin FY *et al*. J Infect Dis. 2004;190:928-934

GBS maternal immunisation expanded programme

Phase II trivalent vaccine antibody data shows response at period of greatest risk



Based on capsular polysaccharide (CPS) from 5 dominant GBS serotypes conjugated to a protein carrier



5 dominant serotypes

Decision to expand composition to pentavalent, to help protect against >95% of prevalent serotypes

Development of internationally standardised assay

Validate the correlate of protection and agree clinical development plan with FDA

Expect phase I start of pentavalent ~2020

Le Doare, Vaccine 31(4) D7, 2013 ; GSK clinical data, unpublished

A new vaccine concept for COPD

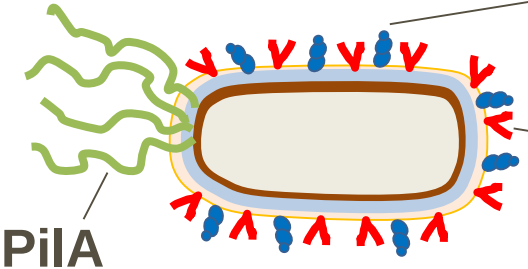
Role of microbes in acute exacerbations of COPD

Bacteria	Prevalence in acute exacerbations of COPD
Haemophilus influenzae	20-30%
Moraxella catarrhalis	10-15%
Streptococcus pneumoniae	10-15%
Pseudomonas aeruginosa	5-10% mostly in advanced disease

Adapted from Sethi S & Murphy TS N Engl J Med. 2008;359:2355-65

Testing hypothesis for a COPD vaccine

Non-typeable *Haemophilus influenzae* (NTHi)



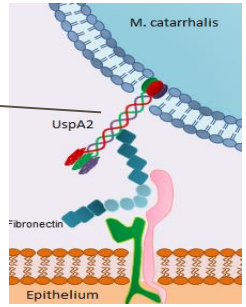
PE
serum resistance, adhesion, invasion

PD
serum resistance, adhesion

PilA
motility and biofilm formation

Moraxella catarrhalis (Mcat)

UspA2
adhesion, serum resistance

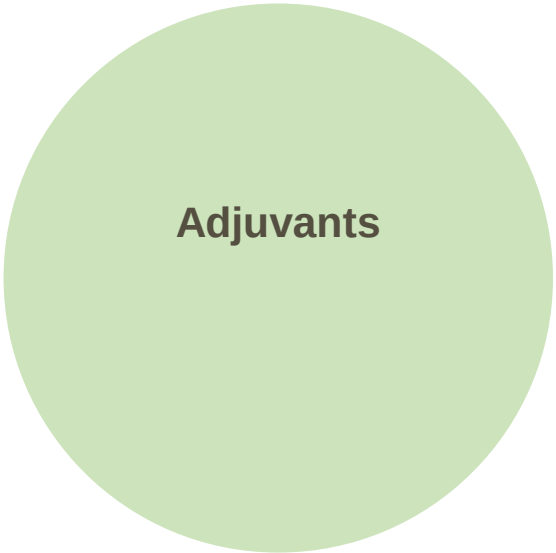


AS01

Proof of concept in humans expected to be completed by 2019

Unique expertise in platform technologies

Supports current and future pipeline



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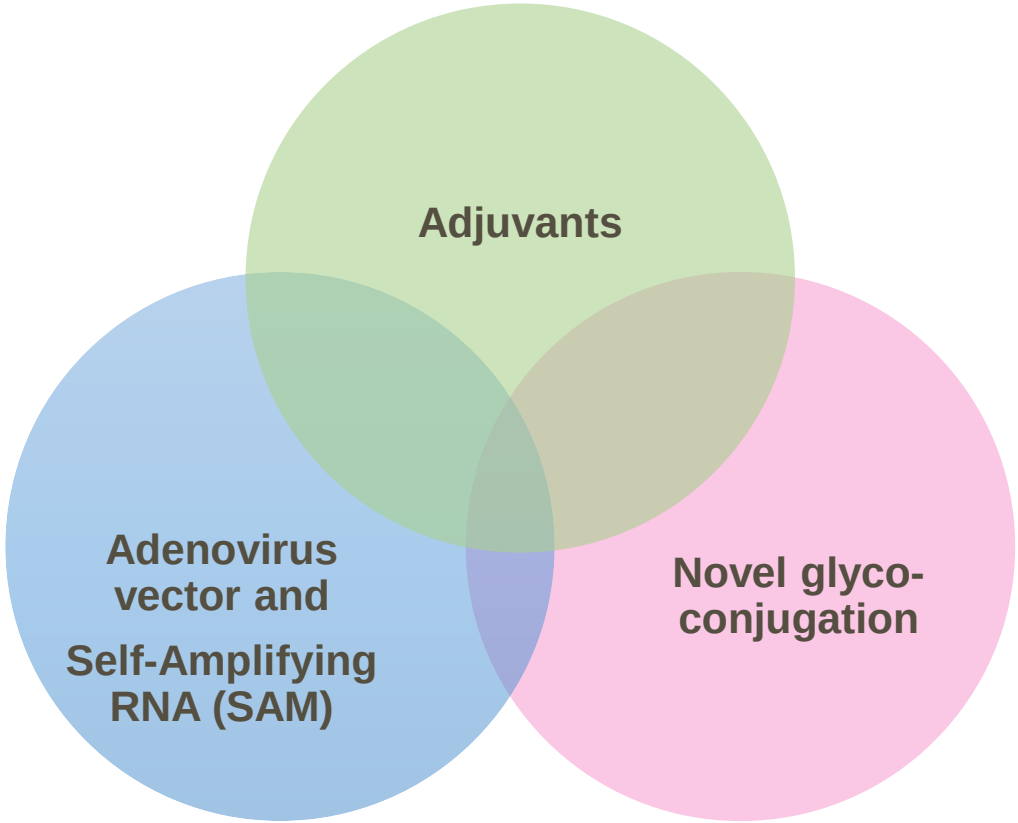


Vaccines Global Manufacturing Network

John McGrath
Head of Global Industrial Operations, GSK Vaccines

How long does it take to manufacture a single dose of vaccine?

QUIZ

Options:

A. Between 3 and 8 months

B. Between 6 and 12 months

C. Between 6 and 18 months

D. Between 10 and 26 months

How long does it take to manufacture a single dose of vaccine?

Options:

A. Between 3 and 8 months

B. Between 6 and 12 months

C. Between 6 and 18 months

D. Between 10 and 26 months

What percentage of the world's children receive at least one GSK vaccine?

Options:

A. 10%

B. 20%

C. 40%

D. 50%

What percentage of the world's children receive at least one GSK vaccine?

QUIZ

Options:

A. 10%

B. 20%

C. 40%

D. 50%

What percentage of the world's countries receive our vaccines?

Options:

A. 50%

B. 70%

C. 80%

D. 90%

What percentage of the world's countries receive our vaccines?

Options:

A. 50%

B. 70%

C. 80%

D. 90%

Our strong manufacturing network is a competitive advantage: our people, buildings & processes

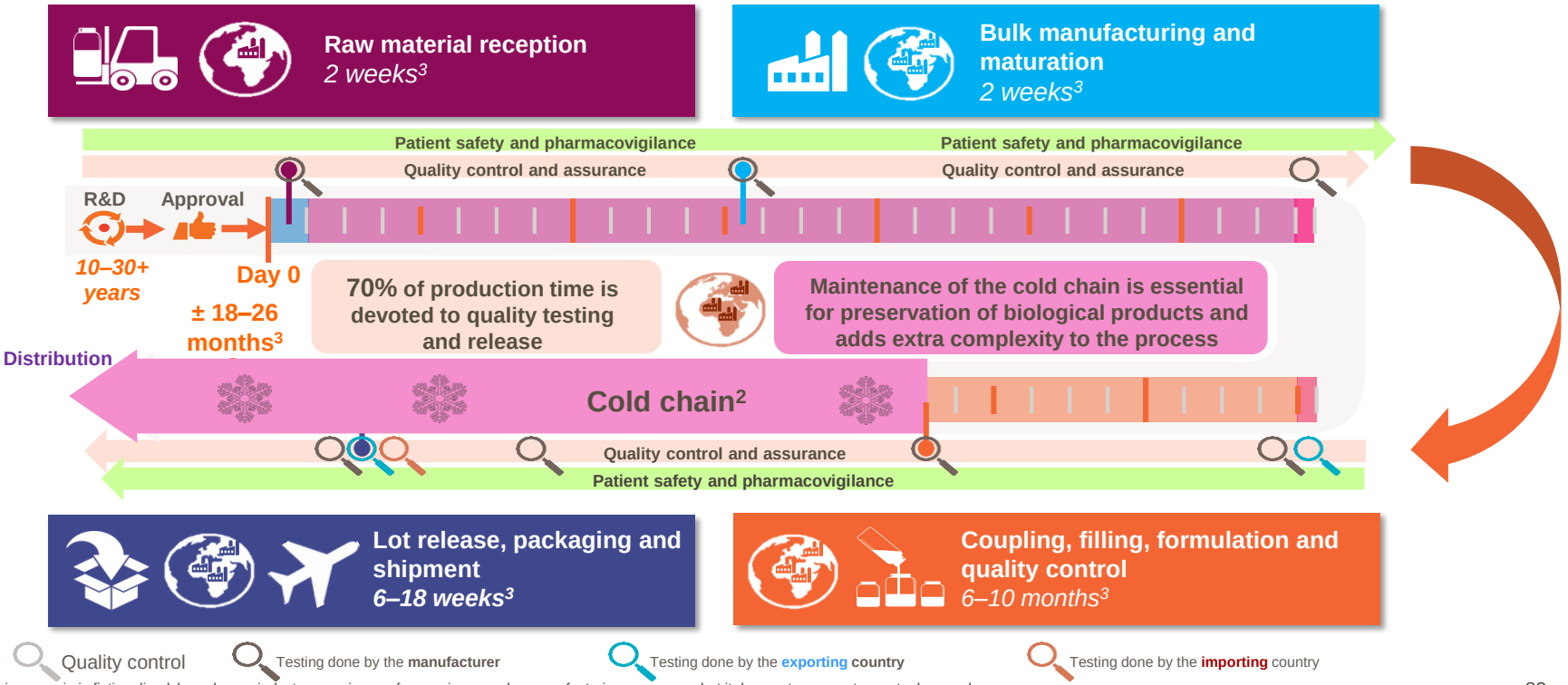
- Ability to navigate a complex regulatory environment
- Extensive capacity (~1bn doses/year) and investing to expand
- Able to respond to variability in short term demand
- Expertise in balancing supply and demand over the long term

Vaccines differ from medicines in many aspects, from composition to development and administration

	Vaccines	Non-biological drugs
Composition	Complex with **various core components**[1]	Typically a **single active chemical** component[1,5]
Trials	Large community-based trials in **healthy subjects**[2]	Typically smaller clinical trials in **patients** with a disease or conditions
Regulatory approval	**Complex** and **time consuming**[1]	Usually **less complex**
Supply	Cold chain **required**[3]	Cold chain **less common**
Time to market from production to supply	**Long** lead time[1]	Typically **shorter** lead time
Administration	Multiple injections with **extended periods between doses** (months or years)[4]	Regular intervals, often with **daily schedules**[6]

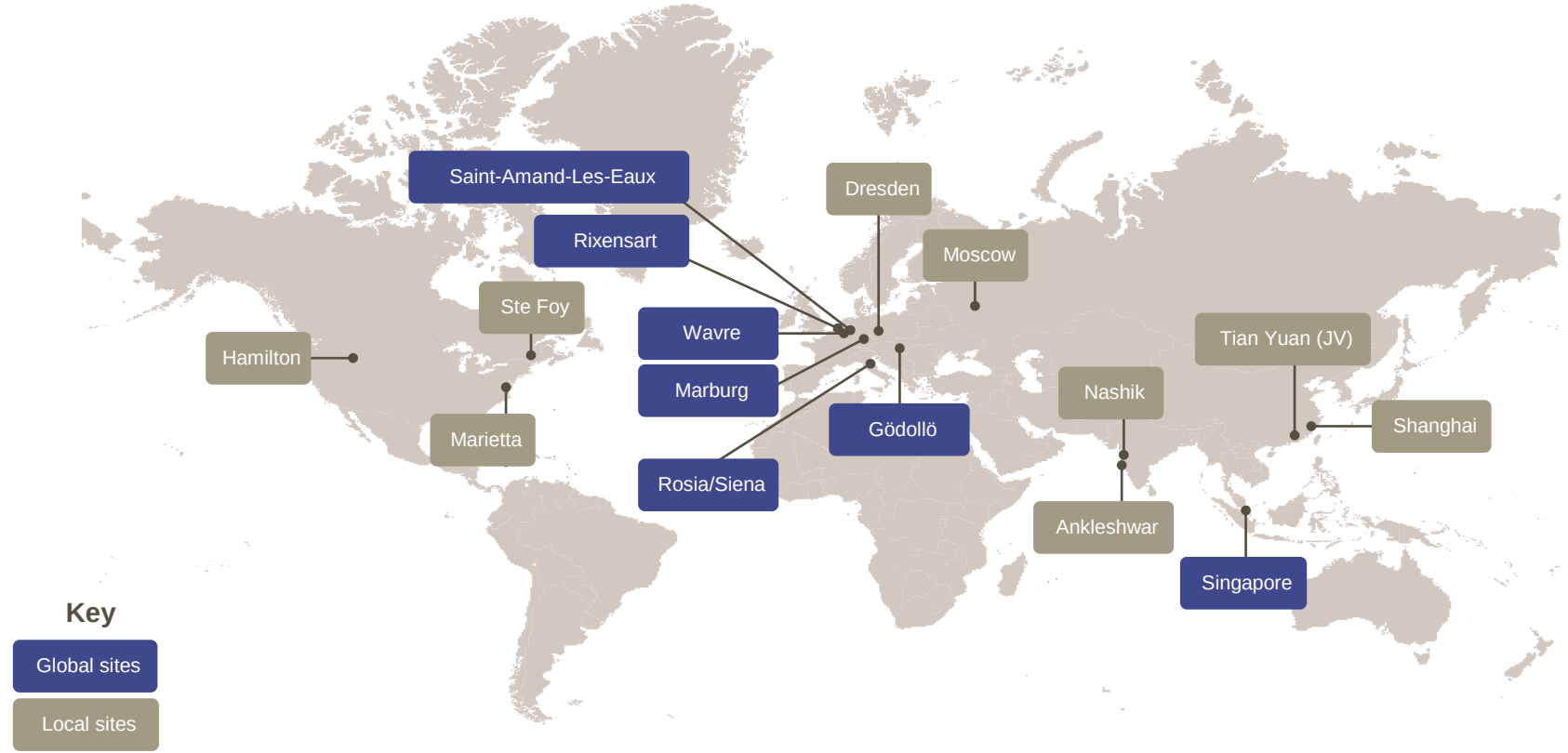
1. International Federation of Pharmaceutical Manufacturers and Associations. The complex journey of a vaccine. 2014. Available at: http://www.ifpma.org/resource-centre/the-complex-journey-of-a-vaccine-2/. Accessed May 2016; 2. World Health Organisation. Clinical evaluation of vaccines. Last updated, 26 November 2015. Available at: http://www.who.int/biologicals/vaccines/clinical_evaluation/en/. Accessed May 2016; 3. Public Health England. Immunisation against infectious disease: the green book. 2013. Available at: https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3. Accessed May 2016; 4. Centers for Disease Control and Prevention. Recommended immunization schedule for persons aged 0 through 18 years – United States, 2016. Available at: www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-schedule.pdf. Accessed May 2016; 5. Morrow T & Felcone LH. Biotechnology Healthcare 2004; 1: 24-29; 6. British Medical Association and Royal Pharmaceutical Society of Great Britain. British National Formulary. March 2009. Available at: http://www.esoph.org/af/books/BNF%2057.pdf. Accessed May 2016.

A complex manufacturing journey



Note: This scenario is fictionalised, based upon industry experience of managing complex manufacturing processes, but it does not represent an actual example.
Figure adapted from International Federation of Pharmaceutical Manufacturers and Associations. The complex journey of a vaccine. 2014. Available at: http://www.ifpma.org/resource-centre/the-complex-journey-of-a-vaccine-2/. Accessed May 2016; 2. Public Health England. Immunisation against infectious disease: the green book. 19 March 2013. Available at: https://www.gov.uk/.../uploads/.../Green_Book_Chapter_3_v3_0W.pdf. Accessed May 2016. 3. GSK, Data on file 26 April 2016. DNG#_2016N281954_00.

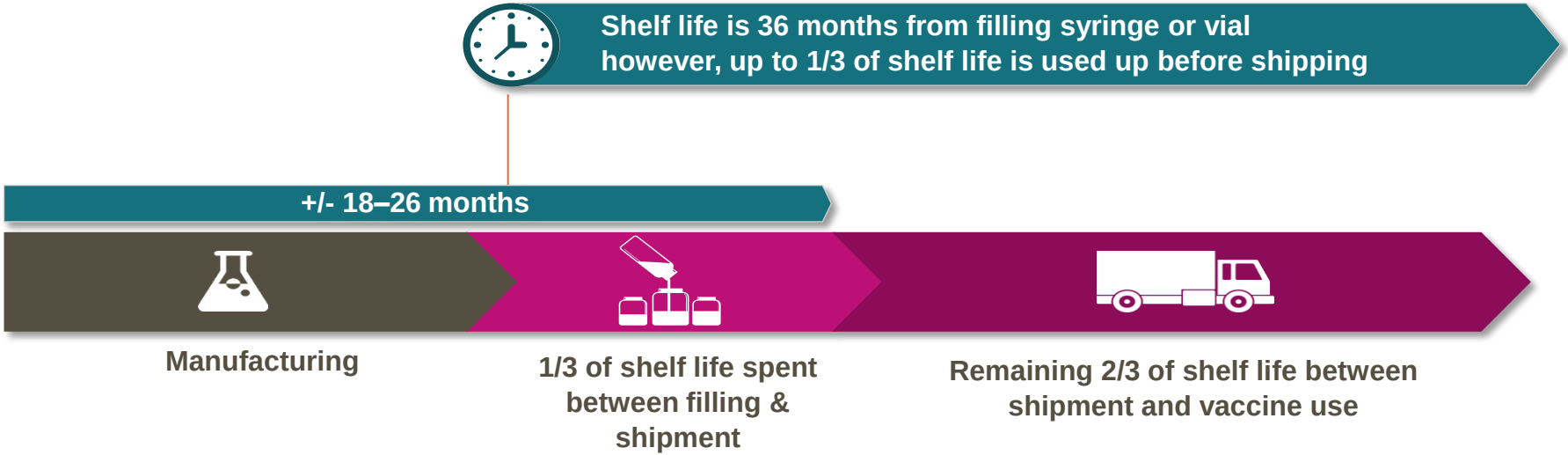
Our global manufacturing network



Shelf life management is critical

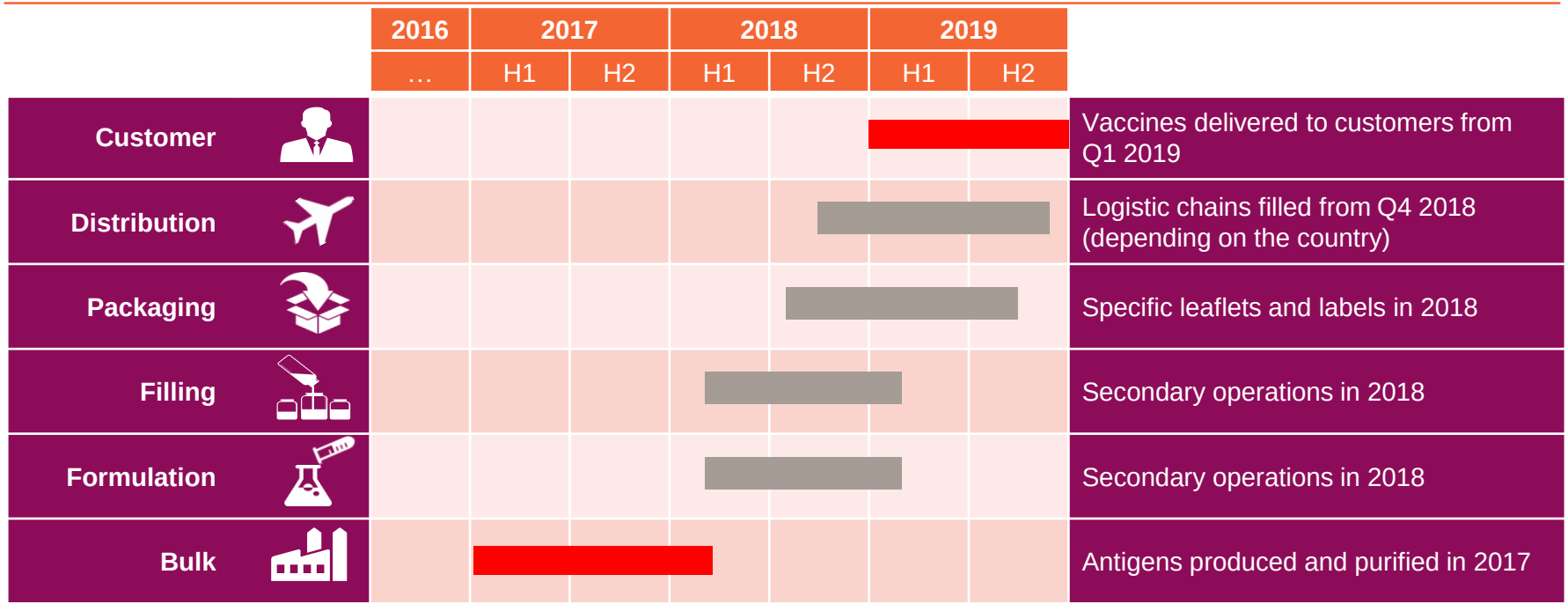
What does it mean from a supply perspective?

Example: vaccine with a 36 month shelf life



Accurate forecasting of vaccine demand is critical to optimising the shelf life available to the customer

For a vaccine available in 2019:
When would manufacturing be initiated?*



*This scenario is illustrative based upon industry experience of managing complex manufacturing processes

Manufacturing sites for vaccines are first approved and then regularly inspected by regulatory authorities

US FDA[1]

EMA Europe (one member state RA)[2]

WHO pre-qualification[3]

National Regulatory Authorities[4] (e.g. Brazil, Japan)

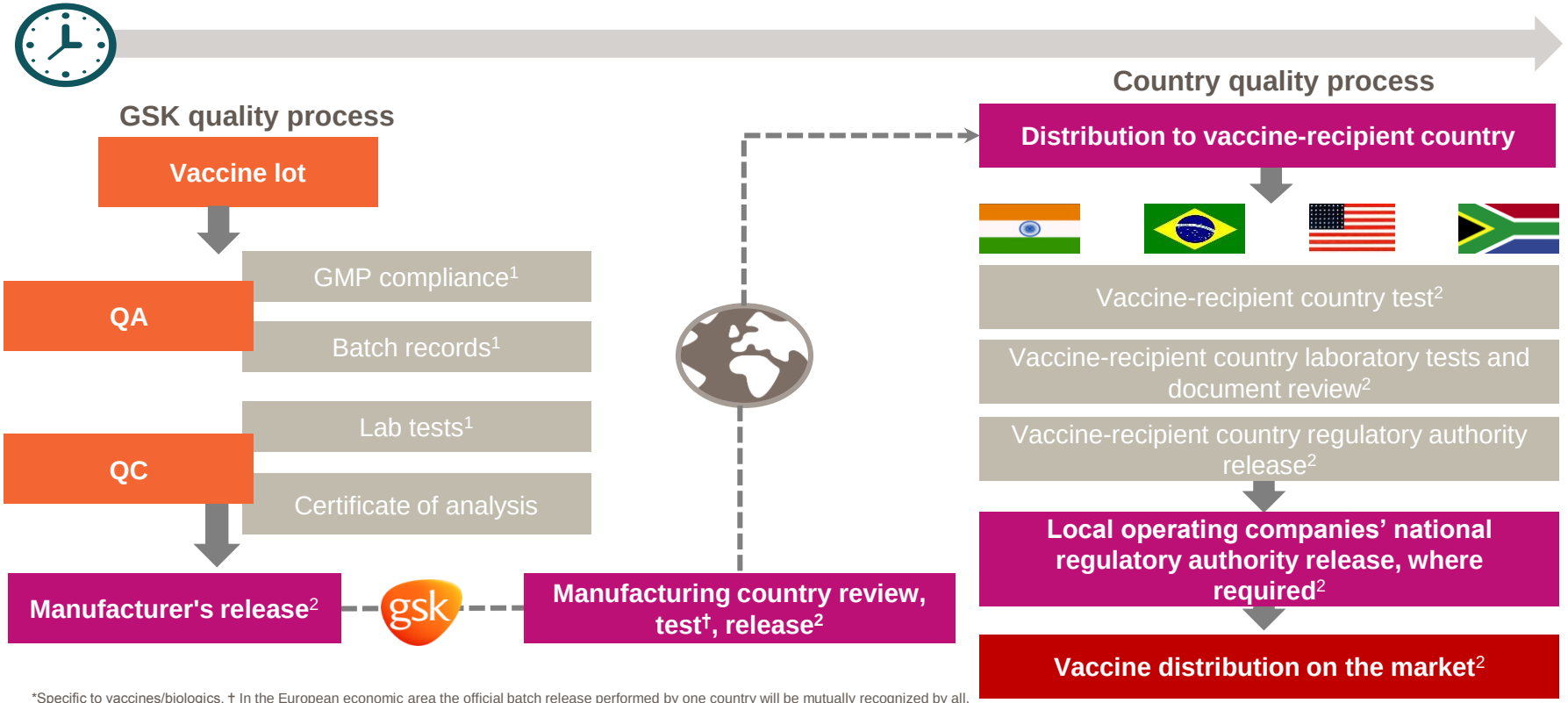
Internal audits by Quality Assurance[5]

Frequent inspections[4]

EMA, European Medicines Agency; FDA, Food and Drug Administration; RA, regulatory authority, WHO, World Health Organization.

1. US Food and Drug Administration. Inspections database. Last updated 14 January 2016. Available at :http://www.fda.gov/ICECI/Inspections/ucm222557.htm. Accessed May 2016;
2. European Medicines Agency. Co-ordination of good-manufacturing-practice inspections. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000171.jsp. Accessed May 2016. 3. World Health Organisation. A system for the prequalification of vaccines for UN supply. Last updated March 1 2016. Available at: http://www.who.int/immunization_standards/vaccine_quality/pq_system/en/. Accessed May 2016; 4. International Federation of Pharmaceutical Manufacturers and Associations. The complex journey of a vaccine. 2014. Available at: http://www.ifpma.org/resource-centre/the-complex-journey-of-a-vaccine-2/. Accessed May 2016; 5. US Food and Drug Administration. Guidance for industry, Q7A good manufacturing practice guidance for active pharmaceutical ingredients. Available at: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm200364.htm#P391_17701. Accessed May 2016.

Each vaccines batch undergoes repeated, rigorous quality testing[1,2]



*Specific to vaccines/biologics. † In the European economic area the official batch release performed by one country will be mutually recognized by all.
QC, quality control; QA, quality assurance; GMP, good manufacturing practice. 1. WHO GMP for biological products. 2015. Available at: http://www.who.int/biologicals/GMP_For_Biologicals_version_Post_ECBS.pdf?ua=1. Accessed June 2016. 2. International Federation of Pharmaceutical Manufacturers and Associations. The complex journey of a vaccine. 2014. Available at: http://www.ifpma.org/resource-centre/the-complex-journey-of-a-vaccine-2/. Accessed May 2016.

We are investing in capacity expansion

Proactive upgrading of supply network

Designed to meet and exceed regulatory requirements: quality and current GMP

Ensure sustainability for the long term

Tackling recent supply constraints impacting HepA and Pa containing vaccines

Our strong manufacturing network is a competitive advantage: our people, buildings & processes

- Ability to navigate a complex regulatory environment
- Extensive capacity (~1bn doses/year) and investing to expand
- Able to respond to variability in short term demand
- Expertise in balancing supply and demand over the long term

"Vaccines is a business where experience really counts"

Question & Answer session