

# Dr Moncef Slaoui

## Vaccines business overview

6 May 2015

# The value of vaccination



Widely recognised as one of the very best investments in healthcare

**Tremendous progress for global health...**

**~3m**  
deaths  
prevented  
annually

**Target populations are growing...**

**~1bn**  
60+ year olds  
by 2020  
(+20%)

**...but still underserved populations**

**~22m**  
infants still  
missing basic  
vaccines

**...and major diseases remain without vaccines**

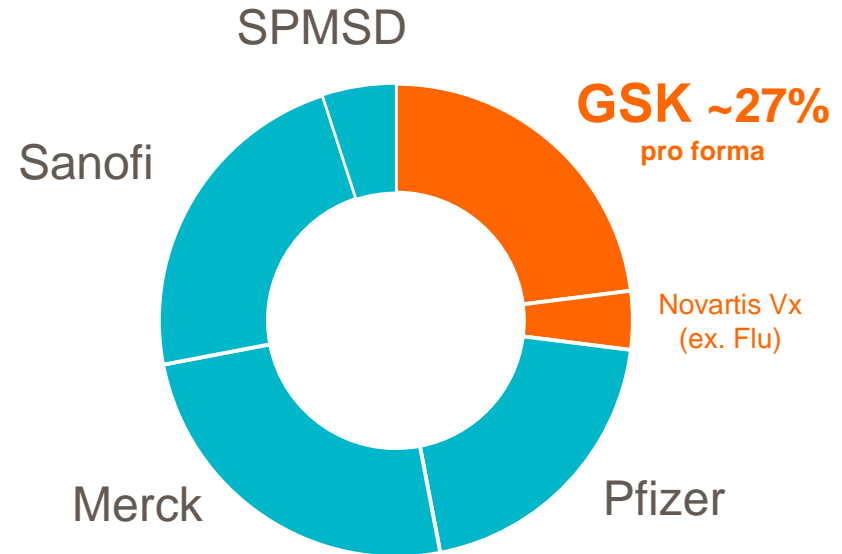
RSV  
Group B Strep  
TB  
HIV  
& more...

# Vaccines is an attractive business



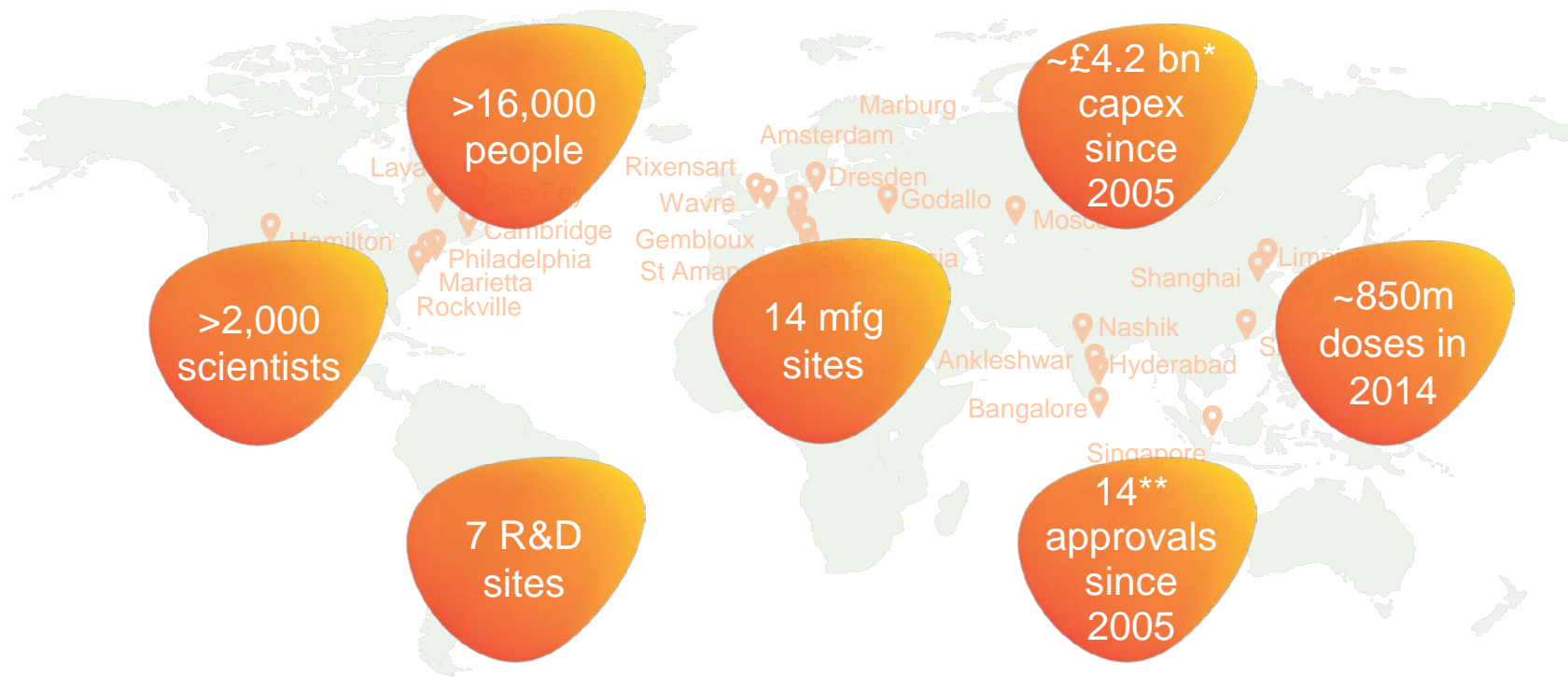
- Growing market: ~£17bn in 2014<sup>1</sup>
- Few global players
- Large capital investment
- Complex manufacturing
- Importance of combinations/lifecycle management
- Intellectual property
- Very long product lifecycles
- Pharma like operating margins

## #1 global company 2014 sales



<sup>1</sup> Market data from Evaluate Pharma, GSK internal estimates.

# GSK Vaccines: a snapshot



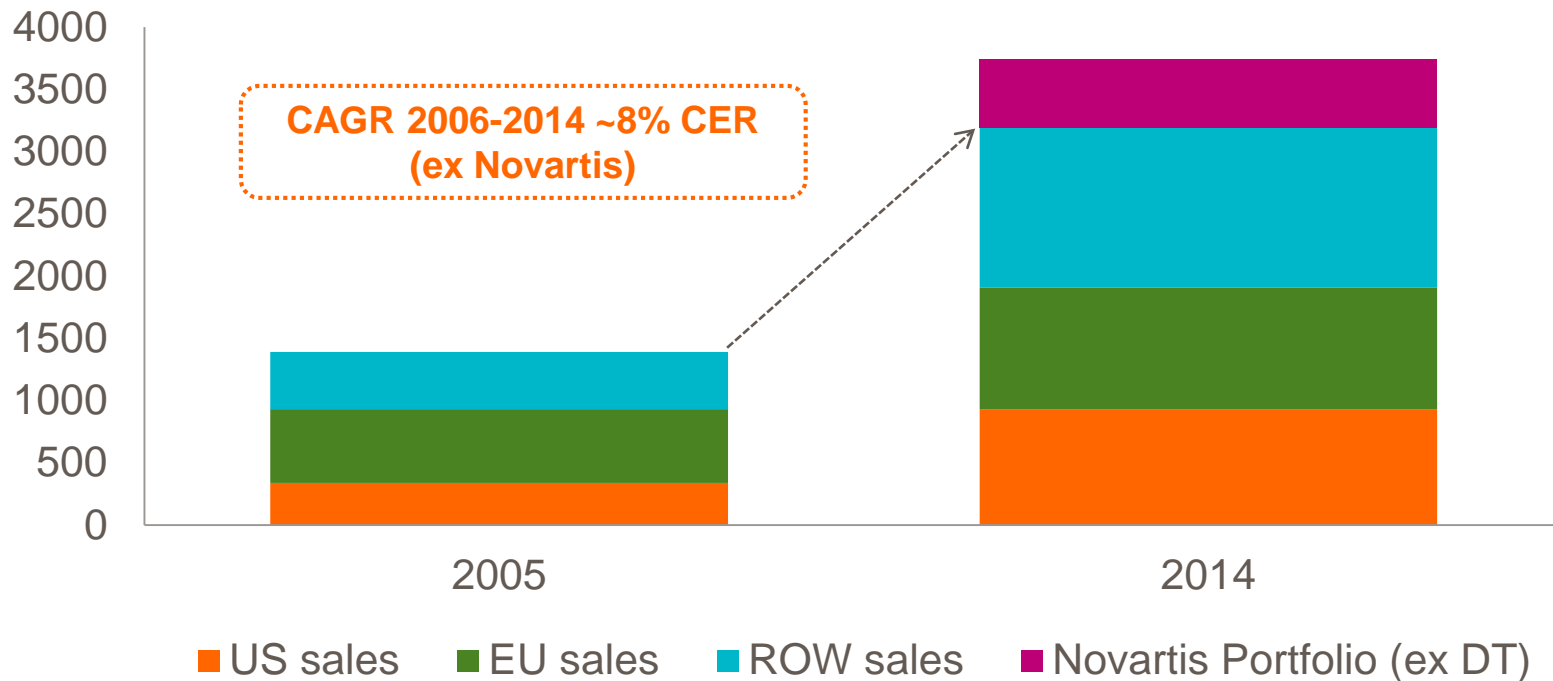
\* CapEx excludes Novartis investments. All other data represents pro forma business.

\*\*Includes major market approvals: Arepandrix, Bexsero, Cervarix, Fendrix, Fluarix / FluLaval (QIV), Ixiaro, Menhibrix, Menitorix, Menveo, Pandemrix, Prepandrix, Priorix Tetra, Rotarix, Synflorix. Excludes Nimenrix (to be divested).

# Strong track record of growth



Supply constraints impacted 2014 growth (-1% CER)



# Broadest vaccines portfolio offering worldwide (pre-transaction)






## Key immunisation segments



<b><u>Pediatric</u></b>				
Diphtheria, tetanus, & acellular Pertussis (DTaP)	✓	✓		
DTaP hexa	✓	✓	✓	
Inactivated Polio (IPV)	✓	✓		
Haemophilus influenzae type b (Hib)	✓	✓	✓	
Meningitis ACWY	✓	✓		
Meningitis B				
Pneumococcal	✓			✓
Measles, Mumps, Rubella (MMR) and Varicella	✓		✓	
Rotavirus	✓	P	✓	
Hepatitis A and B	✓	✓	✓	
Influenza	✓	✓		
<b><u>Adolescent</u></b>				
Human papillomavirus (HPV)	✓	✓	✓	
Tdap booster	✓	✓		
Meningitis ACWY	✓	✓		
Meningitis B				✓
Hepatitis A and B	✓	✓	✓	
Influenza	✓	✓		
<b><u>Adults/Travellers</u></b>				
Tdap booster	✓	✓		
YF		✓		
JE		✓		
TBE		✓		
Rabies		✓		
Typh	✓			✓
Hepatitis A and B	✓	✓	✓	
Influenza	✓	✓		
<b><u>Elderly</u></b>				
Zoster	P		✓	
Pneumococcal			✓	✓
Influenza	✓	✓		

P – Project in late stage pipeline

# Broadest vaccines portfolio offering worldwide (pre-transaction)

Key immunisation segments	 US				
<b><u>Pediatric</u></b>					
Diphtheria, tetanus, & acellular Pertussis (DTaP)	✓	✓	✓		
DTaP hexa		✓	✓	✓	
Inactivated Polio (IPV)	✓	✓	✓		
Haemophilus influenzae type b (Hib)	✓	✓	✓	✓	
Meningitis ACWY		✓	✓		
Meningitis B					
Pneumococcal		✓			✓
Measles, Mumps, Rubella (MMR) and Varicella	P	✓		✓	
Rotavirus	✓	✓	P	✓	
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Typh	✓	✓			✓
Hepatitis A and B	✓	✓	✓	✓	
Influenza	✓	✓	✓		
<b><u>Elderly</u></b>					
Zoster	P	P		✓	
Pneumococcal				✓	
Influenza	✓	✓	✓		✓

P – Project in late stage pipeline

## Keys to success

Supply

Recommendations

Portfolio breadth by segment

Geographic footprint

Price/Volume

R&D productivity and clinical trials infrastructure



## GSK well-positioned

World class, some volume constraints

>90% of portfolio with US/EU universal recommendations

Strong ex-US, improving in US

177 countries, global Rx benefits

Best in class mix

Over 1 million subjects in clinical trials since 2000



# Our strategic focus

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Reliable  
sustainable  
supply

Focus on  
US approvals  
and success

Bolster  
innovation  
pipeline

Build  
broader  
talent pool

Flawless  
execution

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Novartis transaction accelerates strategy

# Strong portfolio synergy post-transaction

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Zoster	P	P		✓	
Pneumococcal				✓	
Influenza	✓	✓	✓		✓

P – Project in late stage pipeline.

## Novartis integration – well underway

Commercial operations in countries almost complete

R&D: accelerated and portfolio review completed

Manufacturing: ongoing above site, no disruption within sites

Delivery of cost synergies: ~£400m by 2017

# Vaccines global R&D centre in US

Rockville, Maryland



## Proactive upgrading of supply network

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

Ensure sustainability for the long term

Some supply constraints impacting HepA and Pa containing vaccines: 2014-2016



State-of-the-art pertussis mfg site

# Key growth drivers

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**Key near term drivers 2015-2016**  
Meningitis franchise, Flu QIV, Synflorix, Rotarix



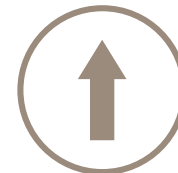
## New products 2017-2018

Expected launches: Shingrix (HZ/su), malaria, MMR US  
Late stage development: Group B Strep, RSV, MenABCWY



## Key near term drivers 2015-2016

Meningitis franchise, Flu QIV, Synflorix, Rotarix





# Shingrix HZ(su): Significant opportunity to prevent herpes zoster



- Risk of shingles doubles every decade over age 50
- Non-live, recombinant, 2-dose, adjuvanted vaccine
- Excellent efficacy across all age groups, ~97%
- Acceptable safety and tolerability
- Ongoing trials in 70+ and immuno-compromised
- Expect US, EU, Japan filings in 2016
- Low global penetration of current marketed vaccine

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

## 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 Chilbek, M.D., Ph.D., Javier Diez-Domingo, M.D., Ph.D., Shin-jang Hwang, M.D., Myron J. Levin, M.D., Janet E. McElhane, M.D., Airi Pöder, 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\*

ABSTRACT

### BACKGROUND

In previous phase 1–2 clinical trials involving older adults, a subunit vaccine containing varicella-zoster virus glycoprotein E and the AS01<sub>1</sub> adjuvant system (called HZ(su)) had a clinically acceptable safety profile and elicited a robust immune response.

### METHODS

We conducted a randomized, placebo-controlled, phase 3 study in 18 countries to evaluate the efficacy and safety of HZ(su) in older adults (≥50 years of age), stratified according to age group (50 to 59, 60 to 69, and ≥70 years). Participants received two intramuscular doses of the vaccine or placebo 2 months apart. The primary objective was to assess the efficacy of the vaccine, as compared with placebo, in reducing the risk of herpes zoster in older adults.

### RESULTS

A total of 15,411 participants who could be evaluated received either the vaccine (7698 participants) or placebo (7713 participants). During a mean follow-up of 3.2 years, herpes zoster was confirmed in 6 participants in the vaccine group and in 210 participants in the placebo group (incidence rate, 0.3 vs. 9.1 per 1000 person-years) in the modified vaccinated cohort. Overall vaccine efficacy against herpes zoster was 97.2% (95% confidence interval [CI], 93.7 to 99.0;  $P < 0.001$ ). Vaccine efficacy was between 96.6% and 97.9% for all age groups. Solicited reports of injection-site and systemic reactions within 7 days after vaccination were more frequent in the vaccine group. There were solicited or unsolicited reports of grade 3 symptoms in 17.0% of vaccine recipients and 3.2% of placebo recipients. The proportions of participants who had serious adverse events or potential immune-mediated diseases or who died were similar in the two groups.

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Heineman at Global Clinical Research and Development, GSK Vaccines, 2301 Renaissance Blvd., King of Prussia, PA 19406, or at thomas.c.heineman@gsk.com.

Drs. Chilbek, Diez-Domingo, Hwang, Levin, McElhane, Pöder, Puig-Barberà, Vesikari, Watanabe, Weckx, and Zahaf contributed equally to this article.

\*A complete list of investigators in the Zoster Efficacy Study in Adults 50 Years of Age or Older (ZOE-50) is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on April 28, 2015, at NEJM.org.

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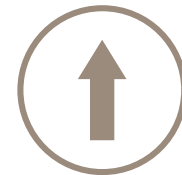
**New segments 2019-2020 and beyond**  
Pregnant women



**New products 2017-2018**  
Expected launches: Shingrix (HZ/su), malaria, MMR US  
Late stage development: Group B Strep, RSV, MenABCWY



**Key near term drivers 2015-2016**  
Meningitis franchise, Flu QIV, Synflorix, Rotarix



# Key growth drivers



\* Expected CAGR to 2020, using 2015 as the base year. All expectations and targets regarding future performance should be read together with the "2015-2020 Outlook" and "Assumptions and cautionary statement regarding forward-looking statements" sections of the Q1 Results Announcements dated 6 May 2015. All sales growth rates at CER.

# Margin improvements



GSK Vx (35.4%) + NVS loss making  
~22% OPM 2014 pro forma

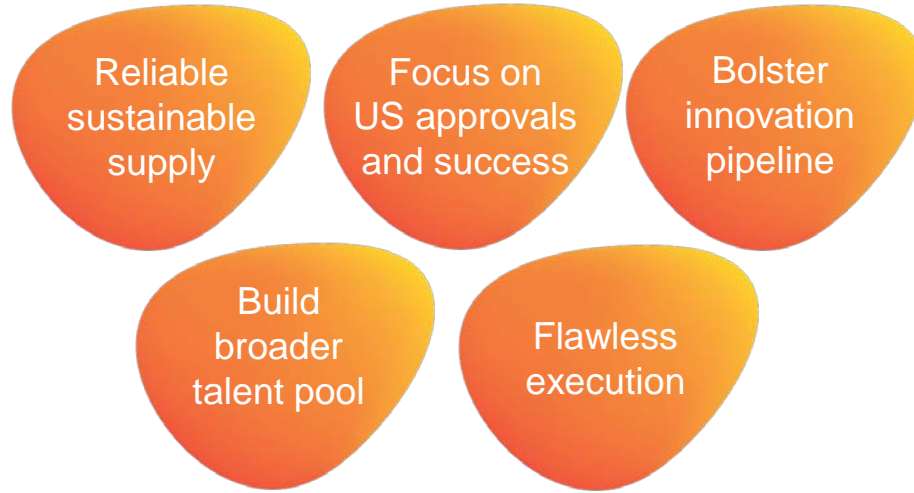
Improved leverage from sales growth  
(CoGS, SG&A and disciplined R&D investments)

Transaction cost savings ~£400m by 2017

Maintain CapEx investments

Overall vaccines margin 30%+ by 2020

# Positioned to be global leader for a very long time



Novartis transaction accelerates strategy



Strong prospects for revenue and profit growth

# Cautionary statement regarding forward-looking statements

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This presentation may contain 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 Disclosure and Transparency Rules of the Financial Conduct Authority), 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.

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 2014 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 November 24, 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 Directors on the date of this report.

A number of adjusted measures are used to report the performance of our business. These measures are defined in our Q1 2015 earnings release and annual report on Form 20-F.

# Unaudited pro forma financial information



The unaudited pro forma financial information in this presentation has been prepared to illustrate the effect of (i) the disposal of the oncology assets, (ii) the Consumer Healthcare joint venture (i.e. the acquisition of the Novartis OTC Business), and (iii) the acquisition of the Vaccines business (which excludes the Influenza Vaccines business) on the results of the Group as if they had taken place as at January 1, 2014.

The unaudited pro forma financial information has been prepared for illustrative purposes only and, by its nature, addresses a hypothetical situation and, therefore, does not represent the Group's actual financial position or results. The unaudited pro forma financial does not purport to represent what the Group's financial position actually would have been if the disposal of the Oncology assets, the Consumer Healthcare joint venture and the Vaccines acquisition had been completed on the dates indicated; nor does it purport to represent the financial condition at any future date.

In addition to the matters noted above, the unaudited pro forma financial information does not reflect the effect of anticipated synergies and efficiencies associated with the Oncology disposal, the Consumer Healthcare joint venture and the Vaccines acquisition.

The unaudited pro forma financial information does not constitute financial statements within the meaning of Section 434 of the Companies Act 2006. The unaudited pro forma financial information in this presentation should be read in conjunction with the financial statements included in (i) the Group's Q1 2015 earnings report dated May 6, 2015 and furnished to the SEC on Form 6-K, (ii) the Group's Annual Report on Form 20-F for 2014 and (iii) the Circular to Shareholders and Notice of General Meeting furnished to the SEC on Form 6-K on November 24, 2014.