\*\*\*\*New release Jan 2012\*\*\*

# MarketVIEW: universal pneumo vaccines (CAT: VAMV030)

Product Name	:	MarketVIEW: universal pneumo vaccines
Description	:	Global vaccine commercial opportunity assessment
Contents	:	Executive presentation + 2 forecast models
Therapeutic Area	:	Novel pediatric vaccines
Publication date	:	January 2012
Catalogue No	:	VAMV030

# Background

Vaccines to prevent serious infections caused by *Streptococcus pneumoniae* or "pneumo" currently form the largest component of the global vaccine market (\$4 – 5bn/yr). Notable examples are Prevnar/Prevenar (PCV7) first marketed to cover the seven most common US serotypes causing infant invasive *pneumococcal* disease (IPD) and now recently extended to a new 13-valent form (PCV13). Pfizer vaccines (formerly Wyeth) are also expanding PCV13 indications into older age groups especially those with underlying co-morbidities who are currently vaccinated with 23-valent Pneumovax (PPSV). Pneumococcal vaccines are being rolled out to GAVI-funded markets in developing countries where the burden of pneumo related diseases is more extreme.

The ultimate Pneumo vaccine would be able to prevent disease covered by the majority of ~90 serotypes, cheap to produce and therefore available on a global scale. Investigators in both the commercial and academic/not-for-profit sector are investigating these "universal" protein-based vaccines (PUPV) which could eventually replace conjugated forms although many development challenges remain.

This **MarketVIEW** product is a comprehensive opportunity assessment focused on understanding the commercial potential of new "universal" protein-based vaccines should they be licensed. As well as an Executive presentation, the product contains two detailed value/volume forecast models at the country level which detail all the latest dynamics between product forms and all target groups being in mind evolution in US/EU/ROW policy recommendations. The possible entry of new PUPV(s) is then modelled and current development issues/approaches discussed.

Bringing life to vaccine strategy...

## www.vacZine-analytics.com

# **Methodology**

VacZine Analytics has closely monitored all significant source material pertaining to pneumococcal disease epidemiology/vaccines. Example, secondary source materials used are literature articles, government websites/databases, medical bodies and associations, conference proceedings and previously analyses (where publically available). Previously published research by VacZine Analytics in field of pediatric vaccines has also been utilised. \*\*\*See Bibliography for exact sources.

### PRODUCT CONTENTS: Published January 2012 (CAT No: VAMV030)

\*\*\*\*This product is composed of two models and an Executive presentation

### Contents - Executive presentation (MS PowerPoint based)

Author's note **Executive Summary** Pneumo vaccines: key model model outputs All pneumo vaccines: available market (\$000s) to 2030 All pneumo vaccines: estimated volume ('000s doses) to 2030 Pneumo vaccines by type: available market (\$000s) to 2030 Pneumo vaccines by type: available infant market (\$000s) to 2030 Pneumo vaccines by type: all adult market (HI) (\$000s) to 2030 Pneumo vaccines: adult market 65yrs+ (HI) (\$000s) to 2030 Pneumo vaccines: adult market 18-64yrs (HI) (\$000s) to 2030 Pneumo vaccines by type: all adult market (LO) (\$000s) to 2030 Pneumo vaccines: adult market 65yrs+ (LO) (\$000s) to 2030 Pneumo vaccines: adult market 18-64 yrs (LO) (\$000s) to 2030 Pneumo vaccines: available market (\$000s) to 2030 by vaccine type Pneumo vaccines: key model assumptions Markets covered to 2030 Populations modelled: per age segment Key model assumptions: product entry and switching Pricing assumptions applied overall Pricing assumptions applied per country Pricing: reimbursement, private/private split Adult Pneumo indications and vaccination policies Adult Pneumo indications: definition of risk segments Adult Pneumo indications: risk groups % of 18-64 yrs cohort Adult Pneumo indications and vaccination policies: per country PCV13: adult roll-out assumptions PUPV: roll-out overall rationale PUPV: roll-out assumptions per country Company reported sales analysis Pneumo vaccines: company reported sales analysis Company reported sales analysis by vaccine type Company reported sales analysis by region (cont...) Epidemiology of pneumococcal disease Bacterial meningitis per age group (child)/pathogen US 2003-2007\*

# Bringing life to vaccine strategy...

# www.vacZine-analytics.com

Sringing life to vaccine strategy...

#### CONTINUED.....

Bacterial meningitis per age group (adult)/pathogen US 2003-2007 Epidemiology of pneumococcal disease: post vaccine era Epidemiology of pneumococcal disease: impact of PCV in US Epidemiology of pneumococcal disease: non PCV7 serotypes (UK) Epidemiology of pneumococcal disease: non PCV13 serotypes (UK) Epidemiology of pneumococcal disease: mortality per serotype Vaccine coverage rates: infants Vaccine coverage rates: adults New Pneumo vaccines: brief overview of current R&D Concept of a protein based pneumo vaccine PUPV: ideal product profile GSK2189242A: recombinant-conjugated vaccine GSK2189242A: Gambia trial Sanofi Pasteur: multi-protein based PUPV Sanofi Pasteur: PUPV Bangladesh trial Current commercial pneumo vaccine pipeline (clinical) Novel pneumo protein antigens PATH - new pneumococcal vaccine development PATH - pneumo vaccine project: overview of collaborators Bibliography Disclaimer About VacZine Analytics

#### PAGES: ~70 MS PowerPoint slides, fully referenced/sourced. Available in .pdf form

### Contents - Vaccine demand model(s) (MS Excel-based)

#### \*\*\*NOTE\*\*\* - there are 2 models (LO & Hi scenarios) each with ~ 90 individual sheets

Title sheet Important notes Charts - Val Charts - Vol **GRAND VALUE SUMMARY** PCV Vol/Val PPSV Vol/Val PUPV Vol/Val 0 – 2 yrs per country US infant Canada infant UK infant Germany infant France infant Italy infant Spain infant Belgium infant Netherlands infant Greece infant Portugal infant Poland infant Other Europe infant Australia infant Japan infant South Korea infant

# Bringing life to vaccine strategy...

## www.vacZine-analytics.com



#### CONTINUED.....

Other high income infant Brazil infant Mexico infant Turkey infant Other UMI infant Other UMI infant (upside) GAVI active infant GAVI planned infant 18 – 49 yrs per country US "at risk" Canada "at risk" UK "at risk" Germany "at risk" France "at risk" Italy "at risk" Spain "at risk" Belgium "at risk" Netherlands "at risk" Greece "at risk" Portugal "at risk" Poland "at risk" Other Europe "at risk" Australia "at risk" Japan "at risk" South Korea "at risk" Other HI income 18-64 yrs "at risk" 65+ yrs per country US >65 yrs Canada >65 yrs UK >65 yrs Germany >65 yrs France >65 yrs Italy >65 yrs Spain >65 yrs Belgium >65 yrs Netherlands >65 yrs Greece >65 yrs Portugal >65 yrs Poland >65 yrs Other Europe >65 yrs Australia >65 yrs Japan >65 yrs South Korea >65 yrs Other HI income >65 yrs Populations => Births 18-64 yrs 65 yrs only 65 yrs + Sources => PPSV price summary PCV and PUPV price summary Pub Priv split At risk groups Pipeline Company reported sales

## Bringing life to vaccine strategy...

### www.vacZine-analytics.com



### **PRODUCT COST:**

VacZine Analytics will grant a [enter region] license to [enter client name], for the price of:

o USD \$9995.00/ GBP £6665.00<sup>#</sup> (Region license)\*

\*A region is North America, Europe or ROW For orders in the UK, VAT at 20% will be added to final invoice total *# indicative only rate will be applied on date of transaction* 

### HOW TO ORDER:

To order please contact your region account manager or order direct at <u>orders@vaczine-analytics.com</u> This report can also be purchased on-line. Please review the **TERMS and CONDITIONS** of purchase.



VacZine Analytics (R) is a trading division of Assay Advantage Ltd, UK Company Number: 5807728 VacZine Analytics (R) and the "spiral logo" are UK Registered Trademarks, 2009

Bringing life to vaccine strategy...

### www.vacZine-analytics.com

### **BIBLIOGRAPHY:**

- 1. WHO. Immunization surveillance, assessment and monitoring. Available at: <u>http://www.who.int/immunization\_monitoring/data/en/</u>. Accessed: December 2011
- 2. Fedson DS et al. Pneumococcal polysaccharide vaccination for adults: new perspectives for Europe. Expert Review of Vaccines, August 2011, Vol. 10, No. 8, Pages 1143-1167.
- 3. MMWR. Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23). September 3, 2010 / 59(34);1102-1106
- Prevnar 13 (PCV13). Vaccines and Related Biological Products Advisory Committee November 16, 2011
  Study Evaluating a 13-Valent Pneumococcal Conjugate Vaccine (13vPnC) in Adults (CAPITA). Available at:
- Study Evaluating a 13-valent Pheumococcal Conjugate Vacche (13vPhC) in Adults (C/ http://clinicaltrials.gov/ct2/show/NCT00744263. Accessed December 2011
- 6. Pilishvili, T. Pneumococcal Disease Prevention among Adults: Opportunities and Challenges. Advisory Committee on Immunization Practices June 22-23, 2011
- 7. Prevention of Pneumococcal disease Among >65 yrs and children. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR December 2010 / Vol 59/ No RR-11.
- 8. Advisory Committee on Immunization Practices (ACIP). Summary Report October 22-23, 2008. Available at: http://www.cdc.gov/vaccines/recs/acip/downloads/min-archive/min-oct08.txt. Accessed December 2011.
- 9. GlaxoSmithKline plc. Form 20-F. March 4, 2011
- 10. Pfizer Reports Fourth-quarter And Full-year 2010 Results. Available at: www.pfizer.com/files/investors/presentations/q4performance\_020111.pdf. Accessed: December 2011.
- 11. Merck & Co., Inc. FORM 10-K. February 28, 2011
- 12. David S Fedson DS et al. Pneumococcal polysaccharide vaccination for adults: new perspectives for Europe. Expert Review of Vaccines, August 2011, Vol. 10, No. 8, Pages 1143-1167.
- 13. Pilishvili, T. Pneumococcal Disease Prevention among Adults: Opportunities and Challenges. Advisory Committee on Immunization Practices June 22-23, 2011
- 14. Changing epidemiology of pneumococcal serotypes after introduction of conjugate vaccine: July 2010 report. Wkly Epidemiol. Rec. 85(43), 434–436 (2010).
- 15. Invasive Pneumococcal Disease (IPD) in England & Wales after 7 Valent Conjugate Vaccine (PCV7). Potential impact of 10 and 13 valent vaccines. 24 June 2009. Available at: www.hpa.org.uk/. Accessed: December 2011.
- 16. Cumulative weekly number of reports of Invasive Pneumococcal Disease due to any of the serotypes NOT IN Prevenar13<sup>™</sup> : Children aged < 2 Years in England and Wales by Epidemiological Year: July-June (2005-To Date). November 2011. Available at: www.hpa.org.uk/. Accessed: December 2011
- 17. Active Bacterial Core Surveillance (ABCs). Available at: http://www.cdc.gov/abcs/index.html. Accessed: December 2011.
- 18. Harboe ZB Pneumococcal serotypes and mortality following invasive pneumococcal disease: a population-based cohort study. PLoS Med. 2009 May 26;6(5):e1000081.
- 19. National Immunization Survey (NIS) Children (19-35 months), 2002-2010. Available at: http://www.cdc.gov/vaccines/stats-surv/imz-coverage.htm. Accessed: December 2011
- 20. Centers for Disease Control and Prevention (CDC). Healthy People 2010 Database. Focus area:14-Immunization and Infectious Diseases 08-03-2011. Available at: <u>http://wonder.cdc.gov</u>. Accessed: December 2011.
- 21. Need for and development of a protein-based pneumococcal vaccine. Available at: <u>www.meningitis.org/assets/x/53980</u>. Accessed: December 2011
- 22. Sanofi-Aventis. Annual Report Form 20-F 2010
- 23. Taken from presentation by Mark Alderson. Pneumococcal vaccine project. PATH. Available at: http://www.sabin.org/files/Alderson.pdf . Accessed: December 2011
- 24. Pneumococcal vaccine project. PATH. Fact Sheet. Available at: http://www.path.org/files/VAC\_pvp\_tech\_fs.pdf. Accessed: December 2011

## Bringing life to vaccine strategy...

### www.vacZine-analytics.com

### **TERMS and CONDITIONS:**

VacZine Analytics – a trading division of Assay Advantage Ltd UK Company Number: 5807728 (Herein referred to as "The Company"). (Herein [enter client name] to as "The Client").

1. This finished research product is provided is provided as a Service. Any additional Service required by the client will be subject to a new proposal being prepared.

2. The Service will commence after written (e-mail) or Fax confirmation stating the Client's acceptance of the Service according the description proposed by the Company.

**3. Cancellation policy**. The Company's cancellation policies are in accordance with the EU Consumer Protection (Distance Selling) Regulations 2000 (DSRs). Prior to acceptance of an order the Company will make available written information regarding Clients cancellation rights. This is posted on the Company website and is available for public review.

4. Cancellation rights: For finished documents - a Clients cancellation rights will last for seven working days counting from the day that the order was concluded. If the Services i.e. provision of the documents has taken place with the Clients agreement before this period the Client's cancellation rights have ended.

5. Invoicing will 100% after submission of deliverables to the Client in a form reasonably acceptable to the Client.

6. If not purchased on line invoices are payable within thirty days of the invoice date.

7. All proposals are quoted in \$USD dollars or £GBP and invoices are to be settled in the same currency.

**8.** The Company agrees not to disclose to any third party confidential information acquired in the course of providing the services listed without the prior written consent of the Client. Exception occurs when the information is already in the public domain or when disclosure is necessary to help the Company's employees and agents with the performance of the Company's obligations to achieve satisfactory completion of the project and approved in writing by the Client.

**9.** Force Majeure: The Company will not be liable for any delay or failure to perform any obligation under this Agreement insofar as the performance of such obligation is prevented by an event beyond our reasonable control, included by not limited to, earthquake, fire, flood or any other natural disaster, labour dispute, riot, revolution, terrorism, acts of restraint of government or regulatory authorities, failure of computer equipment and failure or delay of sources from which data is obtained.

10. Please also refer to Master TERMS and CONDITIONS available upon request.

#### **VacZine Analytics**

Warren House Bells Hill Bishops Stortford Herts CM23 2NN United Kingdom Tel: +44 (0) 1279 654514 / +44 (0) 7952470582 / Fax: +44 (0) 1279 655926 E-mail: info@vacZine-analytics.com

Bringing life to vaccine strategy...

### www.vacZine-analytics.com



# About VacZine Analytics:

**VacZine Analytics** is an established strategic research agency based in the United Kingdom. Its aim is to provide disease and commercial analysis for the vaccine industry and help build the case for developing new vaccines and biologics.

For more information please visit our website www.vacZine-analytics.com

VacZine Analytics (R) is a trading division of Assay Advantage Ltd, UK Company Number: 5807728 VacZine Analytics (R) and "the spiral logo" are UK Registered Trademarks, 2009

Bringing life to vaccine strategy...

### www.vacZine-analytics.com