

****Published November 2013****

MarketVIEW: Inactivated polio virus vaccines

Product Name	:	MarketVIEW: Inactivated polio virus vaccines
Description	:	Global vaccine commercial opportunity assessment
Contents	:	Executive presentation + 1 forecast model
Therapeutic Area	:	Pediatric vaccines
Publication date	:	November 2013
Catalogue No	:	VAOPS004

Background

Poliovirus, a member of the *Picornaviridae* family has the potential to cause irreversible paralysis in children < 5yrs, with 5 to 10% mortality. Fortunately, the number of polio cases has decreased 99% since 1988, as a result of vaccination (WHO figures). Now only 3 countries (Afghanistan, Nigeria and Pakistan) remain polio-endemic in 2013, although polio free countries remain at risk of importation of wild poliovirus from these countries (Note: outbreaks in Somalia, Ethiopia and Kenya).

Much of the success in eradicating polio has been due to the launch of the Global Polio Eradication Initiative (GPEI), launched in 1988 and coordinated by national governments and supranational partners such as the WHO, Rotary International, the US Centers for Disease Control and Prevention (CDC), UNICEF and the Bill and Melinda Gates Foundation. Now the GPEI, GAVI and WHO are facilitating a switch from trivalent (Sabin) oral poliovirus vaccine (tOPV) to a bivalent form (bOPV) and beyond that, the introduction of inactivated polio vaccines (IPVs) into global national immunization programs (NIPs).

This **MarketVIEW** product is a comprehensive commercial opportunity assessment detailing the potential market for IPV vaccines (stand-alone and DTP-IPV combinations) to 2030 across GAVI, Non-GAVI, India, China, Indonesia, Brazil, Existing IPV, Mixed OPV-IPV, OPV, (High-income and UMI) public markets. Three forecast scenarios are included BASE, FRACTIONAL and LOW where differing dose levels of IPV are explored. The report is written from the perspective of IPV producers who are faced with the pending decision(s) of supranational stakeholders whether to continue polio eradication with a "5 plus 1" strategy or hexavalent DTwP-Hep B-Hib-IPV vaccine. Domestic vaccine manufacturer (DVM) capabilities are discussed in terms of potential partnerships, technical issues and alliance activity to date. A case study of J&J/Crucell's PER.C6 IPV is included with revenue projections per market.

Methodology

VacZine Analytics has closely monitored all significant source material pertaining to polio virus 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 November 2013 (CAT No: VAOPS004)

****This product is composed of a model and summary presentation

Contents – Summary presentation (MS PowerPoint based)

Author's note
Executive Summary
Inactivated Polio Vaccines (IPV): global volume (doses 000s) to 2030
Inactivated Polio Vaccines (IPV): global value (\$ 000s) to 2030
Inactivated Polio Vaccines (IPV): GAVI volume to 2030
Inactivated Polio Vaccines (IPV): GAVI value (\$ 000s) to 2030
Inactivated Polio Vaccines (IPV): volume by market type, 2020
J&J Crucell's PER.C6-IPV: predicted value by market type, 2020
J&J Crucell's PER.C6-IPV: assumptions applied
Objectives of analysis
Methodology: major milestones and events
Methodology: country groupings
Methodology: scenario definitions
BASE, LOW and FRACTIONAL-IPV scenarios
Methodology: assumptions and uncertainties
Polio epidemiology
Polio epidemiology: confirmed polio cases, 1996-2013
Polio epidemiology: Global wt polio cases, January-September 2013
Polio epidemiology: (VDPV) cases, March-September 2013
Polio vaccines: background to OPV
Polio vaccines: background to IPV
Polio vaccines: comparing OPV to IPV
IPV Polio vaccine manufacturers
Polio vaccine manufacturers: Sanofi Pasteur and GlaxoSmithKline
Polio vaccines: OPV production, prequalification
IPV Polio vaccine manufacturers: summary table
Poliovirus immunization schedules
Poliovirus immunization schedules: IPV vs OPV

Continued.....

Poliovirus immunization schedules: mixed schedules
Poliovirus immunization schedules: Country NIPs by polio vaccine type
GPEI Polio Eradication & Endgame Strategic Plan
The Polio Eradication & Endgame Strategic Plan: timeline
Accessing Affordable IPV
Affordable IPV: Serum Institute of India reduces IPV price
Affordable IPV: comparing options
GPEI Strategic Plan budget
GPEI plan budget: by category, 2013-2018
IPV dosing in low and high risk countries
IPV dosing: VDPV cases by poliovirus type, 2010-February 2013
Ongoing trials with IPV: summary table
Fractional-IPV versus full-IPV: review of studies
Ongoing trials with IPV
Fractional-IPV line-extension
Alternate cell lines
Alternate cell lines: PER.C6-IPV compared to Salk-IPV20
Sabin-IPV
Sabin-IPV: other points to note
Estimated IPV demand: WHO
Introducing IPV into schedules: 2015 to 2019
Introducing IPV into schedules: 2020
WHO vaccines prequalification priority list 2013-14
Domestic vaccine manufacturer (DVM) capabilities
Introducing IPV into schedules: 2020 – strategies
The hexavalent IPV option: background
The Pentavalent platform for IPV: influence of GAVI
Pentavalent: Summary visual roadmap - GAVI
Hexavalent IPV vaccines: current status
Current and potential future hexavalent products
Developing hexavalent products: technical issues
Developing hexavalent products: issues with dosing
Domestic vaccine manufacturer (DVM) capabilities: DTP
Domestic vaccine manufacturers: Crucell partnership options
DVM capabilities: target options for IPV producers
IPV standalone (5+1) or hexavalent combination?
IPV standalone (5+1) or hexavalent combination: case for
IPV standalone (5+1) or hexavalent combination: case against
Hexavalent demand & supply
GAVI countries
Disclaimer
About **VacZine Analytics**

PAGES: 91 MS PowerPoint slides, fully referenced/sourced. Available in .pdf form



Contents – Vaccine demand model(s) (MS Excel-based) – 1 model

Title sheet
Charts
PER.C6-IPV analysis
Value summary
Volume summary
Country groups
Existing IPV
Mixed OPV-IPV
OPV only (High-income and UMI)
OPV only (non-GAVI)
OPV (GAVI-high risk)
OPV (GAVI-low risk)
China
India
Indonesia
Brazil
Source material
Birth cohorts
Country database
GAVI
VDPV
NIPs (IPV standalone)
NIPs (IPV combi)
NIPs (OPV)
NIPs (non-IPV combi)
DTP NIP analysis
WHO PQ vaccines
Polio cases
Pol3 coverage
World bank
Back Page

WORKSHEETS: ~32

PRODUCT COST:

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

- FULL PRODUCT - USD **\$9995.00**/ GBP **£6245.00**[#] (Region license)*
- PRESENTATION OR MODEL ONLY - USD **\$4995.00** (Region license)*

[#] Indicative rate only. Prevailing rate applied to date of transaction.

*A region is North America, Europe or ROW

For orders in the UK, VAT at 20.0% will be added to final invoice total

HOW TO ORDER:

To order please contact your region account manager or order direct at orders@vaczine-analytics.com

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

BIBLIOGRAPHY:

1. WHO. Poliomyelitis. 4 June 2010. Available at: <http://www.who.int/immunization/topics/polio/en/index.html>. Accessed: September 2013.
2. WHO. Polio Case Count. Updated 20-Sep-2013. Available at : http://apps.who.int/immunization_monitoring/en/diseases/poliomyelitis/case_count.cfm Accessed: September 2013.
3. The Global Polio Eradication Initiative. Data and monitoring. Available at: <http://www.polioeradication.org/>. Accessed: September 2013
4. UNICEF Procurement and Supply Updates for OPV 11th WHO/UNICEF Consultation with OPV/IPV Manufacturers and NRAs UNICEF Supply Division 25th October 2012 Geneva.
5. PolioPipeline. Global Polio Eradication Initiative (GPEI). March 2013. Issue 9
6. CDC Vaccine Price List. Prices last reviewed/updated: July 24, 2013. Available at: <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>. Accessed September 2013
7. The Global Polio Eradication Initiative. Oral polio vaccine (OPV). Available at: <http://www.polioeradication.org/Polioandprevention/Thevaccines.aspx>. Accessed: September 2013.
8. WHO prequalified vaccines: Date of last revision of vaccine list: 26 August 2013. Available at: www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en. Accessed: September 2013
9. Sanofi From 20F, For the fiscal year ended December 31, 2012
10. GlaxoSmithKline Form 20F, For the fiscal year ended December 31, 2012
11. WHO. Immunization surveillance, assessment and monitoring. Reported immunization schedules by vaccine. Available at: http://apps.who.int/immunization_monitoring/data/data_subject/en/index.html. Accessed: September 2013
12. Fiocruz . Poliomielite Inativada. Available at: <http://www.bio.fiocruz.br/index.php/produtos/vacinas/virais/poliomielite-inativada>. Accessed: September 2013
13. World Health Organization. Polio Eradication & Endgame Strategic Plan 2013-2018. Available at: <http://www.polioeradication.org/ResourceLibrary/Strategyandwork.aspx>. Accessed: September 2013
14. World Health Organization. Note for the record from 5th Meeting of the SAGE Polio Working Group World Health Organization, Geneva, 3-4 September, 2012. Available at: http://www.who.int/immunization/sage/meetings/2012/november/presentations_background_docs/en/index.html. Accessed: September 2013.
15. Serum Institute of India. Bill Gates visits Serum Institute, meets vaccine hero Poonawalla. June 1, 2012. Available at: http://www.seruminstitute.com/content/news_7.htm. Accessed: September 2013
16. Financial Resource Requirements 2013-2018. As of 1 June 2013. Available at: <http://www.polioeradication.org/ResourceLibrary/Strategyandwork.aspx>. Accessed: September 2013.
17. Polio (Pol3) immunization coverage among 1-year-olds (%). Available at: <http://apps.who.int/gho/>. Accessed: September 2013.
18. Poliomyelitis: intensification of the global eradication initiative. Report by the Secretariat. 14 December 2012
19. Davis R et al. Inactivated polio vaccine: its proposed role in the final stages of polio eradication. Pan Afr Med J. 2013 Mar 13;14:102.
20. Progress Toward A Low COGs PER.C6 based IPV. 11th WHO/UNICEF Consultation with OPV/IPV Manufacturers and NRAs Geneva, Switzerland 25 October, 2012
21. Polio vaccine technology transfer continues. March 20, 2013. Available at: <http://www.polioeradication.org/>. Accessed: September 2013.
22. Projected Global Requirements for Oral and Inactivated Poliovirus Vaccine 2013 - 2018 Vaccine Manufacturer's Meeting. 25 October 2012 .
23. Update on activities of the SAGE IPV Working Group. Meeting of OPV/IPV Manufacturers and NRAs, Geneva, 2 December, 2010
24. GPEI. Frequently asked questions on OPV cessation. Available at: <http://www.polioeradication.org/>. Accessed September 2013.
25. Mahmood K et al. Hexavalent IPV-based combination vaccines for public-sector markets of low-resource countries. Human Vaccines & Immunotherapeutics 9:9, 1894–1902; September 2013
26. WHO prequalified vaccines. Immunisation standards. 26th of August 2013. Available at: http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/. Accessed October 2013
27. GAVI Alliance. The market shaping goal. Shake vaccine markets to provide appropriate and affordable vaccines. Pentavalent roadmap. Update May 2013
28. GAVI: Countries eligible for support. Available at: <http://www.gavialliance.org/support/apply/countries-eligible-for-support/>. Accessed: September 2013

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

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

Follow us on Twitter **@vaczineanalytic**

Signup to our newsletter ExpertREACT - <http://www.vacZine-analytics.com/products-expertreact.asp>

Signup to our free vaccine pipeline database - <http://www.vaccinestats.com>