

****New release September 2009***

MarketVIEW: H1N1 pandemic vaccine - GLOBAL (CAT: VAMV007)

Proposal No/#PO : [Enter client specific #PO]

Product Name : Pandemic specific vaccine H1N1 – vaccine value/volume

forecast model (quarterly), Global version

Project Initiation Date : n/a
Billable days : n/a

Initiator(s)

[Enter client name, function and address]

Therapeutic Area : Pandemic influenza, H1N1

Product (if applicable) : CAT No: VAMV007, updated September 2009

Background

H1N1 or "Swine flu" is a pandemic strain of the influenza A virus which emerged in April 2009. Due to its rapid global spread, the virus prompted the World Health Organisation (WHO) to lift its pandemic alert status to level 6 and manufacturers to begin pandemic specific vaccine production. So far, the virus has similar transmissibility to that of seasonal influenza viruses, although observed clinical disease severity has been for the most part mild in most infected persons who were initially healthy Despite this, H1N1 still has caused around 3250 deaths (WHO update 65, 11th September 2009), mainly in people with underlying comorbidities. H1N1 is predicted to cause marked excess mortality as the winter months arrive in the Northern hemisphere.

In late August 2009, the US Advisory Committee on Immunization practices (ACIP) published recommendations regarding who should receive the H1N1 vaccine once it becomes available 1 The following "initial target groups" were listed:

- · pregnant women,
- · persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel,§
- persons aged 6 months--24 years, and
- persons aged 25--64 years who have medical conditions that put them at higher risk for influenza-related complications.

If vaccine is initially limited, further "priority subsets" of the above were also listed. In the EU, the EU Health Security Committee (HSC)/ Early Warning and Response System (EWRS) also made a statement on H1N1 target and priority groups for vaccination²

Use of Influenza A (H1N1) 2009 Monovalent Vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. MMWR. August 28,2009 / 58(RR10); 1-8



Purpose of Study

Using currently available information regarding the expected profile, predicted deployment of H1N1 specific vaccine and current prediction of pandemic severity, **VacZine Analytics** has modelled potential H1N1 global vaccine demand (mio doses) per Western and Emerging regions. The provided model and presentation also give estimations of demand per quarter according to each designated vaccination group.

Using adjustable inputs of vaccine penetration, number of doses and pricing the model also estimates potential cumulative revenue (for vaccine manufacturers) and approximate market share based on contracts awarded so far.

PRODUCT CONTENTS:

Updated September 2009 (CAT No: VAMV007)

This product is composed of a model and summary presentation

Contents – Summary presentation (MS Powerpoint-based)

Markets included in model

Broad assumptions for H1N1 vaccine: theoretical demand (US)

Broad assumptions for H1N1 vaccine: theoretical demand (US)

Major model assumptions (global)

Estimated numbers in US vaccination Tiers

Vaccine demand model assumptions – Western Markets

Vaccine demand model assumptions – Emerging Markets

Theoretical predicated H1N1 vaccine demand per quarter (000 doses)

Cumulative revenue potential (Q3 2009 – Q4 2012)

Statements on required/planned vaccine volume per country (Western)

Statements on required/planned vaccine volume per country (Emerging)

Other statements on required/planned vaccine volume

Company statements on required/planned vaccine volume (Medimmune)

Company statements on required/planned vaccine volume (GSK Biologicals)

WHO tenders

About VacZine Analytics

Disclaimer

PAGES: 22 MS PowerPoint slides, fully referenced/sourced. Available in .pdf form

² HSC/EWRS Statement on Influenza A(H1N1) 2009: target and priority groups for vaccination. European CDC. 25 August 2009. Available at: http://ec.europa.eu/health/ph_threats/com/Influenza/docs/HSC_EWRS_statement_en.pdf. Accessed September 2009.



Contents - Vaccine demand model (MS Excel-based)

Title sheet

Charts (Western)

Cumulative revenue (company)

Value summary (Western)

Value summary (Emerging)

Market share summary (Western)

Market share summary (Emerging)

Volume summary (Western)

Volume summary (Emerging)

H1N1 North America

US priority subsets

US initial target groups

Canada priority subsets

Canada initial target groups

H1N1 EU

UK priority subsets

UK initial target groups

France priority subsets

France initial target groups

Germany priority subsets

Germany initial target groups

Italy priority subsets

Italy initial target groups

Spain priority subsets

Spain initial target groups

Other EU priority subsets

Other EU target groups

US priority subsets

US initial target groups

H1N1 (Japan + Australia)

Japan priority subsets

Japan initial target groups

Australia priority subsets

Australia initial target groups

H1N1 (Major Asia)

India priority subsets

India initial target groups

China priority subsets

China initial target groups

Russia priority subsets

Russia initial target groups

H1N1 (Latin America - LATAM)

Brazil priority subsets

Brazil target groups

Mexico priority subsets

Mexico initial target groups

Argentina priority subsets

Argentina initial target groups



Population database 6 mos – 24 yrs H5N1 material US H5N1 tier definitions US H5N1 tier subpriority US Extrapolation Source material Back page About VacZine Analytics Disclaimer

PROJECT METHODOLOGY:

VacZine Analytics has closely monitored all significant source material pertaining to the H1N1 outbreak. Source materials used are literature articles, government websites, medical bodies and associations, conference proceedings etc. Previously published research focused on H5N1 pre-pandemic vaccines from **VacZine Analytics** has also been utilised.

BIBLIOGRAPHY:

- 1. Use of Influenza A (H1N1) 2009 Monovalent Vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. MMWR. August 28,2009 / 58(RR10); 1-8
- HSC/EWRS Statement on Influenza A(H1N1) 2009: target and priority groups for vaccination. European CDC. 25 August 2009.
 Available at: http://ec.europa.eu/health/ph_threats/com/Influenza/docs/HSC_EWRS_statement_en.pdf. Accessed September 2009.
- Sanofi Pasteur receives order from US Government to produce new H1N1 vaccine. Press release. May25 2009.
 Available at: http://198.73.159.214/sanofi-pasteur2/ImageServlet?imageCode=25854&siteCode=SP_CORP. Accessed September 2009
- 4. H1N1 swine flu vaccine. Parliamentary Office of Science and Technology. Available at: http://www.parliament.uk/documents/upload/postpn331.pdf. Accessed September 2009
- H1N1 Swine flu vaccination program. UK Department of Health. 26 June 2009.
 Available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_101630.pdf.
 Accessed September 2009.
- Sanofi Pasteur receives order to produce Novel Influenza H1N1 vaccine. Press release. July 16 2009.
 Available at: http://198.73.159.214/sanofi-pasteur2/ImageServlet?imageCode=26090&siteCode=SP_CORP. Accessed 2009.
- 7. Germany orders 50 million doses of swine flu vaccine. News Article. July 24 2009. Available at: http://online.wsj.com/article/BT-CO-20090724-710032.html. Accessed September 2009
- Italy Starts Swine flu vaccination in November. News Article. Available at:. http://www.independent-bangladesh.com/2009090411291/health/italy-starts-swine-flu-vaccination-in-nov.html. Accessed September 2009
- Italy: Swine Flu vaccine to be offered from November. News Article. August 26 2009. Available at: http://www.adnkronos.com/AKI/English/Security/?id=3.0.3697866202. Accessed September 2009.
- 10. Japan to buy Glaxo, Novartis H1N1 vaccines. News Article. September 11th 2009. Available at: http://news.yahoo.com/s/nm/20090911/hl nm/us flu japan vaccines; ylt=AvAh9TtFHqR0k8LVAq4uWFoQ.3QA; ylu=X3oDMTJzanFwdm5zBGFzc2V0A25tLzlwMDkwOTExL3VzX2ZsdV9qYXBhbl92YWNjaW5lcwRwb3MDMTYEc2VjA3luX3BhZ2luYXRIX3N1bW1hcnlfbGlzdARzbGsDamFwYW50b2J1eWds. Accessed September 2009.
- 11. Novartis has swine flu vaccine shortfall Dutch Gov't. News Article. September 9 2009. Available at: http://online.wsj.com/article/BT-CO-20090908-711456.html. Accessed September 2009
- 12. Public Health Agency of Canada. August 6 2009. Available at: http://www.phac-aspc.gc.ca/media/nr-rp/2009/2009 0806-eng.php. Accessed September 2009
- 13. Sanofi Pasteur and Butantan Institute to provide H1N1 vaccine to Brazilian Government. Press release. Sept 7 2009. Available at:



http://198.73.159.214/sanofi-pasteur2/lmageServlet?imageCode=26243&siteCode=SP_CORP. Accessed September 2009.

- China set to provide first swine flu vaccines. News Article. Sept 7 2009. Available at: http://edition.cnn.com/2009/HEALTH/09/09/china.swine.flu.vaccine. Accessed September 2009.
- 15. Sinovac Obtains Initial Order of H1N1 Vaccine from Chinese Central Government. Sinovac Corporate Press Release. Sept 4 2009. Available at:
 - http://www.sinovac.com/Investors/2009/9/m9sfj22vky.htm. Accessed September 2009.
- India developing indigenous swine flu vaccine. News Article. August 16th 2009. Available at: http://timesofindia.indiatimes.com/life-style/health-fitness/health/India-developing-indigenous-swine-flu-vaccine/articleshow/4873696.cms. Accessed September 2009.
- 17. WHO supports fair access to influenza A (H1N1) vaccine. An interview with Marie-Paule Kieny, WHO Health Organisation (WHO). September 4 2009. Available at: http://www.who.int/bulletin/volumes/87/9/09-030909/en/index.html. Accessed September 2009
- 18. H1N1 orders top \$1bn says WHO. News Article. August 2009.

 Available at: http://www.medicalnewstoday.com/articles/161291.php Accessed September 2009
- 19. Medimmune Corporate Website. September 2009. Available at: http://www.medimmune.com.asp. Accessed September 2009
- 20. GSK Corporate Website. August 2009. Available at:

http://www.gsk.com/media/pressreleases/2009/2009_pressrelease_10081.htm. Accessed September 2009

PRODUCT COST:

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

USD \$5995.00/ GBP £3695.00 (Region license)*

*A region is North America, Europe or ROW For orders in the UK, VAT at 15% will be added to final invoice total

HOW TO ORDER:

To order please contact your region account manager or order direct at order@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



TERMS and CONDITIONS:

VacZine Analytics – a trading division of Assay Advantage Ltd UK Company Number: 5807728 (Herein refered 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