

****Published August 2016****

MarketVIEW: Universal influenza vaccines (CAT: VAMV020)

Product Name	:	MarketVIEW: Universal influenza vaccines
Description	:	Vaccine opportunity assessment
Contents	:	Executive presentation (.pdf) + commercial forecast model (.xls)
Therapeutic Area	:	Novel viral vaccines
Publication date	:	August 2016
Catalogue No	:	VAMV020

Background

Influenza is an acute febrile disease of the respiratory system caused by an enveloped RNA virus where types A and B cause disease in humans. Influenza occurs in yearly epidemics (seasonal) and unpredictable pandemics. It exerts enormous global burden in terms of mortality, morbidity and economic cost. In the US, influenza kills around 20,000 people per year and over 100,000 influenza related hospitalizations. Although the recent H1N1 “swine flu” pandemic has been referred to as mild, the 1918 pandemic “Spanish flu” is estimated to have caused 50 million deaths worldwide demonstrating the lethality of the virus.

Yearly vaccination is the mainstay of protection against the constantly changing influenza virus. Currently, a number of influenza vaccines are available and given according to national recommendations to an increasing percentage of the population. There is focus on protecting the most vulnerable such as the very young, old and immunocompromised. Influenza vaccines are of the trivalent inactivated (TIV), LAIV or Quadrivalent format (QIV) produced either by older technology in egg-based production systems or more recently in cell-based systems. Current influenza vaccines have a number of limitations, the most concerning being limited efficacy due to strain mismatch. In the 2014/15 VE was as low as 18% resulting in the highest recorded hospitalization rate (> 65yrs) since records began. Therefore, a more desirable goal is to produce a “universal vaccine” that can protect against all types of influenza viruses.

This **MarketVIEW** product is a comprehensive MS Excel-based model + summary presentation that forecasts the potential commercial value of universal influenza vaccines across major Western markets to 2035. The model contains value (\$ m) and volume (mio doses) predictions along with launch timeframe, TPP, pricing and penetration estimates for all key commercial segments. The BiondVax M-001 candidate is assessed in some detail as a pandemic, seasonal primer and standalone vaccine. A detailed analysis of the current “novel” influenza pipeline is provided with discussion of all relevant scientific and clinical issues.

Methodology

VacZine Analytics has closely monitored all significant source material pertaining to influenza vaccines and novel vaccine approaches. Source materials used are literature articles, government websites, medical bodies and associations, conference proceedings etc. Previously published research by **VacZine Analytics** in the field of novel viral vaccines has also been utilised.

PRODUCT CONTENTS:

Published August 2016 (CAT No: VAMV020)

****This product is composed of [one forecast model \(.xls\)](#)¹ and [a summary presentation \(.pdf\)](#)²

Contents
Author's note
Executive summary
Key commercial model outputs
Universal vaccine: predicted pandemic primer demand to 2035 (doses 000s)
Universal vaccine: predicted pandemic primer value to 2035 (\$ 000s)
Predicted pandemic primer value to 2035 per country (\$ 000s)
Predicted seasonal primer demand to 2035 (19-65 yrs) (doses 000s)
Predicted seasonal primer value to 2035 (19-65 yrs) (\$ 000s)
Predicted seasonal primer demand to 2035 (>65 yrs) (doses 000s)
Predicted seasonal primer value to 2035 (>65 yrs) (\$ 000s)
Peak year revenues per country per age: seasonal primer (\$ 000s)
Predicted seasonal primer/standalone value to 2035 (19 - 65 yrs) (\$ 000s)
The limitations of current influenza vaccines: review of current challenges
Influenza vaccine mismatching and reduced efficacy
Current innovations in influenza vaccines: review of major licensed products
Licensed influenza vaccines: innovation areas
Influenza vaccines: product innovations - strain coverage
Influenza vaccines: product innovations - HA content
Influenza vaccines: product innovations - delivery systems
Influenza vaccines: product innovations - production systems
Influenza vaccines: product innovations - adjuvantation
Innovation examples in licensed influenza vaccines: increment analysis
Influenza vaccine product innovations improve pricing at first introduction
Other innovation areas
Future innovation in influenza vaccines - review of R&D pipeline
Searching for further innovation in influenza vaccines: methodology
Innovation search: key findings
Novel influenza vaccine pipeline: by development phase
Novel influenza vaccine pipeline: by antigen type
Novel influenza vaccine pipeline: by organisation type
Novel influenza vaccine pipeline: by innovation/segment type

Continued.....

¹ Model contents available upon application

² Presentation titles may apply to more than one slide

Universal influenza vaccines: the next wave of innovation?
Potential benefits to universal influenza vaccines
Overview of approaches: to universal vaccines
Viral targets for broadly reactive universal vaccines
Mechanisms of virus neutralization: summary
Classification of viral targets in terms of response
Universal approaches: points to note
Universal vaccine pipeline by Phase
Universal influenza vaccine programs at preclinical stages
Universal influenza vaccine programs at clinical stages
Focus on BiondVax: multimeric-001
Multimeric-001 (BiondVax) - Phase II priming data
BiondVax: latest update for M-001
Universal vaccines: other notable programs (SEEK)
Universal vaccines: other notable programs (Inovio)
Other innovations in influenza vaccines (seasonal vaccines)
Other innovations in influenza vaccines (pandemic vaccines)
Challenges in technical and regulatory assessment
Universal influenza vaccines: modelling potential demand/commercial value
Universal influenza vaccine opportunity: target product profile (TPP)
Universal influenza antigens: possible use scenarios
Universal influenza vaccine - modelling rationale
Predicted launch sequence: M-001 (BiondVax)
M-001 (BiondVax) pandemic primer - estimated launch
Overall modelling methodology: pandemic primer
Framework for targeting pandemic primer influenza vaccine (US)
Vaccination target groups for a pandemic primer vaccine
Estimated numbers in vaccination target groups (US)
Estimated numbers in vaccination tiers (US)
Tier1 equivalent populations: outside US
Manufacturers of vaccines and antivirals
Assessing Tier1 stockpile size – Europe
Assessing Tier1 yearly demand
Overall modelling methodology: seasonal primer
M-001: Standalone vaccine?
Pricing methodology
Model caveats and limitations
Appendix 1
Novel influenza vaccine technologies by type/phase
Countries included in seasonal demand forecast model
Novel inactivated virus vaccines
Novel live attenuated influenza virus vaccines
Novel vectored influenza vaccines
Novel recombinant influenza peptides
Novel recombinant influenza proteins
Novel recombinant influenza DNA
Novel influenza immunoglobulin
Bibliography
Disclaimer
About **VacZine Analytics**
Slide number = 98

PRODUCT COST:

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

- FULL PRODUCT - USD **\$9995.00**/ GBP **£7600.00**# (Region license)*

Indicative company 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

Consultancy rates (commercial use) are available upon request

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.



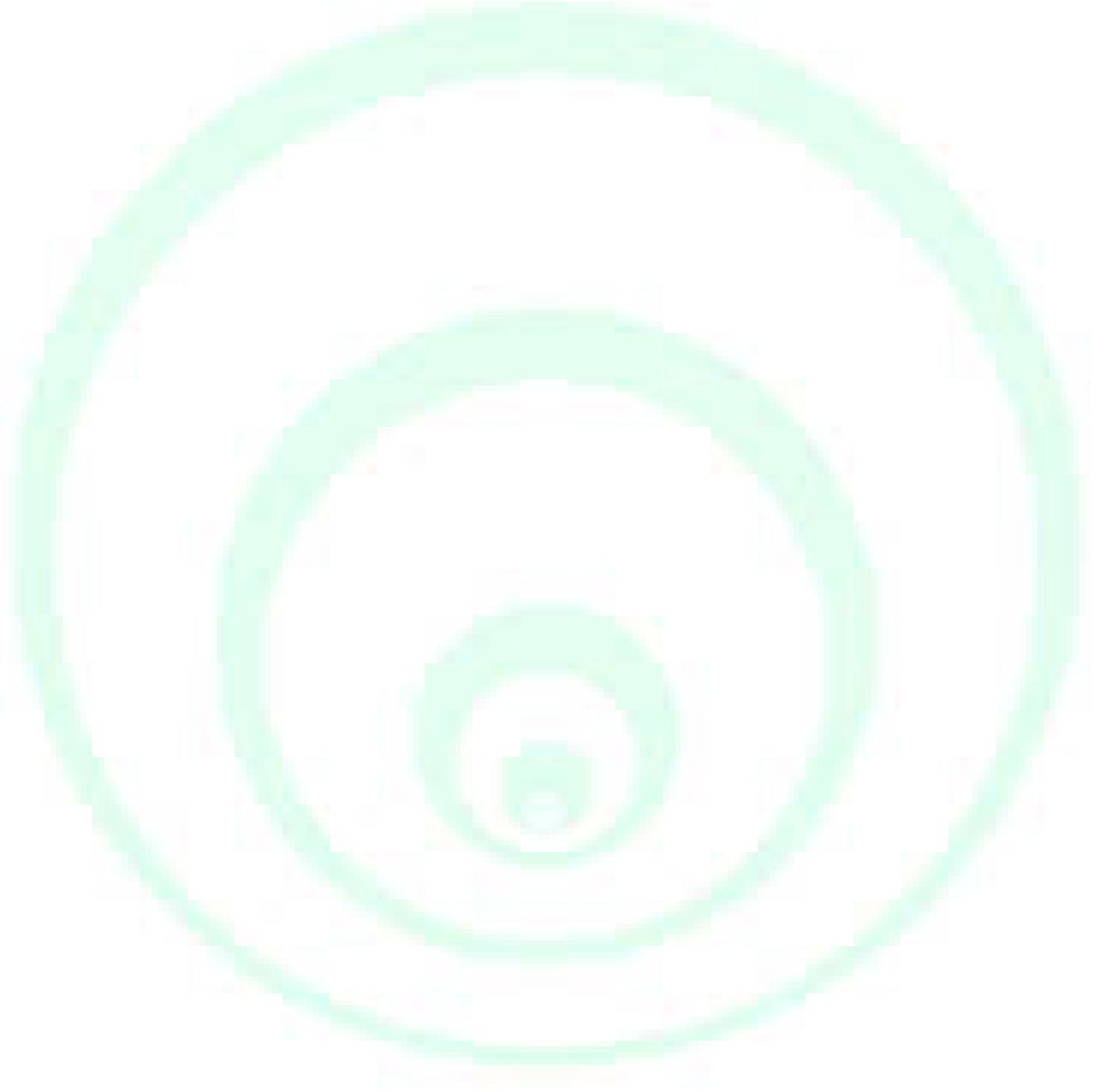
VacZine Analytics (R) is a trading division of Assay Advantage Ltd, UK Company Number: 5807728

VacZine Analytics (R) and the “**spiral logo**” are UK Registered Trademarks, 2009

BIBLIOGRAPHY

1. Soema PC et al. Current and next generation influenza vaccines: Formulation and Production strategies. *European Journal of Pharmaceutics and Biopharmaceutics* 94 (2015) 251-263
2. Scorza F~B et al. Universal influenza vaccines: Shifting to better vaccines. *Vaccine* 34 (2016) 2926-2933
3. Carlos A et al. Efficacy of High-Dose versus Standard-Dose Influenza Vaccine in Older Adults. *N Engl J Med* 2014; 371:635-645 August 14, 2014
4. US Centres for disease control and prevention. Influenza vaccine prices - 2013. Available at:<http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/> Accessed July 2016
5. US Centres for disease control and prevention. Influenza vaccine prices. - 2014 Available at: <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/> Accessed July 2016
6. World Health Organisation. Status of Vaccine Research and Development of Universal Influenza Vaccine. Available at: http://who.int/immunization/research/meetings_workshops/Universal_Influenza_VaccineRD_Sept2014.pdf. Accessed July 2016
7. Daiichi Sankyo and Terumo Announce Application in Japan for Manufacturing and Sales Approval of Intradermal Seasonal Influenza Vaccine. Available at: http://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006267.html. Accessed July 2016
8. Sanofi Pasteur Corporate Press Release. Available at: <http://www.sanofipasteur.com/en/articles/sanofi-pasteur-reveals-its-research-on-a-universal-influenza-vaccine.aspx>. Accessed July 2016
9. Rotzschke O, Falk K, Stevanovič S, Jung G, Walden P, Rammensee H. Exact prediction of a natural T cell epitope. *Eur J Immunol* 1991;21(11):2891e4.
10. Cho A et al. Implications of broadly neutralizing antibodies in the development of a universal influenza vaccine. *Current Opinion in Virology* 2016, 17:110–115
11. Graves PN et al: Preparation of influenza virus subviral particles lacking the HA1 subunit of hemagglutinin: unmasking of cross-reactive HA2 determinants. *Virology* 1983, 126:106-116. 42.
12. Steel J et al.: Influenza virus vaccine based on the conserved hemagglutinin stalk domain. *MBio* 2010:1.
13. Ben-Yedidia T, Marcus H, Reisner Y, Arnon R. Intranasal administration of peptide vaccine protects human/mouse radiation chimera from influenza infection. *Int Immunol* 1999;11:1043e51
14. Adar Y, Singer Y, Levi R, Tzehoval E, Perk S, Banet-Noach C, et al. A universal epitope-based influenza vaccine and its efficacy against H5N1. *Vaccine* 2009;27(15):2099e107. 26.
15. Atsmon J et al. Priming by a novel universal influenza vaccine (Multimeric-001)-a gateway for improving immune response in the elderly population. *Vaccine*. 2014 Oct 7;32(44):5816-23. doi: 10.1016/j.vaccine.2014.08.031
16. Gottlieb T et al. Epitope-based approaches to a universal influenza vaccine. *J Autoimmunity*. 2014 Nov;54:15-20
17. Data presented at the Influenza Congress 2011 (USA), Arlington, Virginia, FLU-v 002: A randomised double-blind, placebo controlled, Phase II study in 28 volunteers to evaluate the safety, tolerability and protective efficacy of a single subcutaneous dose of the influenza vaccine candidate FLU-v in an influenza
18. Universal influenza vaccine at step closer. SEEK news release. November 2015. Available at: <http://www.seekacure.com/news/downloads/NIH%20agreement%20flu%20media%20release%20FINAL.PDF>. Accessed April 2016
19. Study of VGX-3400X, H5N1 Avian Influenza Virus DNA Plasmid + Electroporation in Healthy Adults (NCT01142362). *Clinical trials.gov*
20. BiondVax Corporate Presentation. April 2016. The Universal Flu Vaccine. Available at: http://www.biondvax.com/wp-content/uploads/2016/04/BiondVax_Presentation-1.pdf. Accessed July 2016
21. Guidance on allocating and targeting pandemic influenza vaccine. US Department of Health and Human Services. Available at: http://www.flu.gov/images/reports/pi_vaccine_allocation_guidance.pdf. Accessed June 2016
22. World Health Organisation. Mapping the Global Vaccine Manufacturing Workforce: Preliminary Results of a Survey among vaccine manufacturers. Available at: http://www.who.int/phi/news/Draft_Survey_Report_Phases1-2.pdf. Accessed July 2016

23. Surveillance of Vaccination Coverage Among Adult Populations – United States, 2014. Available at. Accessed July 2016: <http://www.cdc.gov/mmwr/volumes/65/ss/ss6501a1.htm>. Accessed July 2016



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