

Updated May 2014

MarketVIEW: Group B Streptococcus vaccines (CAT: VAMV008)

Product Name:	Group B Streptococcus vaccines
Description	Global vaccine commercial opportunity assessment
Contents	Executive presentation + forecast model
Therapeutic area	Novel vaccines
Publication date	May 2014
Catalogue No	VAMV008

Background

Group B beta streptococci (GBS) or *Streptococcus agalactiae* is an encapsulated Gram-positive coccus capable of producing a range of diseases in humans of all age ranges. In the neonate, the bacterium can cause severe life threatening sepsis and meningitis (early and late onset disease) due to ascending spread of GBS from the birth canal of colonized females (~30% of total) who are typically asymptomatic. In the 1970s GBS was the leading infectious cause of neonatal morbidity in the US with estimated 7,500-8000 cases occurring annually. Presently, GBS is still estimated to cause disease (EOD+LOD) in approximately 0.5/1000 US births although the widespread implementation of screening and intrapartum antibiotic prophylaxis (IAP) has reduced disease burden dramatically. GBS can also cause life threatening invasive disease in the immunocompromised non-pregnant adult with approximately 2.44 to 5.77 (18-49 yrs) cases per 100,000 population (CDC Figures)¹. Recent studies indicate that the rate of adult disease may be increasing².

A number of manufacturers are considering the development of a GBS prophylactic vaccine. Such a vaccine may be offered to adolescents to prevent neonatal disease after pregnancy later in life or for older women planning or during a pregnancy. Other possible uses might be in immunocompromised/elderly individuals who are hospitalized and reside in long-term care facilities.

¹ US Centers for Disease Control and Prevention. ABC Report: Group B Streptococcus, 2012. Available at: <http://www.cdc.gov/abcs/reports-findings/survreports/gbs12.html>. Accessed May 2014

² Phares CR, Lynfield R, Farley MM, Mohle-Boetani J, Harrison LH, Petit S, et al. Epidemiology of invasive group B streptococcal disease in the United States, 1999-2005. *JAMA*. May 7 2008;299(17):2056-65

Methodology

Using currently available information regarding the expected profile and predicted deployment of a GBS prophylactic vaccine **VacZine Analytics** has modelled potential vaccine demand (mio doses) and revenue estimates (\$ 000s) per major Western market and vaccine target segments. The provided model also gives estimates of market share per development company and includes adjustable inputs of vaccine penetration, number of doses and pricing.

VacZine Analytics has closely monitored all significant source material pertaining to the GBS. Source materials used are literature articles, government websites, medical bodies and associations, conference proceedings etc. Previously published research on hemolytic *Streptococci* **VacZine Analytics** has also been utilised.

PRODUCT CONTENTS:

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This product is composed of a model and summary presentation

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- Trivalent (Ia, Ib, III) vaccine launch timeline
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GBS vaccination attitudes among US pregnant women
Influenza vaccine uptake rates in pregnant women
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Disclaimer

PAGES: >50 MS PowerPoint slides, fully referenced/sourced. Available in .pdf form

Contents – Vaccine demand model (MS Excel-based)

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Worksheets = >60

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Bibliography

1. Schrag SJ et al. Intrapartum antibiotic prophylaxis for the prevention of perinatal group B streptococcal disease: experience in the United States and implications for a potential group B streptococcal vaccine. *Vaccine*. 2013 Aug 28;31 Suppl 4:D20-6.
2. Immunization Action Coalition. Pneumococcal Vaccines (PCV13 and PPSV23) http://www.immunize.org/askexperts/experts_pneumococcal_vaccines.asp#ppsv23_boosters
3. Colbourn TE et al. Preventive strategies for group B streptococcal and other bacterial infections in early infancy: cost effectiveness and value of information analyses. *BMJ*. 2007 Sep 29;335(7621):655.
4. Colbourn T et al. Prenatal screening and treatment strategies to prevent group B streptococcal and other bacterial infections in early infancy: cost-effectiveness and expected value of information analyses. *Health Technol Assess* 2007;11(29)
5. Kim SY et al. Cost-effectiveness of a potential group B streptococcal vaccine program for pregnant women in South Africa. *Vaccine*. 2014 Apr 7;32(17):1954-63.
6. Palazzi DL et al. Use of type V group B streptococcal conjugate vaccine in adults 65-85 years old. *J Infect Dis*. 2004 Aug 1;190(3):558-64.
7. K. Slobod. Development of a maternal vaccine for Group B Streptococcus (GBS). Meningitis Research Foundation's 2013 conference, Meningitis & Septicaemia in Children & Adults. November, 2013
8. Meningitis Research Foundation funding leads to new GBS vaccine. 29 January 2014. Available at: <http://www.meningitis.org/news-media/meningitis-research-77598>. Accessed: May 2014
9. Edmond KM. et al. Group B streptococcal disease in infants aged younger than 3 months: systematic review and meta-analysis. *Lancet*. 2012 Feb 11;379(9815):547-56.
10. Phares CR et al. Epidemiology of invasive group B streptococcal disease in the United States, 1999-2005. *JAMA*. 2008 May 7;299(17):2056-65.
11. Skoff TH et al. Increasing burden of invasive group B streptococcal disease in nonpregnant adults, 1990-2007. *Clin Infect Dis*. 2009 Jul 1;49(1):85-92.
12. Active Bacterial Core Surveillance (ABCs): Emerging Infections Program Network. Available at: <http://www.cdc.gov/abcs/reports-findings/survreports/gbs12.html>. Accessed: May 2014
13. Lamagni TL et al. Emerging trends in the epidemiology of invasive group B streptococcal disease in England and Wales, 1991-2010. *Clin Infect Dis*. 2013 Sep;57(5):682-8.
14. Lefebvre N et al. [Invasive Streptococcus agalactiae infections in non-pregnant adults]. *Med Mal Infect*. 2007 Dec;37(12):796-801.
15. Huber CA et al. Characterization of invasive and colonizing isolates of Streptococcus agalactiae in East African adults. *J Clin Microbiol*. 2011 Oct;49(10):3652-5.
16. Lambertsen L et al. Characterisation of invasive group B streptococci from adults in Denmark 1999 to 2004. *Eur J Clin Microbiol Infect Dis*. 2010 Sep;29(9):1071-7.
17. Bergseng H et al. Invasive group B streptococcus (GBS) disease in Norway 1996-2006. *Eur J Clin Microbiol Infect Dis*. 2008 Dec;27(12):1193-9. Matsubara K et al. Invasive group B streptococcal infections in a tertiary care hospital between 1998 and 2007 in Japan. *Int J Infect Dis*. 2009 Nov;13(6):679-84.
18. Darbar AA et al. Phenotypical and genotypical characteristics of invasive group B Streptococcus isolates in Western Sydney 2000-2005. *Pathology*. 2007 Dec;39(6):589-93.
19. Wang H et al. High prevalence of fluoroquinolone-resistant group B streptococci among clinical isolates in China and predominance of sequence type 19 with serotype III. *Antimicrob Agents Chemother*. 2013 Mar;57(3):1538-41.
20. Roger VL et al. (2012) Heart disease and stroke statistics--2012 update: a report from the American Heart Association. *Circulation*, 125(1):e2-e220.
21. IDF Diabetes Atlas Sixth Edition, International Diabetes Federation 2013. Available at: <http://www.idf.org/worlddiabetesday/toolkit/gp/facts-figures>. Accessed: May 2014
22. National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC). Available at: <http://kidney.niddk.nih.gov/kudiseases/pubs/kustats/#4>. Accessed: May 2014

23. Dempsey AF et al. Acceptability of a hypothetical group B strep vaccine among pregnant and recently delivered women. *Vaccine*. 2014 May 1;32(21):2463-8.
24. Centers for Disease Control and Prevention (CDC). Seasonal influenza vaccination coverage among women who delivered a live-born infant - 21 states and New York City, 2009-10 and 2010-11 influenza seasons. *MMWR Morb Mortal Wkly Rep*. 2013 Dec 13;62(49):1001-4.
25. Centers for Disease Control and Prevention (CDC). Influenza vaccination coverage among pregnant women: 2011-12 influenza season, United States. *MMWR Morb Mortal Wkly Rep*. 2012 Sep 28;61:758-63
26. Vilca Yengle LM et al. [Influenza vaccination in pregnant women. Coverage, practices and knowledge among obstetricians]. *Med Clin (Barc)*. 2010 Feb 13;134(4):146-51
27. Blondel B et al. Failure of the vaccination campaign against A(H1N1) influenza in pregnant women in France: results from a national survey. *Vaccine*. 2012 Aug 17;30(38):5661-5
28. Maher L et al. Influenza vaccination during pregnancy: coverage rates and influencing factors in two urban districts in Sydney. *Vaccine*. 2013 Nov 12;31(47):5557-64
29. Kfourir Rde A et al. Influenza vaccine in pregnant women: immunization coverage and associated factors. *Einstein (Sao Paulo)*. 2013 Jan-Mar;11(1):53-7.
30. Influenza vaccination uptake monitoring on behalf of the Department of Health. Available at: http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733756886#r1. Accessed: May 2014
31. Liu N et al. Vaccination patterns in pregnant women during the 2009 H1N1 influenza pandemic: a population-based study in Ontario, Canada. *Can J Public Health*. 2012 Jul 18;103(5):e353-8.
32. Annunziata K et al. Vaccination rates among the general adult population and high-risk groups in the United States. *PLoS One*. 2012;7(11):e50553.

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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.

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