****Updated October 2015****

MarketVIEW: Norovirus vaccines (CAT: VAMV015)

Product Name	:	**MarketVIEW:** Norovirus vaccines
Description	:	Global vaccine commercial opportunity assessment
Contents	:	Executive presentation + 1 forecast model
Therapeutic Area	:	Novel vaccines
Publication date	:	October 2015
Catalogue No	:	VAMV015

Background

Noroviruses (NVs) called “Norwalk-like viruses” are a group of single-stranded positive sense RNA viruses and members of the family *Caliciviridae*. NVs are transmitted from human-to-human and are one of the most highly infectious viruses known. In the community, NVs most commonly cause a self-limiting mild disease of short duration with gastrointestinal symptoms usually resolving after 1 to 3 days. However, it is the sheer volume of infections and burden on healthcare systems that presents the biggest challenge. In the US, which does not yet have active national surveillance, norovirus infections may account for an estimated 1.8 million outpatient visits, 400,000 emergency department visits, 56,000–71,000 hospitalizations and 570–800 deaths. NV outbreaks are also a well-known issue for military installations and commercial cruise ship liners.

A key question for vaccine manufacturers is whether norovirus will be the next rotavirus, and so a commercial opportunity for future development. Presently there is only one known norovirus active program being developed by Takeda Pharmaceuticals currently in Phase II testing.

This **MarketVIEW** product is a comprehensive MS Excel-based model + summary presentation which forecasts the potential commercial value of Norovirus across major Western and emerging markets to 2035. The model contains value ($ m) and volume (mio doses) predictions along with launch timeframe, TPP, pricing and penetration estimates. **LO/BASE/HI** forecast scenarios are included based upon the level of populations targeted by a potential vaccine.

Methodology

VacZine Analytics has closely monitored all significant source material pertaining to norovirus epidemiology/vaccines and. 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 travel and nosocomial vaccines has also been utilised.

PRODUCT CONTENTS:

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

Contents – Summary presentation (MS PowerPoint based)

Continued…..

PAGES: 64 MS PowerPoint slides, fully referenced/sourced. Available in .pdf form

Contents – Vaccine demand model (MS Excel-based)

Continued…..

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BIBLIOGRAPHY:

1) Tallant A. et al. Relative cost-effectiveness of a norovirus vaccine in the deployed military setting compared to a vaccine against Campylobacter sp., ETEC, and Shigella sp. Vaccine. 2014 Sep 8;32(40):5156-62.
2) National Center for Health Statistics Health, United States, 2008 With Chartbook Hyattsville, MD: 2009. Table 107. Nursing home residents 65 years of age and over, by age, sex, and race: United States, selected years 1973–2004.
3) Cruise Lines International Association. State of the Industry presentation. 2014. Available at: http://www.cruising.org/sites/default/files/pressroom/PressConferencePresentation.pdf. Accessed: September 2014
4) 2011 Market Profile Study. Available at: http://cruising.org/pressroom-research/market-research. Accessed: September 2014.
5) Bartsch SM et al. The potential economic value of a human norovirus vaccine for the United States. Vaccine. 2012 Nov 19;30(49):7097-104.
6) Hall AJ. Noroviruses: the perfect human pathogens? J Infect Dis. 2012 Jun;205(11):1622-4
7) PHE Monthly National Norovirus Report. Summary of surveillance of norovirus and rotavirus. Available at: http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1287143931777. Accessed: September 2014.
8) Vinje, J., Advances in Laboratory Methods for Detection and Typing of Norovirus. J Clin Microbiol, 2015. 53(2): p. 373-381
9) Ahmed, S.M., et al., Global prevalence of norovirus in cases of gastroenteritis: a systematic review and meta-analysis. Lancet Infect Dis, 2014
10) Hall AJ et al. Norovirus disease in the United States. Emerg Infect Dis. 2013 Aug;19(8):1198-205.
11) Desai R et al. Severe Outcomes Are Associated With Genogroup 2 Genotype 4 Norovirus Outbreaks: A Systematic Literature Review. Clin Infect Dis. 2012 July 15; 55(2): 189–193
12) Ahmed SM et al. Global prevalence of norovirus in cases of gastroenteritis: a systematic review and meta-analysis. Lancet Infect Dis. 2014 Aug;14(8):725-30.
13) Patel MM et al. Systematic literature review of role of noroviruses in sporadic gastroenteritis. Emerg Infect Dis. 2008; 14:1224–31.
14) Tate JE et al. 2008 estimate of worldwide rotavirus-associated mortality in children younger than 5 years before the introduction of universal rotavirus vaccination programmes: a systematic review and meta-analysis. Lancet Infect. Dis. 2012;12:136.
15) Lopman B et al. US Centers For Disease Control and Prevention. Global Burden of Norovirus and Prospects For Vaccine Development. August 2015
16) Payne DC et al. Norovirus and medically attended gastroenteritis in U.S. children. N Engl J Med. 2013 Mar 21;368(12):1121-30.
17) MMWR. Reduction in Rotavirus After Vaccine Introduction --- United States, 2000—2009. October 23, 2009 / 58(41);1146-1149.
18) Junquera CG et al. Prevalence and clinical characteristics of norovirus gastroenteritis among hospitalized children in Spain. Pediatr Infect Dis J. 2009 Jul;28(7):604-7.
19) Oldak E et al. Norovirus infections in children under 5 years of age hospitalized due to the acute viral gastroenteritis in northeastern Poland. Eur J Clin Microbiol Infect Dis. 2012 Apr;31(4):417-22.
20) Bert F et al. Norovirus Outbreaks on Commercial Cruise Ships: A Systematic Review and New Targets for the Public Health Agenda. Food Environ Virol. 2014 May 17.
21) CDC. Vessel Sanitation Program. Outbreak Updates for International Cruise Ships. Available at: http://www.cdc.gov/nceh/vsp/surv/GIlist.htm. Accessed: September 2014.
22) Vega E et al. Genotypic and epidemiologic trends of norovirus outbreaks in the United States, 2009 to 2013. J Clin Microbiol. 2014 Jan;52(1):147-55.
23) CDC. Norovirus in Long-Term Care and Other Healthcare Facilities. Available at: http://www.cdc.gov/features/dsNorovirus/. Accessed: September 2014.
24) Trivedi TK et al. Hospitalizations and mortality associated with norovirus outbreaks in nursing homes, 2009-2010. JAMA. 2012 Oct 24;308(16):1668-75.
25) Harris JP et al. The development of Web-based surveillance provides new insights into the burden of norovirus outbreaks in hospitals in England. Epidemiol Infect. 2014 Aug;142(8):1590-8.
26) Seasonal influenza vaccine uptake. Available at: https://www.gov.uk/government/publications/seasonal-influenza-vaccine-uptake-in-healthcare-workers-winter-2012-to-2013. Accessed: September 2014.
27) Influenza Vaccination Coverage Among Health-Care Personnel — United States, 2012–13 Influenza Season. Morbidity and Mortality Weekly Report (MMWR). September 27, 2013 / 62(38);781-786
28) Norovirus. Diagnostic Methods. US Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/norovirus/lab-testing/diagnostic.html. Accessed October 2015
29) Levine, M.M. and R.M. Robins-Browne, Factors that explain excretion of enteric pathogens by persons without diarrhea. Clin Infect Dis, 2012. 55 Suppl 4: p. S303-11.
30) Atmar, R.L., et al., Norwalk virus shedding after experimental human infection. Emerg Infect Dis, 2008. 14(10): p. 1553-7.
31) Lindesmith, L., et al., Human susceptibility and resistance to Norwalk virus infection. Nat.Med., 2003. 9(5): p. 548-553.
32) Graham, D.Y., et al., Norwalk virus infection of volunteers: new insights based on improved assays. J.Infect.Dis., 1994. 170(1): p. 34-43

33) Atmar, R.L., et al., Norovirus vaccine against experimental human Norwalk Virus illness. N Engl J Med, 2011. 365(23): p. 2178-87.
34) Porter, C.K., et al., Postinfectious gastrointestinal disorders following norovirus outbreaks. Clin Infect Dis, 2012. 55(7): p. 915-22.
35) Mearin, F., Editorial: From the acute infection to the chronic disorder "Don't worry it's just a viral gastroenteritis". Am J Gastroenterol, 2012. 107(6): p. 900-1.
36) Zanini, B., et al., Incidence of post-infectious irritable bowel syndrome and functional intestinal disorders following a water-borne viral gastroenteritis outbreak. Am J Gastroenterol, 2012. 107(6): p. 891-9.
37) Spiller, R. and K. Garsed, Postinfectious irritable bowel syndrome. Gastroenterology, 2009. 136(6): p. 1979-88
38) Marshall, J.K., et al., Postinfectious irritable bowel syndrome after a food-borne outbreak of acute gastroenteritis attributed to a viral pathogen. Clin Gastroenterol Hepatol, 2007. 5(4): p. 457-60.
39) Huang, P., et al., Spike protein VP8* of human rotavirus recognizes histo-blood group antigens in a type-specific manner. J Virol, 2012. 86(9): p. 4833-43.
40) Marionneau, S., et al., Norwalk virus binds to histoblood group antigens present on gastroduodenal epithelial cells of secretor individuals. Gastroenterology, 2002. 122(7): p. 1967-77.
41) Lindesmith, L., et al., Human susceptibility and resistance to Norwalk virus infection. Nat.Med., 2003. 9(5): p. 548-553.
42) Treanor, J.J., et al., A novel intramuscular bivalent norovirus virus-like particle vaccine candidate -reactogenicity, safety, and immunogenicity in a phase 1 trial in healthy adults. J Infect Dis, 2014. 210(11): p. 1763-71.
43) Wyatt, R.G., et al., Comparison of three agents of acute infectious nonbacterial gastroenteritis by cross-challenge in volunteers. J Infect Dis, 1974. 129(6): p. 709-14.
44) Baron, R.C., et al., Serological responses among teenagers after natural exposure to Norwalk virus. J.Infect.Dis., 1984. 150(4): p. 531-534.
45) Phillips, G., et al., Community incidence of norovirus-associated infectious intestinal disease in England: improved estimates using viral load for norovirus diagnosis. Am J Epidemiol, 2010. 171(9): p. 1014-22
46) Pelosi, E., et al., The seroepidemiology of genogroup 1 and genogroup 2 Norwalk-like viruses in Italy. J.Med.Virol., 1999. 58(1): p. 93-99.
47) Simmons, K., et al., Duration of immunity to norovirus gastroenteritis. Emerg Infect Dis, 2013. 19(8): p. 1260-7.
48) Reeck, A., et al., Serological Correlate of Protection against Norovirus-Induced Gastroenteritis. J Infect Dis. 202(8): p. 1212-8
49) Ramani, S., et al., Mucosal and Cellular Immune Responses to Norwalk Virus. J Infect Dis, 2015.
50) Debbink K, Lindesmith LC, Baric RS. The state of norovirus vaccines. Clinical Infectious Diseases. 2014;58(12);1746-1752
51) Status of Vaccine Research and Development for Norovirus Prepared for WHO PD-VAC. Available at: http://www.who.int/immunization/research/meetings_workshops/Norovirus_VaccineRD_Sept2014.pdf. Accessed September 2014
52) Vomiting-Bug Vaccine Seen as Shot in the Arm for Cruises. Jun 27, 2013. Available at: http://www.bloomberg.com/news/2013-06-25/vomiting-bug-vaccine-seen-as-shot-in-the-arm-for-cruises.html. Accessed: September 2014.
53) Bernstein DI et al. Norovirus vaccine against experimental human GII.4 virus illness: a challenge study in healthy adults. J Infect Dis. 2014 Sep 9. pii: jiu497. [Epub ahead of print]
54) Takeda Highlights Data from Clinical Trial of Investigational Norovirus Vaccine Candidate. October 7, 2013. Available at: http://www.takeda.com/news/2013/20131007_6021.html. Accessed: September 2014
55) Simmons K et al. Duration of immunity to norovirus gastroenteritis. Emerg Infect Dis. 2013 Aug;19(8):1260-7.
56) Tamminen K et al. Trivalent combination vaccine induces broad heterologous immune responses to norovirus and rotavirus in mice. PLoS One. 2013 Jul 26;8(7):e70409.
57) Debbink K et al. Chimeric GII.4 Norovirus Virus-Like-Particle-Based Vaccines Induce Broadly Blocking Immune Responses. J Virol. 2014 Jul 1;88(13):7256-66.
58) Nasal spray could protect against norovirus. Available at: http://www.telegraph.co.uk/science/science-news/9088259/Nasal-spray-could-protect-against-norovirus.html. Accessed: September 2014.

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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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