



VacZine Analytics

Bringing life to vaccine strategy...

OpportunitySCAN

Clostridium difficile

August 2008

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Authors Note

This **OpportunitySCAN** product is a qualitative commercial assessment focused on potential vaccine(s) for the management of infections caused by ***Clostridium difficile*** (CDI or CDAD). The product is part of a series and should be used in conjunction with related **DiseaseINFOPACK** (CAT: VADIP001) and **MarketVIEW** (CAT: VAMV001) products which focus on disease dynamics and quantitative elements of the commercial analysis respectively.


International experts in *Clostridium difficile* infections (US + EU) were consulted as part of this research study.

Bibliography

1. Redelings MD et al. Increase in *Clostridium difficile*-related mortality rates, United States 1999-2004. Emerg Infect Dis; 2007;13: 1417-1419
2. *Clostridium difficile*. DiseaseINFOPACK by VacZine Analytics. Published August 2008
3. US Centers For Disease Control and Prevention (CDC) www.cdc.gov (accessed September 2007)
4. Results of the first year of mandatory *Clostridium difficile* reporting: Jan to Dec 2004. CDR Weekly 2005; 15(34):1-3
5. Lai KK et al. *Clostridium difficile* associated diarrhea: Epidemiology, risk factors and infection control. Infect Control Hosp Epidemiol. 1997;18:628-623
6. Barbut F et al. ESCMID Study Group on *Clostridium difficile* (ESGCD). A European Survey of Diagnostic methods and testing protocols for *Clostridium difficile*. Clin Microbiol Infect 2003;9:989-96
7. Gerding D.. Metronidazole for *Clostridium difficile*-associated disease: Is it Okay for Mom? Clin Infect Dis. 2005;40:1598-1600
8. Louie TJ. Tolevamer, a novel non-antibiotic polymer, compared to vancomycin in the treatment of mild to moderately severe CDAD. CID 2006;43: 411-420
9. Gerard L. Rifaximin: a non-absorbable rifamycin antibiotic for use in non-systemic gastrointestinal infections. Expert Rev Anti Infect Ther 2005;3 201-11
10. Jodlowski TZ. Emerging Therapies in the Treatment of *Clostridium difficile* Associated Disease. Ann Pharmacother. 2006; 40(12):2164-2169
11. Credito KL et al. Activity of OPT-80, a Novel Macrocyclic, Compared eight other agents against selected Anaerobic Species. Anti Age and Chem Nov 2004; 4430-4434
12. Warny M et al. Toxin production by an emerging strain of *Clostridium difficile* associated with severe disease in North America and Europe. Lancet. 2005;366:1079-1084
13. Kyne L et al. Asymptomatic Carriage of *Clostridium difficile* and serum levels of IgG antibody against toxin. N Engl J Med 2000;342:390-397
14. Kyne L et al. Association between antibody response to toxin A and protection against recurrent *Clostridium difficile* diarrhea. Lancet 357:189-193
15. Ghose et al. Transcutaneous immunization with *Clostridium difficile* toxoid A induces systemic and mucosal immune responses and toxin A-neutralising Antibodies in mice. Infection and immunity 2007; 75(6):2826-32
16. Acambis company press release. Available at: www.acambis.com. Accessed August 2008.
17. Jodlowski TZ. Emerging therapies in the treatment of *Clostridium difficile* associated disease. Ann Pharmacother. 2006; 40(12):2164-2169
18. Corthier G., et al. Protection against pseudomembranous colitis in gnotobiotic mice by use of mAbs against *Clostridium difficile* toxin A. Infect Immun 1991; 59:1192-5
19. At the time of writing this report, August 2008
20. Q2 2007 Acambis PLC Conference Call – Final, Voxant FD (Fair disclosure) Wire, 25 September 2007
21. De Frances CJ. et al. 2004 National Hospital Discharge Survey. US Department of Health and Human Services. Advance Data 2006; No 371
22. Opinion Leader Estimates. Raveh. D et al. Longitudinal surveillance of antibiotic use in the Hospital. Q J Med 2001; 94:141-152
23. Estimates from VacZine Analytics, Opinion leader research 2007
24. 33% of CDAD cases classified as “severe complicated disease” by Opinion leader research.
25. US Centers For Disease Control (CDC) www.cdc.gov (accessed September 2007). Confirmed by opinion leader research.
26. De Frances CJ. et al. 2004 National Hospital Discharge Survey. US Department of Health and Human Services. Advance Data 2006; No 371
27. O'Connor KA et al. 2004. Antibiotic prescribing policy and *Clostridium difficile* diarrhea. Q J Med 2004; 97:423-429

About VacZine Analytics:

VacZine Analytics is a brand new research consultancy based in the United Kingdom. Its aim is to provide high quality-disease and commercial analysis to those working within or in collaboration with the vaccine industry.

-  With our product lines:
 - DiseaseINFOPACK
 - OpportunitySCAN
 - MarketVIEW
 - ExpertREACT
 - VaccineSTATS

Our key focus is helping clients to build the case for developing new vaccines.

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VacZine Analytics

Bringing life to vaccine strategy...

www.vacZine-analytics.com

Warren House

Bells Hill

Bishops Stortford

Herts

CM23 2NN

United Kingdom

Tel. +44 (0) 1279 654514

e-mail: info@vacZine-analytics.com

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