DiseaseINFOPACK: Clostridium difficile (CAT: VADIP001)

Proposal No/#PO : [Enter client specific #PO]
Product Name : Comprehensive review/analysis of Clostridium difficile associated disease (DiseaseINFOPACK)
Project Initiation Date : n/a
Billable days : n/a
Initiator(s) : [Enter client name, function and address]

Therapeutic Area : Clostridium difficile/antibiotics
Product (if applicable) : CAT No: VADIP001, published/updated November 2008

Background

Clostridium difficile (C.diff) is a Gram-positive bacterium, which in vulnerable hospitalized patients can cause gastrointestinal infections (CDAD). Outcomes range from mild uncomplicated diarrhea to severe-complicated disease where patients experience fever, tachycardia and psuedomembranous colitis. Risk factors for C.diff infections are >65 yrs of age, hospitalization, severe underlying illness coupled with chronic antibiotic therapy.

Although CDAD can be managed usually by stopping antibiotic therapy or the use of metronidazole and vancomycin treatment, patient mortality can still reach 6-30%1. In some patients with toxic megacolon who require surgical intervention or colectomy, mortality can reach even higher rates of 35-50%. In the UK, C.diff is estimated to have been a factor in the death of over 3000 people in 2005 (ONS Figures) with numbers often exceeding MRSA related deaths. Clostridium difficile can also cause hospital outbreaks associated with ward closures and high economic cost.

In the US, the Centers for Disease Control and Prevention (CDC) estimates that 400-500,000 cases of CDAD occurred in 2004 where incidence is estimated at 10-200 cases per 10,000 admissions2. More significantly, previous research conducted by VacZine Analytics3 with international opinion leaders indicates that they believe the incidence of CDAD is increasingly year-on-year in their countries. This dynamic coupled with increasing disease severity and a lack of newer treatments has prompted the search for newer antibiotics and biologic based strategies including prophylatic vaccines/passive monoclonals.

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3 VacZine Analytics. Clostridium difficile. DiseaseINFOPACK (CAT No: VADIP001) and OpportunitySCAN (CAT No: VAOPS001), previously published August 2008
Canada mortality
Canada – economic impact
Epidemiology: surveillance (Europe)*
Epidemiology: EU incidence – overview
EU – ribotype 027
EU – morbidity/mortality overview
EU – economic impact
England – surveillance
England – mortality
England – ribotype 027
France – surveillance
France incidence and mortality
France – ribotype 027
Germany – surveillance
Germany – incidence and mortality
Germany – ribotype 027
Spain surveillance
Spain – incidence and mortality
Italy – surveillance
Disease trends and dynamics
Forecasting US/EU case numbers
Increasing severity
Reasons for increased severity
Key issues and challenges
Establishing key unmet needs in CDAD
Current R&D pipeline – CDAD treatments
Expert viewpoints: emerging treatments
A C.diff vaccine is currently in development^*^ For an in depth analysis of the C.diff active vaccine opportunity please refer to products CAT Nos: VAOPS001 and VAMV001

APPENDIX: 

PAGES: >100 powerpoint slides, fully referenced/sourced

PROJECT METHODOLOGY:

VacZine Analytics has conducted a comprehensive secondary research to review all available information regarding Clostridium difficile in major EU/Canada and US markets. Source materials used are literature articles, government websites, medical bodies and associations, conference proceedings etc.

Published research from VacZine Analytics has also been utilised.

**NOTE*** International global opinion leaders/experts in CDI were interviewed as part of this research. Their contribution is anonymous.
PRODUCT COST:

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

- **USD $8995.00/ GBP £5995.00 (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 orders@vaczine-analytics.com
This report can also be purchased on-line. Please review the TERMS and CONDITIONS of purchase.

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**BIBLIOGRAPHY:**

15. 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
18. Credito KL et al. Activity of OPT-80, a Novel Macrocycle, Compared eight other agents against selected Anaerobic Species.


Cheknis, AK et al. Epidemic BI/NAP1 is the Dominant Strain of Clostridium difficile Found in Patients in the OPT-80 vs.


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the emergence of NAP1/027. Am J Gastroenterol. 2007 Dec;102(12):2781-8
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.

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About VacZine Analytics:

VacZine Analytics is a new 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

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