Clostridium difficile – vaccines must be part of future action plan.

LONDON, UK----05 December 2007----ExpertREACT. New studies released by the strategic research consultancy, **VacZine Analytics** suggest that a vaccine could be the most effective weapon against *Clostridium difficile*, the dangerous hospital "super-bug".

New research from **VacZine Analytics** recommends that vaccines alongside other non-antibiotic strategies must be prioritized as part of any future action plan for *Clostridium difficile*. This is because experts believe disease frequency will continue to increase and consider current infection control policies insufficient. The research also calculates that there is enough economic incentive to pursue a vaccine approach, which is predicted to be a blockbuster opportunity (>$1 bn peak yearly revenues).

Clostridium difficile (C.diff) is a Gram-positive bacterium, which can harmlessly colonize the gut of humans. Colonization with C.diff does not always cause disease except in people that are mainly older than 65 years and have undergone intensive antibiotic therapy. This population, which resides mainly in the hospital, has colonization rates of 30-40% because the normal flora of the gut is diminished allowing C.diff to flourish.

In vulnerable patients C.diff can cause disease by producing toxins that cause inflammation and colitis. Outcomes range from mild diarrhea to severe-complicated disease where patients experience fever, tachycardia and psuedomembranous colitis. Mortality rates can reach 6-30%. In some patients with toxic megacolon who require surgical intervention or colectomy, mortality can reach 35-50%.

As part of the research, leading experts agreed that C.diff had now joined MRSA in being one of the most serious hospital infections they faced. Of major concern was that experts had seen dramatic rises (10-20% per annum) in the rates of C.diff and associated increases in disease severity. These observations were in agreement with official trends released from the US Centers of Disease Control and Prevention (CDC) and UK Health Protection Agency (HPA). Although some experts were hopeful C.diff incidence could be reduced, others saw no reason why the problem would decrease without radical developments in prevention. An aging population, continued high use of antibiotics and a new strain of C.diff (027/Nap1) were cited as key drivers behind the current "epidemic".

C.diff disease is currently treated with two antibiotics, vancomycin and metronidazole. Both treatments are mostly effective but around 20% of patients suffer disease recurrence and must undergo repeat treatment. Failure rates after pretreatment increase to 30-50% with some patients then suffering multiple relapses. Experts agreed that the need for new strategies was highest in this group but when questioned about emerging drug treatments did not expect any great changes in the next 1-3 years. They suggested that biotherapeutics rather than antibiotics were the way forward.

Inability to prevent disease is also key challenge with C.diff, hence notable hospital outbreaks in the UK and US. If a form of primary prophylaxis, was effective it would then also reduce the rate of recurring disease. Experts indicated that there are some future possibilities with the toxin-binding agent; Tolevamer (Genzyme) or probiotic agents, but a prophylatic vaccine appeared the strongest option. Evidence in the scientific literature has linked a patient's ability to mount an immune response to C.diff toxins with improved clinical outcome. This important finding suggests a vaccine approach is feasible. However, the vaccine concept will only be effective if individuals are protected before they are at greatest risk of C.diff infection e.g. on hospitalization.

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Dr John Savopoulos who led the research commented, “after modelling different scenarios with experts, the most logical option would be to vaccinate people at highest risk in community so when they enter the hospital they are protected or further boosted. This could be done alongside pneumococcal or influenza vaccines”. **Dr Savopoulos** further stated, “because the number of vulnerable people is growing, even taking conservative estimates of coverage we estimate the opportunity to be around 20 million doses per annum at peak ”

Currently the vaccine company Acambis have the only C.diff vaccine in development (Phase I). Based on the high profile and unmet medical need associated with C.diff it is likely other companies will soon consider vaccine approaches.

For more information about this research please visit www.vacZine-analytics.com
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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.