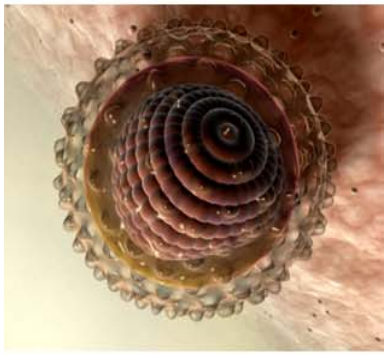
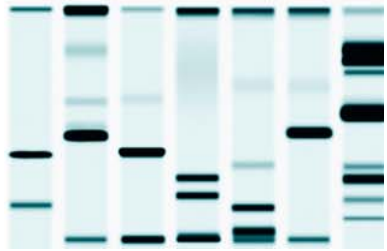
48th Annual ICAAC/IDSA, Washington DC – vaccines update





LONDON, UK----30 October 2008----ExpertREACT. At the recent 48th Annual ICAAC/IDSA, Washington DC vaccine companies released data on many differing fronts. Wyeth prepared the ground for their new 13-valent *pneumococcal* vaccine, while Merck & Co and GSK positioned in rotavirus. Novartis Vaccines gave background to *N.meningiditis* and Sanofi released data on their high-dose influenza vaccine in elderly.

Every year the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) brings together thousands of attendees from around the globe to discuss up-to-date findings on the diagnosis, treatment and management of numerous infectious diseases. This year the conference, also partnered with the Infectious Disease Society of America (IDSA) gave a good focus on disease prevention with active and passive immunological approaches being covered by both the private and public sector.

For vaccines used to prevent invasive pneumococcal disease (IPD), especially Wyeth's Prevnar (PCV-7), a number of posters concentrated on various aspects of the vaccine's impact since its introduction to the routine infant schedule around the globe. It is now well documented that Prevnar has dramatically reduced the incidence of IPD due to PCV-7 serotypes most markedly in children younger than 2 yrs. During a slide session given by representatives of the US CDC **(1),** estimations were made that PCV-7, since its introduction has prevented 210,000 cases of IPD and saved approximately 14,000 lives of which around 50% were in adults. Due to herd immunity, PCV-7 has effected a ~92% reduction of IPD in the elderly although there has been an observed increase in non-vaccine serotypes, mainly 19A.

For new pneumococcal vaccines, Wyeth released Phase III data suggesting their follow-on product 13-valent Prevnar (PCV-13) may broaden protection against IPD in children younger than 2 **(2).** The company, which has conducted 13 core studies to support regulatory filing of PCV-13 prospectively compared PCV-13 immunogenicity data to PCV-7 in infants (Germany, UK and Poland) and found the vaccine response was non-inferior to PCV-7 also eliciting functional antibodies for all 13 serotypes. Wyeth expect to complete US filing for pediatric use of the vaccine in the first quarter of 2009 and are also studying the vaccine in adults (Phase III). However, with such a large impact of PCV-7 on adult disease, some observers at ICAAC commented on the positioning of PCV-13 in this group and potential impact on serotype dynamics. Counter to this challenge, a poster also presented at the conference suggested that a significant burden of adult disease will remain even after 6 years of PCV-7 vaccination in US children **(3).**

Another noticeable aspect of vaccine data released at ICAAC, independent and company-sponsored, was the impact of new rotavirus vaccines on US disease burden with around 25 recorded abstracts covering the topic. Back in 2006, Merck & Co heralded the return of rotavirus vaccines with ROTATEQ (G1, G2, G3, G4 and G9). According to the company the vaccine had penetrated ~60% of the US birth cohort **(4)** and sold an impressive $586m in 2007**.** However, CDC data from six sentinel immunization information systems (IIS) monitoring vaccine uptake, presented at ICAAC, suggested that coverage with the full 3-dose vaccine was as low as 27%-45% at 7 months of age and 18%-32% at 13 months of age. Although the authors state that by the end of 2007, >10 million doses of rotavirus vaccine had been distributed, it seems there is more work to be done in terms of increasing coverage, at least in terms of compliance beyond the first dose. This observation, along with emerging data in pre-term infants might favor GSK Biologicals whose Rotarix is a two dose vaccine (G1, G3, G4 and G9).

Beyond issues of compliance to rotavirus vaccines, it is clear that the rollout is having a dramatic impact on disease incidence. According to data generated in a new US observational study, Merck & Co state that ROTATEQ reduced rotavirus related hospitalizations and ER visits by 100 percent during the 2007 and 2008 seasons **(5).** The same impact, albeit at a lower percentage range was also reported in a range of abstracts from around the US at the state and national level.

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In new *N.meningiditis* vaccines, Novartis Vaccines held a satellite symposium covering the global burden on meningococcal disease directed to setting the scene for their new serogroup B and ACWY vaccines in development. Again the company presented the safety and immunogenicity Phase III data of Menveo (MenACWY-CRM) vaccine in adults versus licensed Menactra (Sanofi Pasteur). Although the company claims the immunogenicity data is superior to Menactra, one month post dosing it was stated that this is not proven to translate into enhanced protection. Comments were raised about the longer term trends of antibody persistence and the observations that the differences in geometric mean titres (GMTs) were not substantial.

Lastly, in influenza vaccines, the most significant data released was from dominant flu vaccine supplier Sanofi Pasteur with their high-dose influenza vaccine **(6).** The company released data from a Phase III study of around 4,000 elderly people, >65yrs indicating that after 28 days serum hemagglutination inhibition (HAI) titres in vaccinees who received the higher dose were significantly higher than standard vaccine. This effect has the potential to translate to better protection against disease. It is well documented that that majority of influenza related deaths occur in the elderly group hence manufacturer efforts to reposition in the segment with claims of higher efficacy. **VacZine Analytics** has previously stated that the Sanofi strategy of pursuing non-adjuvanted approaches for the US market is far less risky than Novartis Vaccines (Fluad, MF-59) and GSK Biologicals (MPL-based "improved flu"). Both MF-59 and MPL adjuvants, although having EU approval, are not expected to be approved in the US in near-term.

References:

1) C.G. Whitney et al. Long-term effect of 7-valent Pneumococcal conjugate vaccine (PCV-7) use on invasive pneumococcal disease in the US. Slide Session 49(G), Presentation G-761. 48th ICAAC/IDSA, Washington DC, USA, October 25-28th 2008

2) Wyeth Vaccines. News Release. ICAAC/IDSA, Washington DC, USA, October 25-28th 2008

3) Snedecor., SJ et al. Significant disease burden to remain in elderly US adults 6 years after introduction of PCV-7 in young children. Poster G-2077, 48th ICAAC/IDSA, Washington DC, USA. October 25-28th 2008

4) Merck & Co company presentation. Available at http://media.corporate-ir.net/media_files/irol/73/73184/ABB07/ABB_2007_GHH.pdf (Accessed: February 2008)

5) Merck & Co News Release. ROTATEQ Substantially Reduced Rotavirus-related Hospitalizations and ER visits combined in New U.S. Observational Study. ICAAC/IDSA, Washington DC, USA, October 25-28th 2008

6) Sanofi Pasteur. News Release. High-Dose influenza Vaccine shows Increased Immune Response Among 65 years of Age and Older. ICAAC/IDSA, Washington DC, USA, October 25-28th 2008

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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.

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