

The vaccine movers and shakers of 2008 – looking towards 2009/10.

LONDON, UK----12 December 2008----ExpertREACT. Early signs indicate that the vaccine industry continues to experience year-on-year revenue growth with 2008 predicted to exceed 2007. Unsurprisingly, Merck & Co's Gardasil (HPV vaccine) and Wyeth's Prevnar (PCV-7) are the best selling vaccines each achieving well over \$1 bn in revenues so far. However, with US sales of Gardasil already flattening, it will be of interest to observe Merck & Co's international strategy. This, in addition to the launch of new *pneumococcal* and *meningococcal* vaccines is expected to initiate a new phase of industry growth in 2009/2010.

In 2008, the vaccine industry continued to power ahead. According to our calculations up until the end of the third quarter of this year, the top 5 companies sold nearly \$13 bn* of vaccines, which was more than the whole year in 2006. If the top 5 companies experience the same sales revenue in Q4 2008 relative to Q3 as they did in 2007, we predict the full year 2008 figures will be in the order of \$16.4 bn. This figure is even higher if taking into account the growing sales of SPMSD, the joint venture between Merck & Co and Sanofi Pasteur which is responsible for the sales of certain vaccine products in the European region. At this early stage it is likely the full 2008 year sales will exceed 2007.

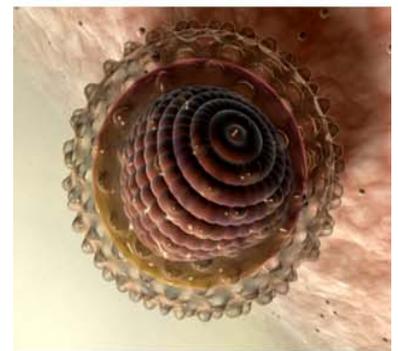
Aside from pediatric combinations, unsurprisingly the top selling vaccine products so far in 2008 include the human papilloma virus (HPV) vaccine Gardasil developed by Merck & Co and Wyeth's *pneumococcal* vaccine, Prevnar (PCV-7, launched in 2000). So far Merck & Co state they have sold an estimated 30 million doses of Gardasil. In 2008, the product has generated over \$1 bn in US sales (to Q3 2008) but is also growing strongly in the EU region (1). Whereas in 2007 sales of Gardasil in the EU were less than a third of US sales; by the end of 2008 they could reach almost 70% of the US total as the company won further EU government tenders in France, Germany and Belgium. Although Gardasil is aiming for 2 supplementary filings in the US for use in adult women to 45 and males, these are considered challenging segments. To achieve growth, Merck & Co must continue to internationalize the product rapidly before GSK Biologicals gains further tenders with Cervarix (bivalent HPV vaccine). Cervarix notably won the UK governmental contract back in June 2008 (2) suggesting the product can compete in the major markets despite its lower coverage and novel MPL adjuvant. Interestingly Merck & Co has recently stated that they are developing a nine-valent HPV vaccine (V503) to provide broader HPV disease coverage. The company state that the V503 Phase III clinical program is underway and they anticipate a filing with the FDA in 2012 (3). Because HPV vaccines are a proven market place, a number of companies are now also pursuing HPV vaccines, some with a planned therapeutic mode of action. Three vaccines are in clinical trials (Nventa, Virionics and VGX). Other companies with active preclinical programs include Genvax, Transgene, and Large Scale Biology Corporation (4).

Wyeth's *pneumococcal* vaccine, Prevnar (PCV-7, launched in 2000) continues to sell strongly gaining ~\$2.1bn so far in 2008 (to Q3). Prevnar (Prevenar), now a fully mature product, initially recorded strong US sales but now derives more revenues from outside the US with inclusion on 31 national immunization programs (as of November 2008). For example, recently the company gained a national immunization program (NIP) tenders in South Africa and earlier, in Cyprus and Ireland. Wyeth also recently submitted its European marketing authorization for its wider coverage 13-valent vaccine in infants and young children (5) based on the data from 12 Phase 3 studies (7,000 subjects). Approval and launch of PCV-13 could be as early as next year making Wyeth's immediate goal to promote a switch from PCV-7 in higher income markets, ideally before GSK's Synflorix (10-valent vaccine) becomes gains a foothold. Bearing in mind the initial manufacturing problems with PCV-7, Wyeth has also taken steps to reassure the investment community that PCV-13 can be manufactured at all its existing facilities with top end estimates of 120 million doses production capacity (6).

The advancement of new *meningococcal* vaccines will also become a key area of focus in 2009 with the continued development of Novartis Vaccines' Menveo (MenACWY) and later the first predicted *meningococcal* B vaccine. Sanofi's incumbent conjugated quadrivalent vaccine, Menactra (MenACWY, MCV4) recommended for US teenagers, so far recorded 381 million Euros in the first nine months of 2008 (1). However, a recent MMWR survey indicated that MCV4 overall coverage among teens 13-17 yrs was as low as 32.4% in 2007, despite an improvement over the 2006 figure of 11.7% and the vaccine being only a single shot (7).

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Although there is clearly more work to be done driving MCV4 uptake in US teenagers, both Sanofi Pasteur and Novartis Vaccines are hoping the US ACIP will eventually recommend their vaccines for routine use in the infant group (<2 yrs) where a larger proportion of disease burden actually lies. Note, currently, MCV4 is only recommended in the 2-10 yrs group for children at heightened risk of invasive *meningococcal* disease.

Importantly, the addition of Menveo to the routine US schedule will involve another four vaccine doses per child; a step that may encounter resistance from parents concerned about over vaccination. Menveo is expected to be first available for the 11-55 yrs group in the EU in 2008/09. However, because serogroup Y disease is less prevalent in the EU than in the US, conjugate quadrivalent *meningococcal* vaccines are only relevant to pilgrims visiting the Haj at Mecca, Saudi Arabia. Historically, in this group the quadrivalent polysaccharide vaccines have been used despite some disadvantages regarding longevity of vaccine protection. It is clear that the real prize for Novartis Vaccines and possibly Sanofi Pasteur will be getting their product on the US routine infant schedule. If they succeed, along with PCV-13, these vaccines will contribute to a new phase of industry growth in the coming years.

*The top five companies are considered Merck & Co, Wyeth, GSK Biologicals, Sanofi Pasteur and Novartis Vaccines. SPMSD is a joint venture between Merck & Co and Sanofi Pasteur in the EU.

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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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