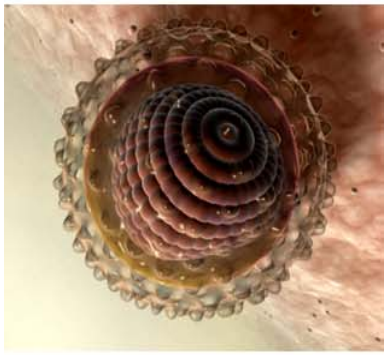
2012 – another year in the vaccine industry

LONDON, UK---11th December 2012----ExpertREACT. As another year of the vaccine industry draws to a close, once again **VacZine Analytics** reviews the major highlights for each of the major players* and looks towards 2013. 2012 was mostly a quiet year where companies battled against the impact of austerity measures and pushed on life cycle management initiatives. Novartis Vaccines stood out ending the year with a burst of 2 new product approvals one of which may shape significant newsflow in 2013.



Overall GSK's year in vaccines was lackluster with essentially flat sales and only "me too" product approvals in the *meningococcal* vaccine space coupled some headway in lifecycle management/data building to support its influenza (H5N1, QIV) and *pneumococcal* (Synflorix) vaccine franchises. In late October GSK had reported ~£2.5bn worth of vaccine sales with a 6% decline (at constant exchange rates) on the same period of 2011 (1). Corporate activity was also limited but with a notable agreement in March 2012 with Japan's Daiichi Sankyo Co., Ltd. to form a Joint Venture (JV) which was expected to create the number one vaccines company in Japan (2).

In *meningococcal* vaccines GSK's MenHibrix (Hib-MenCY-TT) was approved by the FDA in June 2012 and later in October 2012 received a limited recommendation for infants at an increased risk for *meningococcal* disease from the US Advisory Committee on Immunization Practices (ACIP). Previously MenHibrix had gained two FDA complete response letters. GSK's other new *meningococcal* vaccine: Quadrivalent Nimenrix (serogroups A, C, W-135 and Y) was also approved by the European Medicines Agency (EMA) earlier in April 2012. The company as of Q3 2012 stated that launches were underway in several countries throughout Europe including the UK, Germany and the Netherlands. As of Q3 2012 results Nimenrix had recorded an initial £1m sale(s) in the EU region. For 2013, GSK expects to receive approval for its Quadrivalent (QIV) influenza vaccine filed in both the US and EU (Spring 2012) and further progress of its Phase III candidates for MAGE-3 (melanoma and NSCLC) and Herpes Zoster (Shingles prophylaxis).

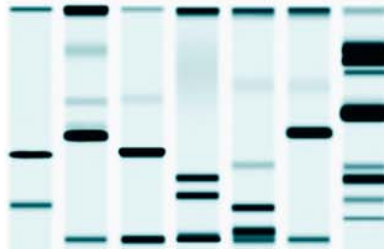
Undoubtedly the highlight (or some would argue lowlight) of major player Sanofi Pasteur's year was the release of data from a Phase IIb efficacy study of its live attenuated dengue vaccine (CYD-dengue) candidate announced back in July (3). The trial was conducted in 4,002 children aged 4 to 11 years in collaboration with Mahidol University in Ratchaburi province, Thailand. The vaccine (3 doses, 0, 6 and 12 mos) was shown to generate antibody responses against all four dengue virus serotypes however, evidence of protection was demonstrated against three of the four dengue virus serotypes. The full analysis of vaccine efficacy against each serotype, reflecting real-life conditions (intent to treat analysis) showed vaccine efficacy to be 61.2% against dengue virus type 1, 81.9% against type 3 and 90% against type 4. The vaccine was not efficacious against serotype 2.

Despite the limitation shown in the Phase IIb study Sanofi's dengue vaccine has shown clinical proof of concept (published (4)) and is being further investigated in large-scale phase III clinical studies with 31,000 children and adolescents in Latin America (Mexico, Colombia, Honduras, Puerto Rico and Brazil) and in Asia (the Philippines, Vietnam, Malaysia, Indonesia, and Thailand. The vaccine has also gained US FDA fast track designation. During 2013 and beyond the dengue vaccine's effectiveness in differing epidemiological settings will be elucidated thus determining its eventual adoption by regional policy makers and commercial value to Sanofi Pasteur. In any case, the program is a giant leap forward for control of dengue which reportedly can affect ~3 bn people worldwide.

Improving on GSK's performance, Sanofi Pasteur had a relatively flat year to Q3 2012 recording €1,481m 0.7% increase (at constant exchange rates) of vaccine sales although some US influenza sales have now extended into Q4 for the first time (5). Sanofi has 13 vaccines in R&D (Phase I to registration) and similar to GSK is also expecting approval of its QIV vaccine (Fluzone/QIV) in 2013.

Despite declining sales on 2011 and little coverage from its corporate parent Novartis Vaccines (so far) will end 2012 on a good note recovering from some issues with its seasonal influenza vaccines back in the autumn. Italian authorities put a temporary halt on distribution of Agrippal® and Fluad® manufactured in Italy due to the detection of small particles in the vaccines (6). Later other agencies Health Canada and SwissMedic took similar action. After further analytical testing all agencies then lifted their restrictions. The major US market where Novartis shipped 30m doses of Fluvirin for the 2012/2013 season remained unaffected.

Things took a positive turn in mid November when the *meningococcal* serogroup B vaccine (Bexsero®) (which was submitted for EU regulatory review approximately two years ago) finally received positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) (7). Bexsero® should receive full EU approval in 2013 after which it will closely monitored which EU countries adopt the vaccine into national immunization programs (NIPs) especially in the current challenging economic climate. Again in influenza vaccines Novartis Vaccines achieved another milestone in new product development by gaining FDA approval for the first cell culture derived seasonal influenza vaccine Flucelvax® (8). Flucelvax® is approved for adults >18 yrs and will become the 10th available vaccine in the US.



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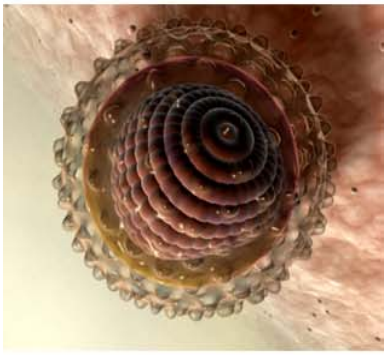
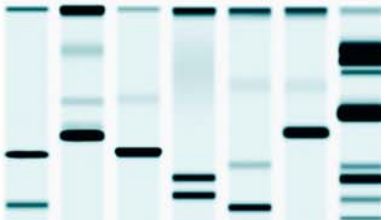
During 2012 Pfizer Vaccines continued its efforts to expand recommended usage of its top selling vaccine Prevnar-13 (PCV-13) into adult age groups in light of some hesitancy from the US ACIP earlier in June. In the US the vaccine is indicated for adults >50 yrs although the company has already submitted in the EU for the 18-49 yrs group based on demonstrating non-inferiority to the immune response observed in the 60-64 yrs group **(9)** Pfizer has gained FDA approval for >50 yrs *via* an accelerated approval pathway, WHO prequalification and also is investigating vaccine usage to prevent a first episode of community acquired pneumonia (CAP) in the CAPITA efficacy study. Positive data from the latter will likely cement the ACIP recommendation the company seeks in the critical US market. Similar to other US vaccine player Merck & Co, Pfizer did not report any significant events in 2012 regarding its new product development pipeline. As of November 8th – the company had 5 vaccines in development also including *meningococcal* serogroup B (Phase III).





***Top 5 companies:** GSK Biologicals, Sanofi Pasteur, Merck & Co, Pfizer (Wyeth) and Novartis Vaccines and Diagnostics.

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