

## Vaccine major players – Q3 2011 round up of results and R&D

**LONDON, UK-----7<sup>th</sup> November 2011-----ExpertREACT.** Provision of vaccines to the public is based on medical need but also increasingly economics. Although some companies have mentioned government austerity programs affecting their sales, the industry is on course to at least equal 2010 sales. Even without the \$3.5 bn from H1N1 vaccines.

According to our analysis, the vaccine major players\* sold around \$6.7 bn worth of vaccines in Q3 2011 and \$15.5 bn for the year so far. By comparing on a reported basis with the same time last year, the industry appears to be “resilient” with continued underlying growth. For the same three quarters of 2010, the industry recorded approximately \$16.9bn of sales; remember this contained \$3.5 bn of H1N1 monovalent vaccine sales. This **ExpertREACT** article will examine some of the current industry growth drivers for each major company.

In reported dollar terms, GSK sold \$1.83 bn (£1,142m) of vaccines in Q3 (1). In its results release GSK stated that its underlying vaccine sales, excluding pandemic flu, grew by 21%. Among the growth drivers was the bivalent HPV vaccine, Cervarix, which was benefiting from a national immunization program (NIP) in Japan. Cervarix is already close to doubling last year’s sales of \$375m, although it seems that the majority of its growth is attributable to a one time catch-up program of five cohorts as part of the Japanese program. Globally, the fact that the US ACIP has recently voted to expand HPV vaccination to adolescent boys (2) and coverage (of all 3 doses) within teenage girls appears to be low (~30%) (3) does suggest that HPV vaccines still have further potential. Most nations, over time, tend to harmonize with US vaccine recommendations although in challenging economic times, some governments may forego this additional measure for HPV. Indeed, GSK itself stated that for Cervarix that EU tenders were lowered and pricing seemingly under pressure. In other GSK vaccine news – Rotarix for the first 9 months of 2011 grew +49% accounting for its full return to market post the PCV-1 episode.

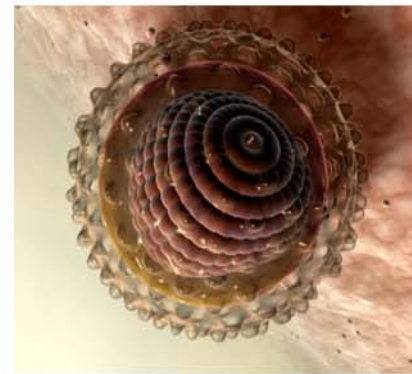
For Q3 2011 Sanofi Pasteur reported sales of €1,343m (4). Like GSK, the division was keen to show it was still growing despite the absence of monovalent H1N1 pandemic vaccine sales. Sanofi reported strong seasonal flu vaccine sales in Q3 of €602m with 48% of the total derived from the US market which received the majority of its supply by the end of quarter. Sanofi’s efforts to differentiate its influenza vaccine portfolio face some important milestones in the coming months. Fluzone High Dose (HD) and Intradermal (ID) will be closely monitored for their US performance in the new season, and the company’s quadrivalent strategy (QIV) has its first predicted US filing this time next year. With many more entrants into the influenza vaccine business, and rival GSK seemingly ahead in terms of adjuvantation (re: Pandemrix/adults) Sanofi’s strategy must pay off to hold dominance.

For its *meningococcal* vaccine, Menactra®, Sanofi uses the term “continued resilience” no doubt because of direct competition from Novartis’ Menveo® in the US. The recent US ACIP (Jan 2011) recommendation for a booster dose in adolescents (5) stimulates demand for both competitors. However, with Menactra® sales only down 2.4% on the year (€334) and Novartis reporting \$100m so far in 2011 Menveo®, Sanofi appears still in control. Although there is still no ACIP ruling on ACWY vaccines for infant immunization, GSK’s receipt of a second FDA complete response letter for its *meningococcal* and Hib combination vaccine candidate, MenHibrix again is potentially one less rival for Sanofi.

Novartis Vaccines and Diagnostics (NVS) sold \$655m in Q3 2011 (6). The company probably has been most affected by the absence of H1N1 monovalent sales which boosted 2010 figures by \$1.3bn. For seasonal influenza the company, which had already shipped 24m doses to the US, mentioned that overall volumes were trending lower with sales for the quarter down 24% compared to the prior year period.

As discussed earlier Novartis’ *meningococcal* franchise appears to be making headway with Menveo® and growth of meningococcal (menC) in emerging markets. The franchise awaits an all important EU decision on Bexsero® meningococcal serogroup B vaccine which was filed last year.

CONTINUED.....



**CONTINUED.....**

Aside from vaccine approval, for Bexsero® (and the Pfizer candidate) there have been some challenges, at least in the UK by the JCVI (7) which noted that the number of *meningococcal* serogroup B cases has declined from a peak in 2000/01 and remains low. Also the rate of serogroup B disease in teenagers is not as prominent as it was for serogroup C prior to vaccine introduction. Economic modeling studies also currently suggest that Bexero® is also unlikely to be cost effective at greater than £40 per dose.

Merck & Co reported strong growth of its HPV vaccine Gardasil (\$445m for Q3) (8). Similar to GSK, the company mentioned the new US ACIP recommendation regarding male HPV vaccination and demand from the Japan immunization program. Rotateq, like Rotarix was stronger than the previous year. Merck & Co will be conducting an R&D briefing on November 10<sup>th</sup> 2011 for which it is hoped the company has early stage pipeline replacement(s) to make up for its failed *Staphylococcus aureus* program (V710) developed in collaboration with Intercell AG. Merck still did pay a milestone to Intercell for V710.

Lastly, Pfizer reported vaccine sales of \$1104m for its PCV-7 and PCV-13 *pneumococcal* vaccines (9). This time last year PCV-13 sold approximately 4 times the amount of PCV-7. This quarter the ratio has increased to 10:1 indicating a rapid global switch to the enhanced product. Some of the major players have mentioned government austerity cuts affecting tender volumes and product pricing. It is possible Pfizer's drive to promote PCV-13 uptake happened just in time.

**\*\*\*NOT FOR UNAUTHORIZED COPYING AND DISTRIBUTION\*\*\***

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

**References and Notes:**

- 1) GSK Corporate Results. Q3 2011. 26<sup>th</sup> October 2011. Available at: [http://www.gsk.com/investors/quarterly\\_results.htm](http://www.gsk.com/investors/quarterly_results.htm). Accessed November 2011
- 2) ACIP recommends all 11-12 year-old males get vaccinated against HPV. October 25<sup>th</sup> 2011. Available at: [http://www.cdc.gov/media/releases/2011/t1025\\_hpv\\_12yoldvaccine.html](http://www.cdc.gov/media/releases/2011/t1025_hpv_12yoldvaccine.html). Accessed November 2011
- 3) US CDC, Update HPV vaccination coverage among US adolescent females. Available at: <http://www.cdc.gov/vaccines/recs/acip/downloads/mtd-slides-oct10/08-3-hpv-Female.pdf>. Accessed November 2011
- 4) Sanofi-aventis Corporate Results. Q3 2011. 26<sup>th</sup> October 2011. Available at: [http://en.sanofi.com/Images/29017\\_20111103\\_Q3\\_2011\\_en.pdf](http://en.sanofi.com/Images/29017_20111103_Q3_2011_en.pdf). Accessed November 2011
- 5) Updated Recommendations for Use of Meningococcal Conjugate Vaccines --- Advisory Committee on Immunization Practices (ACIP), 2010. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm>. Accessed November 2011
- 6) Novartis Group Corporate Results. Q3 2011. Available at: <http://www.novartis.com/investors/sales-results/quarterly-results-q3.shtml>. Accessed November 2011
- 7) UK Department of Health. UK Joint Committee For Vaccination. Available at: <http://www.dh.gov.uk/ab/JCVI/index.htm>. Accessed November 2011.
- 8) Pfizer Corporate Results. Q3 2011. Available at: <http://www.pfizer.com>. Accessed November 2011
- 9) Merck & Co. Corporate Press Release. Q3 2011. Available at: <http://phx.corporate-ir.net/External.File?item=UGFYZW50SUQ9NDIxMDE1OHxDaGlsZEIETQ0NDk4OXxUeXBIPtI=&t=1>. Accessed November 2011

**A printable version of this article is available upon request.**

VacZine Analytics<sup>(R)</sup> is a trading division of Assay Advantage Ltd, UK Company Number: 5807728  
VacZine Analytics<sup>(R)</sup> and "the spiral logo" are UK Registered Trademarks, 2009

