

Vaccine major players – Q1 2010 round up of results and R&D

LONDON, UK---7th May 2010---ExpertREACT. After an all time high of yearly sales in FY 2009, the major vaccine companies have now announced their Q1 sales. H1N1 vaccine sales again have largely impacted upon results adding another ~\$3bn to industry fortunes. With the possibility that H1N1 might now fade, it is only likely that new meningitis vaccines can boost the industry, but certainly not in the short term.

According to our analysis, the vaccine major players* sold around \$6.5 bn worth of vaccines in Q1 2010, which was almost double the amount sold in the equivalent period in 2009. GSK were the leading company selling approximately \$2.2 bn (£1.41m) of vaccines (1) followed by Novartis Vaccines at \$1.36 bn (2). Again three of the five major companies (incl Sanofi Pasteur) capitalized widely on the production and supply of pandemic vaccine(s), where for Q1, sales of H1N1 vaccines accounted for around 45% of total vaccine sales. This article will discuss each company's results separately with a brief R&D round-up.

By the end of Q1 2010, Novartis Vaccines had shipped more than 150 million monovalent doses since the declaration of the pandemic. The company confirmed it had largely fulfilled 2009 government orders and had stopped production of H1N1 vaccine. In total, Novartis has so far recognized ~\$2.2 bn H1N1 vaccine sales: far above the total sales of the V&D division in years 2008 and before. Novartis appears to be the only company giving future guidance of H1N1 sales stating "modest upside remains". Although Novartis has recently gained US and EU approval of the new meningitis ACWY vaccine, Menveo® (> 11yrs), according to our forecasts, this product alone will not replace lost H1N1 revenue unless it gains infant (<1 yrs) recommendation. Currently **VacZine Analytics** forecasts <\$50-100m US revenues for Menveo® by 2010 year end (3). As discussed in previous articles, the other potential high revenue generator for the company is the "first to market" vaccine to prevent meningitis B infections, currently in Phase III (EU) and due for submission in 2010. Also, in its Q1 results announcement Novartis confirmed that its US end of Phase II meeting for the same program was to be held with the FDA in Q3 2010.

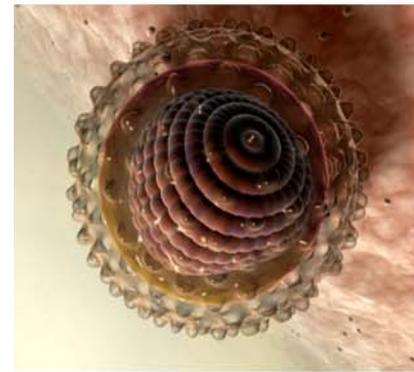
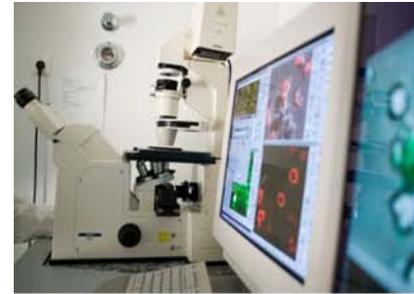
For Q1 2010, GSK reported an additional £698m (~\$1bn) of H1N1 vaccine sales. So far the company has recognized ~\$2.4bn in H1N1 vaccine sales, although some governments had modified their initial orders. Recently in March, GSK reported that the Japanese government (Ministry of Health, Labor and Welfare) amended its contract to receive around 68 percent of its original order (4). When questioned by analysts, GSK maintain that the sale of pandemic vaccine to the Japanese government was a major step forward for the company and signaled that the country is a priority growth area for its vaccine business. Other notable elements of GSK's Q1 results were a 60% growth in Cervarix sales (£77m) and strong growth in hepatitis vaccines. For its late stage R&D meningitis vaccines: Menhibrix (HibMenCY-TT) - the company was expecting a date for a US VRBPAC meeting and for Nimenrix (MenACWY), the company planned to file in the EU for H2 2010.

Sanofi Pasteur, the world's largest producer of seasonal flu vaccines, also reported an additional €413m in H1N1 vaccine sales for Q1 2010 (5). A rough sales split provided by the company indicates that H1N1 was responsible for ~43% of its Q1 sales. So far, the company appears to have fared to least in the H1N1 opportunity with a total of ~\$1 bn in sales to date. Sanofi appears more interested in protecting its dominant seasonal flu franchise by pushing forward a newer differentiated egg-based offering, possibly to counter nearer term competitor moves into cell culture technologies. Unlike H1N1, these revenue streams are importantly long-term and sustainable to the company. Back in late December 2009, the FDA licensed its Fluzone® high dose product for >65 yrs (6) and recently in April 2010, the company has also announced the US filing of Fluzone® ID (microinjection) in the US market (5). It is of high interest whether these products will make significant market share gains over standard needle-base TIV flu vaccines.

Sanofi, in common with both GSK and Novartis Vaccines, has late stage meningitis ACWY vaccines with Menactra (Infant/toddler – 9,12 mos, Phase III) and a second generation MenACWY candidate (Phase II) for infants. For the former, the company expects to file in the US in Q2 but faces the similar challenges to Menveo in the infant segment. In the >11 yrs age group, the company's incumbent Menactra franchise, which sold ~\$747m in 2009 is now facing competition in the US market from Novartis' newly released Menveo®.

In Q1 2010, Merck & Co reported \$791m of vaccine sales. Again the company experienced a decline (-11%) in Gardasil sales compared with the same period last year, although its other viral vaccines which include VARIVAX, MMR-II and PROQUAD, experienced 27% growth over Q1 2009. Merck & Co have not capitalized on the H1N1 vaccine opportunity directly, although the company entered the US seasonal flu business in September 2009 with acquisition of exclusive marketing rights to Australian-based CSL's seasonal vaccine AFLURIA (7).

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Merck & Co is advancing its characteristically “thin” R&D pipeline with a nine-valent HPV vaccine (V503, Phase III), a Staph aureus vaccine (V710, Phase II/III) and an undisclosed pediatric vaccine (V419, Phase II). The company has stressed, that despite the amalgamation of its R&D organization with that of Schering-Plough, it remains committed to novel vaccines and biologics by increasing capacity at its Durham, NC campus.

Pfizer (formerly Wyeth), now reports its vaccines business within the Specialty Care Unit which recorded \$3,521m in Q1 2010 (8). An actual figure for the Prevnar/Prevenar franchise is not available but, based on Q1 2009 sales of \$705m, it is likely that sales for Q1 2010 are similar since the 7-valent version of the product has reached maturity within its lifecycle and is being replaced by 13-valent Prevnar. According to Pfizer senior management, the new Pfizer vaccines R&D portfolio was confirmed in January 2010 of which the prominent vaccine program for meningitis B (rLP2086, Phase II) is the next predicted significant revenue generator. We have discussed in previous **ExpertREACT** articles the competitive positioning of this program versus its main, more advanced rival program operated by Novartis Vaccines.

The vaccine industry has benefited enormously from the H1N1 pandemic with much controversy fueled by the anti-vaccine lobby. However, it is important to note that since April 2009, when the pandemic first was announced 337 US pediatric deaths have occurred due to influenza of which 281 were confirmed to be due to 2009 H1N1 (9). This is significant level of mortality for a vaccine preventable disease. Although as of April 30th 2010, the US CDC has reported low influenza-like illness across the US, the virus remains active in parts of West Africa, South and Southeast Asia along with Influenza B and H3N2 viruses. For the next winter in the Northern Hemisphere, undoubtedly, the evolution of H1N1 will be a closely watched phenomenon – by many stakeholders for many different reasons.

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References and Notes:

*SSI = surgical site infection, RTIs (Pneu) = pneumonias, BSIs = Blood stream infections, UTIs = urinary tract infections. #Global is defined as US, Canada, Major 5 EU, Other EU and Australia.

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