

Q2 2013 - Roundup of results and R&D

LONDON, UK----5th August 2013----ExpertREACT. Although vaccine sales have slightly increased on this time last year, Novartis' UK setback with its *meningococcal* b vaccine Bexsero[™] strips away significant potential growth for the industry.

According to our calculations, the top 5 vaccine players* reported around \$4.70 billion worth of vaccines in Q2 2013 and \$9.08 billion for the year so far. The figures, which are in non-comparable terms i.e. using different exchange rates for each year show a slight increase on H2 2012, which stood at \$8.9 billion for the same period.

In dollar terms, GSK Biologicals again sold the most for the quarter with \$1.2 bn in revenues (1). The company itself stated sales were flat and drew attention to the mixed performance of the Infanrix/Pediarix franchise which grew in the US (due to a supply shortage of Sanofi's Pentacel) and Europe, but declined in the EMAP region and Japan. Overall the franchise sales increased 18% to £218 million. For the first half of the year the most notable change in sales performance was attributable to the bivalent human papilloma virus vaccine, Cervarix[™], which recorded a 52% sales decline to £86 million. Cervarix, previously had benefited from a vaccination catch-up programme in Japan, but moving forward will be impacted by the recent decision of Japanese health authorities to no longer recommend HPV vaccines due to several adverse reactions. For the GSK pipeline, no significant news was updated in the quarter, despite a number of significant programs (e.g. MAGE A3 and Herpes zoster) being in phase 3 clinical development. In other news GSK agreed to provide an additional 240 million doses of Synflorix[™], *pneumococcal* vaccine over the next 10 yrs to developing countries, via a GAVI Alliance agreement (2).

Sanofi Pasteur recorded €760m of vaccine sales in Q2 2013 (3) an increase of 7.2 % over Q1 at constant exchange rates. The most notable gains were within the Polio/Pertussis/Hib franchise where sales increased 12.5% to €293 million. Although there were supply issues in the US for Pentacel, this was offset by good sales of Pentaxim in Mexico and China. Sanofi's other vaccine category increased 30% recording €69 million of sales mainly attributable to VaxServe, a distribution platform based in the US. Like GSK, Sanofi, which has won FDA approval of its Quadrivalent influenza vaccine (QIV) looks forward to the 2013 influenza season where these vaccines will be available for the first time. Shipments of the first lots of influenza vaccine had already began in July with over 60 million doses delivered and 72% of customer reserve doses shipped by the end of August (4). For vaccine R&D, interestingly, Sanofi was now recording its *Clostridium difficile* vaccine program (ACAM-CDIFF) in Phase 3. This wasn't the case in Q1. A while back the company stated a multinational Phase III trial was planned to start in Q3 2013 after being granted a Fast Track designation by US CBER.

Novartis Vaccines and Diagnostics reported \$411m sales for Q2 2013 and \$718m for the first half of the year (5). The loss-making unit mentioned strong sales growth across the portfolio primarily due to a strong late flu season in the US. For the coming influenza season, the company plans to supply a minimum of 30 million doses to the US market, a conservative estimate, bearing in mind it actually shipped 36.1 million doses of Fluvirin[™] in the previous season. Note the company is also supplying its cell derived influenza vaccine, Flucelvax[™]. Novartis, which has lagged behind in the development of Quadrivalent influenza (QIV) vaccines has stated that cell culture will be the development platform for its internal program. The company also continues efforts to bring MF-59 adjuvanted influenza vaccines to the US market (US National Influenza Summit 2013).

Novartis Vaccines' also received a major setback when the UK government: Joint Committee on Vaccines and Immunisations (JCVI) decided not to recommend its *meningococcal* serogroup b vaccine Bexsero[™] for UK children in its June meeting (6). The UK, considered a pioneer in *meningococcal* vaccination due to its past implementation of *meningococcal* C programs incidentally has one of the highest *meningococcal* B, incidence rates in Europe, therefore the JCVI decision does not bode well for the adoption of the vaccine in other EU member states. The main issues highlighted by JCVI are that the effectiveness of the vaccine had not been directly established against invasive *meningococcal* disease, rather by extrapolation of data from immunogenicity studies. Also, and particularly relevant in today's climate, was that the committee concluded that the vaccine was unlikely to be cost-effective at any vaccine price based on the accepted threshold for cost effectiveness used in the UK.

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VacZine Analytics had previously forecasted this product could realise between 5 yr cumulative revenues of €1.47 bn (lo) to €5.46 bn (hi) between 2013-2017 dependent on various levels of country adoption (7). However, based on the JCVI decision, until Novartis proves the vaccine has an impact on the acquisition of *meningococcus* B carriage it could just be limited to those “at risk” of *meningococcal* disease approximately 1% of target cohorts similar to the recommendation for menACWY.

Merck & Co recorded \$1.2 billion worth of sales in Q2, a slight increase over Q1. Growth was mainly seen in the ProQuad, M-M-R II, Varivax franchise and Gardasil with 20% year-on-year growth (8). Although Gardasil sales in Japan (last year at \$140 million) would be affected by the Japanese government decision, the product enjoys uptake in the US due to the male indication and a future national immunisation programme in Brazil due to begin 2014.

Lastly Pfizer’s PCV-7/PCV-13 franchise registered \$969m in Q2 2012 a slight increase on the \$927m recorded in Q1 (10). The company stated that the Prevnar franchise continued to be affected by a large US government prepurchase programme in Q4 2012. Also topline results were soon expected for use of the vaccine in community-acquired pneumonia (CAPITA).

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

References and Notes:

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