

The vaccine industry – Q2 2012 round of results and R&D.

LONDON, UK---10th August 2012---ExpertREACT. The vaccine industry continues onward at a predictable pace with “me too” product launches, territorial expansion and expanding recommendations driving some marginal growth. A potential blockbuster, CYD-dengue demonstrates efficacy but not against all dengue serotypes

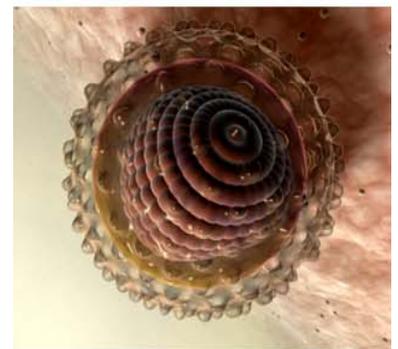
According to our analysis the top 5 major vaccine players sold around \$4.65 bn worth of vaccines in Q2 2012 making the first half year total close to \$9 bn. In reported terms this is marginally higher than the equivalent period in 2011 not taking into account any fluctuations in the major reporting currencies. This **ExpertREACT** article will cover the highlights of the Q2 period from a perspective of both sales and progress in new vaccine research and development.

GSK Biologicals reported \$1.2 bn of sales in Q2 2012 **(1)** and themselves stated that their vaccines business was essentially “flat” in H1 at £1.5 bn. GSK stated that sales of vaccines in the US and Europe were down 1% and 5% respectively for the quarter mainly due to adverse comparisons with the previous quarter where stockpile purchases were made and also continuing government austerity measures. In the “EMAP” region, sales in contrast increased 9% due to strong tender shipments for Rotarix, Synflorix and Infanrix/Pediarix. In Japan, the recent launch of Rotarix increased vaccine sales by 21%. For new product development, GSK reiterated that two *meningococcal* vaccines had since been approved: Nimenrix by the EMA (MenACWY) and Menhibrix (Hib C/Y) by the US FDA for children aged six weeks to 18 months. The success of the latter heavily depends on the outcome of a US ACIP meeting in Q4 2012 which may decide schedule inclusion/recommendation. GSK has also filed for its Quadrivalent (QIV) influenza vaccine and is expecting data for its MAGE A3 breast cancer vaccine in 2013.

Sanofi Pasteur reported a 3% increase in vaccines sales for Q2 2012 at €783m **(2)**. The increase was mainly supported by a record performance for the flu vaccine business in the Southern hemisphere at €167m. For the pending Northern Hemisphere flu season the company had already begun shipping the first of its 60m doses to the major US market. Sanofi also reported that order limitations in the US had affected its Polio/Pertussis/Hib vaccines business (€273m, -5.2%) due to manufacturing delays although its sales of Menactra (conjugated *meningococcal* ACWY vaccine) still increased despite competition in the US from Novartis' Menveo.

In R&D progress the biggest news for Sanofi and undoubtedly on an industry wide level was the announcement that Sanofi's dengue vaccine (CYD) demonstrated proof of efficacy against dengue as observed in a Phase IIb study in Thailand. The vaccine generated an antibody response against all four dengue virus serotypes (DEN 1, 2, 3 & 4) but only demonstrated protection against three of the four virus serotypes circulating in Thailand. Further clinical studies are ongoing in 10 other countries to elucidate further the protective effect of the vaccine in different target populations and settings. Previous analysis by **VacZine Analytics** has revealed CYD's blockbuster potential despite its suboptimal administration profile (3 doses over 12 months) **(3)**.

Merck & Co reported Q2 sales of \$1.1 bn buoyed by a 17% increase in Gardasil sales (\$324m) due to vaccination of US males (new ACIP recommendation) and launch in Japan **(4)**. Sales of Zostavax (Zoster vaccine live) also grew strongly with 22 percent growth in the quarter. The company expects to file V503 (9-valent HPV vaccine) in 2012 which should capitalize on the success laid down by Gardasil



Pfizer Vaccines reported \$1bn sales in Q2 characteristically dominated by Prevenar/Prevnar-13 (5). Growth in the quarter was driven by the timing of government purchases of the vaccine in Turkey but offset by the absence of other tenders which contributed in previous reporting quarters e.g. Mexico. Lastly Novartis Vaccines and Diagnostics reported \$349m sales in Q2 2012 (6). Novartis, which derives the bulk of its revenue from the Q3/Q4 US influenza season, still awaits news regarding its *meningococcal* serogroup B vaccine, Bexsero which was submitted for review in December 2010.

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References:

1. GSK Biologicals. Q2 Results 2012. Available at: http://www.gsk.com/investors/quarterly_results.htm. Accessed August 2012
2. Sanofi Pasteur. Q2 Results 2012. Available at: <http://www.sanofipasteur.com/>. Accessed August 2012
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