2015 Q2 – round up of results and R&D

LONDON, UK----28th August 2015----ExpertREACT. Due to the US ACIP category B recommendation for *meningococcal* serogroup b vaccines this segment will grow slower than expected. All eyes point to vaccines against mosquito borne diseases dengue and malaria to boost industry revenues.

According to our analysis, the vaccine industry four major players* sold just over **$5 bn** worth of vaccines in 2015 (Q2) and **$9.3bn** in 2015 (H1). The following article will analyze the sales results per company and outline any relevant highlights in product sales and new vaccine research and development.

British based **GSK** reported **£814m** worth of vaccines sales in Q2 **(1)** and increase on a reported basis from Q1 2015 **(£699m).** Since the Novartis transaction completed on March 2nd 2015 the reported year to date figures included four months turnover of the former Novartis Vaccines business, which for the first time provides product specific sales for Bexsero, Menveo and Rabipur/RabAvert vaccines which collectively contributed approximately **£88m**. The strong growth of Bexsero in particular helped European sales grow 27% on a reported basis offsetting lower sales elsewhere. In the US, the return to market of a competitor DTP combination vaccine affected sales of Infanrix/Pediarix products, which sold **£187m** in Q2.

Major news for GSK in Q2 was that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive scientific opinion for its malaria candidate vaccine **Mosquirix™**, also known as RTS,S in children aged 6 weeks to 17 months **(2)**. RTS, S was tested in a clinical trial program involved 16,000 young children at African research centres in eight African countries (Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique, Nigeria, and Tanzania). In the trial RTS, S (in addition to bed nets) reduced malaria cases by 39% over fours years of follow-up in children (5-7 months), and by 27% over three years of follow-up in infants (6-12 weeks). The CHMP decision will guide the World Health Organization (WHO) on its own policy recommendation. In Q2 GSK also gained a major label extension of **Synflorix** in the EU **(3).**

Sanofi Pasteur reported **€887m** worth of vaccines sales in Q2 2015, an increase over Q1 (€697m) and 8.6% growth over Q2 2014 at constant exchange rates **(4).** Sales of influenza vaccines **(€114m**) posted 88.1% rise benefiting from the delay of the Southern Hemisphere influenza campaign due to the two new strains included in influenza vaccines for this year. Other growth drivers in the quarter were Menactra **(€133m)** driven by emerging market sales and Adacel benefiting from an increase in production. First-half sales of Adult Booster vaccines increased 10.4% to €213 million. The company also revealed it plans to supply 65m doses of influenza vaccine to the US market this year.

Sanofi updated the investment community with its progress on its first in class vaccine to prevent **dengue**. Regulatory submissions in key endemic countries in Asia and Latin America were completed in June 2015 and the company still anticipates its first license before year-end 2015. A recent article published in the New England Journal of Medicine (NEJM) also presented data confirming that Sanofi's dengue vaccine protected 66% of individuals > 9 yrs (pooled sample from Phase IIIs) against dengue, severe dengue (93%) and prevention of hospitalizations due to dengue (80%) **(5).**

Merck & Co vaccines reported an estimated $1200m worth of vaccine sales in Q2 with its key Gardasil/Gardasil-9 franchise recording $427m in sales compared to $409 in Q2 2014 **(6)**. Merck & Co stated that the US FDA has extended its planned review timeline of the Biologics License Application for **V419**, the investigational pediatric hexavalent combination vaccine, DTaP5-IPV-Hib-HepB, which is being developed and, if approved, will be commercialized through a partnership of Merck and Sanofi Pasteur. If approved the vaccine will be the first hexavalent combination vaccine approved in the US and according to **VacZine Analytics** internal research and calculations has strong commercial potential.

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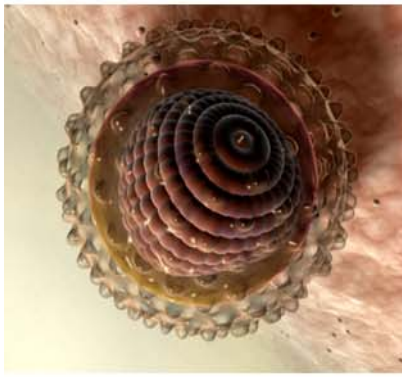

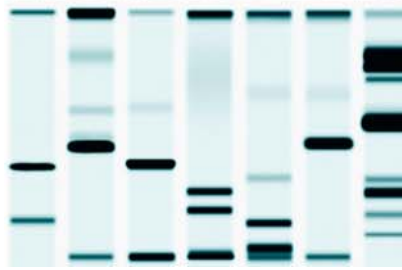

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Pfizer vaccines reported $1,580m in its global vaccines franchise and increase of 44% over the same period in 2014 **(7)**. The company states that much of the growth is due to its lifecycle management efforts on PCV-13 in US adults where US sales grew by 87%. Other contributors to PCV-13 sales were "increased shipments associated with GAVI, the Vaccine Alliance, the favorable impact of Prevenar's inclusion in additional national immunization programs in certain emerging markets compared with the year-ago quarter, as well as the inclusion in second-quarter 2015 of revenues associated with the acquisition of Baxter's portfolio of marketed vaccines in Europe."

Looking forward, Pfizer vaccines expects to recognise addition revenue based upon the June 2015 announcement that the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) vote to recommend the vaccination of adolescents and young adults 16 through 23 years of age against serogroup B *meningococcal* (MenB) disease. In support, recently the company announced positive topline results of two Phase 3 studies which further supported the accelerated FDA approval of their vaccine, **TRUMENBA** **(8)**. In spite of the data, because the ACIP decision was not a blanket recommendation, the company will have to exert a significant degree of marketing effort to influence parents and their practitioners to drive Trumenba uptake. Based on the difficulties experienced with Gardasil, a vaccine to prevent cancer – time will tell if Pfizer are successful with a much rarer disease.

References and Notes:

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5) Sanofi Aventis. News release. 27th July 2015. Available at: http://www.sanofipasteur.com/en/articles/New-England-Journal-of-Medicine-Publishes-New-Analyses-Confirming-that-Sanofi-Pasteur-s-Vaccine-Candidate-Safely-Protects-Pre-Adolescents-to-Adults-Against-Dengue.aspx Accessed August 2015

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