The vaccine industry in 2010: highlights and lowlights

LONDON, UK----14th December 2010----ExpertREACT. VacZine Analytics reviews another year for the vaccine industry. While much progress has been made in vaccine R&D, especially in terms of novel vaccines and those for developing/tropic regions, a few setbacks remind us that the field is as unpredictable as ever.

For the vaccine industry, 2010 was a different year to 2009. While the industry continued to make progress on many fronts in terms of continued revenue growth and new vaccine development, there were some setbacks. **VacZine Analytics** looks back at 2010 as the year draws to a close.

This time last year we commented that for the vaccine industry, the "H1N1" blip would eventually pass; possibly not from a disease point of view but certainly in terms of the financial impact it had on governments procuring the vaccine and companies producing/selling the pandemic vaccine. As 2010 unfolded this appeared to be the case. H1N1 2009 appears to be still relevant and with us.

According to the CDC FluView (week ending December 4th 2010) **(1)**, while overall flu activity in the US remains relatively low influenza A (2009 H1N1) still accounts for about ~20% of tested isolates, probably an underestimate since not all A isolates have been subtyped. In the UK, 2009 H1N1 predominates in the 15-44 yrs group according to HPA Respiratory Virus Unit data **(2)** and has caused a number of deaths. For the industry, producers of monovalent pandemic still managed to book $3.5bn in sales revenues in 2010, but sales essentially "dried up" in Q3 as H1N1 2009 is now covered in current trivalent seasonal vaccine.

GSK who capitalized highly on the H1N1 pandemic suffered a setback for their rotavirus vaccine Rotarix in 2010. Rotarix started the year on a positive note with the release of data indicating the vaccine significantly reduced severe rotavirus gastroenteritis in African infants **(3).** However, in March the company released a statement announcing that the vaccine contained material from porcine circovirus-1 (PCV-1). Although regulatory authorities at the time noted PCV-1 does not replicate in humans and was unlikely to cause a safety risk, Rotarix was temporarily withdrawn from use in the US but maintained in the EU. After continued investigation Rotarix use was resumed in May 2010 but still reduced sales by 40% as reported in the GSK Q3 results. Merck & Co, who market the other rotavirus vaccine, ROTATEQ presented to the US ACIP that fragments of PCV-1 and 2 in the vaccine were either below the limits of detection or at low levels posing no safety risk **(4).**

The uncertainty and risks associated with having to achieve high standards in vaccine manufacturing and quality control also impacted upon Holland-based Crucell in October of 2010 **(5).** Because of microbiological contamination, Crucell had to place a temporary hold of shipments of their pediatric combination vaccine Quinvaxem ® and its hepatitis B vaccine Hepavax-Gene ® both being produced at its Shingal facility in Korea (scheduled to be vacated in 2011). Although both vaccines were expected to be at full availability in early 2011, the company stated at the time that the event would affect their forward financial outlook and possibly the tabled acquisition offer by US giant Johnson & Johnson (J&J). Later in December J&J still launched their recommended public offer to acquire Crucell outstanding shares at a substantial premium to the market price (total value ~$2.3bn) for which the acceptance period remains open to 16th February 2011.

While the J&J/Crucell deal was the biggest M&A story in 2010 there were some other significant developments in terms of partnerships and alliances of which the French major player Sanofi Pasteur appeared the most active. In 2010, Sanofi Pasteur, announced arrangements with Daiichi-Sankyo-Japan, VaxDesign (US), US Navel Medical Research Center, Vivalis and Kalobios **(6);** the latter two deals focused on monoclonals for infectious diseases. Other notable deals, announced in 2010, still maintained a theme of gaining more presence in emerging or underdeveloped markets. For example, GSK announced a further collaboration with Fiocruz of Brazil for neglected tropical diseases and JSC Binnopharm for vaccine production in Russia **(3)**. Another interesting move was from Baxter vaccines who completed an agreement with Takeda of Japan for cell-based influenza vaccines in Japan. The company previously gained approval for PREFLUCEL (cell based influenza vaccine) in Austria **(7)**.

In 2010, new vaccine approvals/filings were low key and mainly part of company life-cycle management activities where newer derivatives of existing vaccines were forwarded by developing companies. A good example was Sanofi's US submission of an intradermal/microneedle (ID) version their influenza vaccine Fluzone, otherwise known as ID Flu or INTANZA in other markets **(6).** In the meningitis sector, Novartis Vaccines received FDA approval of Menveo® back in February which they later showed to be highly immunogenic in infants (n=4500) in October 2010 **(8).** GSK who are also aiming for US infant vaccination with their CY-Hib vaccine (Nimenrix) suffered a setback receiving a complete response letter from the FDA in June **(3).** As mentioned in previous articles, the development of new meningitis vaccines for infant schedules will still remain a key watch point for 2011, particularly serogroup B vaccines both being developed by Novartis and Pfizer (Wyeth) Vaccines.

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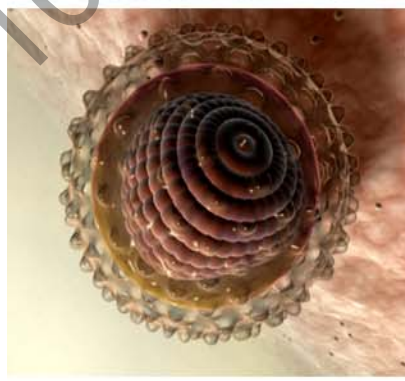

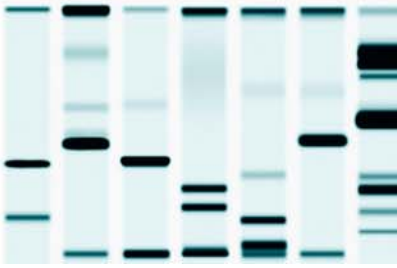

2010 was a good year for the progression of completely novel vaccines with more gains than setbacks. In terms of positive news, a prominent example, was the progression of Sanofi Pasteur's tetravalent Dengue vaccine candidate to Phase III testing in Australia **(6).** The vaccine, which is now at industrial scale production has already been shown to provide a good immune response after 3 doses in adults and children in the US, Asia and Latin America. In other tropical related diseases, Crucell figured highly with the annoucement of new trials/candidates in TB, malaria and HIV in partnership with other organisations such as Aeras, US National Institutes of Health and Harvard (BIDMC) **(5).** Interestingly, US-based Merck also joined the quest for a malaria vaccine with a partnership with PATH and NYU Langone Medical Center **(9).** Overall it would appear from 2010 that diseases of developing/tropical regions are finally beginning to attract the priority level from the industry they deserve.

The emerging nosocomial vaccine segment also progressed in 2010 with positive news related to the fields of *Clostrdium difficile*, *Pseudomonas aeruginosa* and *Staphylococcus aureus* vaccines. New programs were announced from major competitors validating the attractiveness of the sector along with encouraging clinical data. In 2011, Vienna-based Intercell AG, who have emerged the apparent "pioneer" of the sector, will be keen to progress their nosocomial programs in light of their unexpected recent termination of their patch-based Traveler's Diarrhea (TD) Phase III program **(10).**

For other novel vaccine areas, GSK stopped development of their Herpes Simplix Virus (HSV) vaccine Simplirix which reached a second Phase III trial but advanced their Herpes Zoster Virus candidate **(3).** Lastly, 2010 gave some signals mainly from Dendreon (Provenge) and Bavarian Nordic (PROSTVAC) that cancer/therapeutic vaccines may hold some promise. This is certainly something to watch in 2011 and the coming years.

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

References and Notes:

1) US CDC. 2010-2011 Influenza Season Week 48. Available at: http://www.cdc.gov/flu/weekly/. Accessed December 2010.
2) UK Health Protection Agency. HPA Influenza Surveillance Graphs. Available at: http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1284475036543 Accessed December 2010
3) See GSK Corporate Press Releases. Available at: http: www.gsk.com. Accessed December 2010
4) Merck Corporate Press Release. October 28th 2010. Available at: http://www.merck.com/newsroom/company-statements/2010_1028.html. Accessed December 2010.
5) See Crucell Corporate Press Releases. Available at: http: www.crucell.com. Accessed December 2010
6) See Sanofi Pasteur Corporate Press Releases. Available at: http: www.sanofipasteur.com. Accessed December 2010
7) See Baxter Corporate Press Releases. Available at: http: www.baxter.com. Accessed December 2010
8) See Novartis Vaccines Corporate Press Releases. Available at: http: www.novartisvaccines.com. Accessed December 2010
9) Merck Corporate Press Release. December 14th 2010. Available at: http://www.merck.com/newsroom/news-release-archive/research-and-development/2010_1214.html. Accessed December 2010.
10) See Intercell AG Corporate Press Releases. Available at: http: www.intercell.com. Accessed December 2010

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