

Major vaccine players – the race to Japan

LONDON, UK----29th May 2009----ExpertREACT. Over the past year a number of the major vaccine players have made it clear they seek further penetration into the Japanese vaccine market. With a birth cohort of around 1.2 million, good pricing and a comparatively undeveloped pediatric vaccination schedule the strategy makes sense but only with local help.

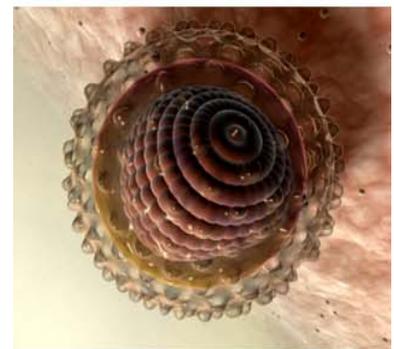
Recently Novartis Vaccines joined the Western vaccine industry's push into Japan with the announcement of a marketing and distribution agreement with Takeda Pharmaceuticals for Vaxem-Hib, a vaccine for the prevention of infections caused by *Haemophilus influenzae* type b (Hib) (1). The vaccine will still need to undergo clinical testing and regulatory submission by Takeda, but if approved may net Novartis an upfront payment of 100 million yen and further milestones and royalties depending on sales revenue. Novartis state their latest deal is part of their international expansion strategy for vaccines which began with their previous agreement with Intercell AG on Ixiaro, a new vaccine against Japanese encephalitis.

Gaining a foothold in Japan's vaccine market is becoming an often cited strategy in Western vaccine company analyst/investor presentations. Last summer, as part of GSK's Q2 results company executives made it clear that "expand in Japan" was part of their vaccine growth strategy (2). At the time the company had no direct presence in the market. Now both GSK and Novartis Vaccines, estimate the Japanese vaccine market is worth around ~\$600m and is expected to grow further. French vaccine company, Sanofi Pasteur, in November 2008 also closed deal also focused on *Haemophilus influenzae* type b (ActHIB) with Daiichi-Sankyo Co. Ltd (3). At the time Sanofi stated that it was the first international company to enter the Japanese pediatric vaccine market. ActHIB was previously licensed in Japan in January 2007 although not available on the Japanese market until October 2008.

Unlike other vaccine growth opportunities in emerging markets such as China, India and Brazil, which are driven by increasing wealth and birth rates, Japan's 1.2 million per year birth cohort is expected to remain flat. However, importantly, the country has a less developed immunization schedule than US and EU regions. The immunization schedule (2005 version) is composed of both voluntary and compulsory vaccination sections where the compulsory group has two categories (I and II). Category I vaccines are strongly recommended by the law "to protect public health" (4). Vaccines in this section include polio (OPV), DTaP/DT, measles, rubella and Japanese encephalitis (JEV). Voluntary vaccines are influenza, varicella, mumps, hepatitis A and B.

Historically, key differences between the Japanese immunization schedule compared to the US and EU counterparts have been less overall coverage against common pediatric pathogens e.g. Hib, *S.pneumoniae* and *meningococcus* and hence, less use of advanced combination products which have become commonplace in the West. For Hib in particular, Japanese authorities have been slow to license vaccines despite their widespread availability in the West since the late 1980s. This is partly due to lower incidence of Hib disease compared to the US and a highly safety conscious regulatory environment. For example, concerns exist within the Japanese literature about endotoxin content of PRP conjugated Hib vaccines (5). Nevertheless, in Japan Hib is still estimated to affect around 500 children per year of which around 25 die and 100 suffer from serious sequelae. Reports also suggest Japanese parents and paediatricians have strongly campaigned for the Hib vaccine's availability.

Western companies sense commercial opportunity in Japan, especially those with a strong presence in pediatric vaccines. With the potential of good private market pricing and high vaccine coverage, these companies are hoping global vaccine schedule harmonization will bring near-term commercial gain even if through partnerships with Japanese players. The race for Sanofi and Novartis to enter the Hib market appears to be a first step or "platform building". If successful, Novartis can build upon Hib possibly with their emerging meningitis franchise and Sanofi their combination products. GSK state they have intentions for Rotarix and Cervarix (2). Merck started trials of Gardasil via their subsidiary Banyu Pharmaceuticals in 2006.



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For adult or elderly vaccines, especially influenza it is inferred that Western companies have a more challenging task to gain market entry. Japan has its own domestic influenza vaccine supply which according to Japanese government officials will begin making H1N1 "swine flu" vaccine. Another potential opportunity might be the travel vaccine market since the Japanese population are well known to be frequent travellers. Overall **VacZine Analytics** believes that the recent deals and corporate intentions are a step in the right direction for Western companies, but also probably a realization that Japanese authorities and domestic companies need to focus more on vaccination.

References:

- 1) Novartis Corporate Press Release. May 26th 2009. Available at: <http://www.novartis.com/newsroom/media-releases/en/2009/1317593.shtml>. Accessed May 2009
- 2) GSK Corporate Q2 results 2008. Available at: http://www.gsk.com/investors/reports/q22008/q22008_presentation_colour.pdf Accessed May 2009
- 3) Sanofi Pasteur Corporate Press Release. 29th April 2009. Available at: http://www.sanofipasteur.com/sanofi-pasteur2/sp-media/SP_CORP/EN/54/720/FLU_290409_ENG.pdf?siteCode=SP_CORP. Accessed May 2009
- 4) Japanese Immunization Schedule 2005. Infectious Disease Surveillance Center (IDSC). Available at: <http://idsc.nih.go.jp/about/index-e.html>. Accessed May 2009.
- 5) Ochiai M., et al. Endotoxin Content in *Haemophilus influenzae* Type b vaccine (2004). Jpn. J. Infect Dis., 57, 58-59

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