

Vaccinating teenagers – growth platform

LONDON, UK----21st September 2009----ExpertREACT. With publication of the latest US National Immunization Survey (NIS-teen) for persons (13-18 yrs) and manufacturers increasingly developing vaccines aimed at this population, **VacZine Analytics** believes the “teenage” segment (est \$3.5-4.0 bn, 2008) will become a new area of industry revenue growth

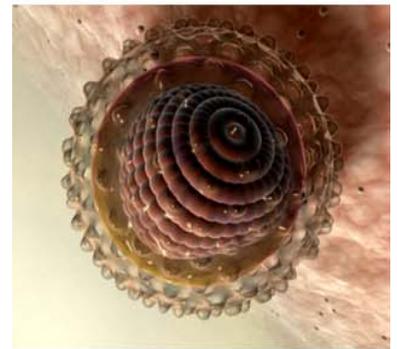
The health and wellbeing of the teenager (13-18 yrs) is presented with numerous challenges during the ascent to adulthood. These arise mainly through the onset of sexual activity, and in the older years, a change of living environment and/or gain of independence. Although the mortality burden in the teenage group is mostly due to unintentional injury (due to motor vehicle accidents) (1), preventative vaccination against infectious diseases is becoming a new focus area both for healthcare policy makers and indeed, commercial manufacturers who once concentrated on the very young and very old. Teenagers are generally considered easier to access for vaccination than older healthy adults.

Recently, the US Centers for Disease Control and Prevention (CDC) published its third annual report of national adolescent vaccination coverage – NIS Teen (2). The latest 2008 survey, which is telephone-based, had been expanded on previous surveys (2006 & 2007) to cover four quarters of the year and includes 17,835 records from 50 US States. The survey indicated that overall vaccination coverage for preteens (11-12 yrs) and teens 13-18 yrs was improving. In the US, teenagers are routinely recommended *meningococcal* conjugate vaccine (MCV4, 1 dose), tetanus, diphtheria acellular pertussis vaccine (Tdap, 1 dose) and for girls, the quadrivalent human papilloma virus vaccine (HPV4, 3 doses). Other vaccines that were missed during childhood such as hepatitis B, varicella and MMR are also recommended (3). It is noteworthy, that the number of vaccines recommended to teenagers has increased significantly with MCV4, Tdap and HPV4 being relatively new additions. The trend does signify an increasing focus on teenage preventative vaccination by the US Advisory Committee on Immunization Practices (ACIP).

The increased vaccination of teenagers has been arguably driven by commercial vaccine manufacturers, notably Merck & Co which the launch of the first HPV vaccine, Gardasil. With its strong case for prevention of cervical cancer, policy makers around the world have been forced to respond to its inclusion in many national immunization programs. Merck & Co recorded \$1.4 bn in revenues for Gardasil in 2008 and posted sales of \$268 million for the second quarter of 2009 (4). According to the recent NIS-teen data, on a national basis, 37.2% adolescents have had 1 dose of Gardasil and only 17.9% completed the full series. The survey indicated some interesting variability among HPV4 coverage due to ethnicities, state geography and poverty status but overall showed that HPV4 coverage had increased on 2007. Both Sanofi Pasteur and GSK Biologicals have also driven the teenage vaccination agenda with Adacel/Menactra and Boostrix products respectively. The NIS teen data showed increases in coverage; MCV4 (from 32.4% to 41.8%) and Tdap (from 20.4% to 40.8%). Tdap is also used in the adult population.

For the US and other major Western countries, there is every reason to believe that the vaccination of teenagers will continue to increase in terms of existing vaccine coverage but also number of vaccines recommended. For the major US market, recent news that the US FDA VRBPAC committee voted in favour of approving GSK's Cervarix™ was a major event for a number of reasons (5). The FDA has not yet approved the use of a novel adjuvant in a vaccine re: MPL contained in AS04, but also Cervarix™, which is experiencing revenue growth, gives GSK's new product portfolio (as a whole) a strong foothold in the US. Over time, GSK may even be able to address low course completion experienced with Gardasil by use of an innovative schedule once data confirming a superior duration of protection/need for boosting are reinforced. Regardless, it is expected that the availability of two vaccines for HPV will drive teenage vaccination uptake.

New vaccines for *meningococcal* infections serogroups ACWY (Novartis, Menveo) and serogroup B (Novartis and Wyeth) are also expected to push further the agenda to vaccinate teenagers. *Neisseria meningitidis*, like other infectious pathogens has high carriage rates in the teenage/young adult population but also shows a notable secondary “spike” of incidence of invasive disease in this group beyond infants.



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For Menveo (ACWY), Novartis received a complete response letter in June 2009 from the FDA regarding its BLA for use of Menveo in the 11-55 yrs group (6) but is expected to address any concerns quickly with an update towards the end of the year. The company will compete with Sanofi's Menactra[™] which has been positioned to US college freshmen for some time posting \$500-600m annual sales in 2007 and 2008. For serogroup B, Novartis has completed recruitment for Phase III EU trials in infants, with a filing planned in 2010. US Phase III trials had been delayed pending completion of preclinical studies (recruitment had not started as of July 2009). Wyeth, the other major competitor for a serogroup B vaccine (rLP2086) started a Phase II trial in adolescents in February 2009 in Australia (7). Like ACWY, both serogroup B vaccines will be considered for eventual teenage recommendation.

There are around 53 million teenagers (13-18 yrs) in the major Western markets*, 31 million of which reside in the US making up around 10% of the total population. Vaccinating teenagers, is estimated to be in the order of \$3.5 to 4.0 bn industry revenues in 2008 and, due to drivers discussed in this article, is considered an attractive area for future industry growth. **VacZine Analytics** believes this growth will be driven in the near term driven by HPV and *meningitis*, but in the longer-term might be due to opportunities within sexually transmitted diseases (STDs) and promoting neonatal health for eventual pregnancy in females. For example, a recent report published in July's Morbidity and Mortality Weekly Report (MMWR) discussed the sexual and reproductive health of persons in the US aged 10-24 yrs (2002-2007) (8). Some example statistics were: 1 million adolescents and young adults were reported to have *chlamydia*, gonorrhea or syphilis; 745,000 pregnancies occurred among US females <20 years. The report concluded that many young persons in the US engage in risky sexual behavior and experience negative reproductive outcomes. Once these data are extrapolated to the Western and then the global population – the story becomes even more compelling.

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References and Notes:

*Major Western markets are considered United States, United Kingdom, France, Germany, Italy and Spain

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