

**New Acambis and Sanofi-Pasteur West Nile deal: more about the relationship than the product.**

**LONDON, UK----14 November 2007----ExpertREACT. VacZine Analytics**, a new strategic research agency focused on vaccine market analysis discusses the rationale behind the recently announced West Nile vaccine deal between Acambis and Sanofi-Pasteur.

Yesterday, UK/US based Acambis recently announced another deal with the giant vaccine maker Sanofi-Pasteur concerning their Phase II West Nile vaccine based on ChimeriVax™ technology. It is the third significant deal with Sanofi-Pasteur and the first under the newly invigorated management team led by CEO Ian Garland.

Acambis is due to receive total payments of around \$70m of which \$10m is upfront. The company states they will receive a “high teens” royalties on predominately US net sales where Sanofi would be responsible for marketing and distribution. Sanofi will also fund R&D of the vaccine although Acambis will be responsible for execution of the program up until supply of bulk and fill-finish from their US facilities. Importantly, Acambis states Sanofi-Pasteur will participate in discussions regarding potential US ACIP recommendations of the vaccine.

West Nile Virus (WNV) is a vector borne disease caused by a flavivirus spread by infected mosquitoes. Birds act as a natural reservoir of the virus (enzootic transmission cycle) and in some cases shown no signs of disease. Most human infections of West Nile Virus are asymptomatic. However, in around 20% of cases a febrile like-illness is observed with fever, headache, body aches, myalgia and anorexia (World Health Organisation). In less than 1% of the cases neuroinvasive disease is reported leading to paralysis and coma resulting in death. Mortality in these situations is around 10%. There is no specific treatment for West Nile Virus disease.

West Nile Virus is considered endemic in the US with those above 50 years of age considered at greatest risk. The US Centers for Disease Control and Prevention (CDC) has recorded 3,265 cases of the disease as of 6 November 2007 with 92 deaths. Since 1999 the number of cases has increased dramatically although there are year-to-year variations and fluctuating risk. An important fact is that not all cases of WNV infection are recorded especially if asymptomatic or fever-based only.

The availability of a preventative vaccine would be a welcome addition to alleviate the burden of West Nile Virus disease in the US. In the future this could be extended to other global regions. The potential WNV vaccine also has the advantages of being single dose and is likely to be highly immunogenic due to its “live” approach. With Sanofi’s strong US capabilities, commercialization of the vaccine is now a more likely prospect. The company has a wealth of experience in the adult/elderly segment by virtue of its influenza vaccines. Through governmental lobbying the company has been involved with the formulation of many US ACIP recommendations including those recently set for conjugated meningitis vaccines e.g. Menactra.

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Although the Acambis WNV vaccine is the most advanced it is fair to assume both parties have factored in the development and regulatory risks. One key challenge will be to find a feasible Phase III developmental pathway because the low incidence and predictability of WNV makes a field efficacy trial economically impossible. Discussions with the FDA could be long and complex because it is not certain the agency will invoke the animal rule. This barrier could impact heavily upon timelines.

Securing widespread ACIP recommendations is also a critical milestone especially in light of other more predictable health priorities and the potential cost burden of widespread vaccination. It should be noted that influenza kills ~36,000 per year and despite widespread ACIP recommendations coverage rates in the >50 years group (~60-70%) are still below governmental targets. Coverage rates for polysaccharide pneumococcal vaccines are even lower (~5-10%) despite thousands of deaths in the elderly of invasive disease. Bearing in mind these benchmarks, from a commercial point of view achieving a higher price per dose to make a WNV vaccine lucrative could be a challenge. Without the significant volume gained through widespread recommendation the vaccine might be limited to a niche private market based on discretionary purchasing much like vaccines previously targetted to Lyme's disease. If Sanofi is limited to marketing the product through primary care (PCPs) this will prove very costly in terms of resources.

**VacZine Analytics** believes that the West Nile Vaccine opportunity is of low-medium potential (\$100-200m) and faces many challenges until approval. Indeed, these challenges will also extend to other less advanced competitor WNV vaccines. **VacZine Analytics** thinks the deal is more centered on reinforcing the relationship between the companies with a view to the future. Acambis has the only known *Clostridium Difficile* vaccine in development, which although has had challenges, is undoubtedly a much larger commercial opportunity worth nurturing. Many also believe that the long-term market for influenza vaccines will evolve to contain a product with universal strain coverage (M1 vaccine). With a significant flu business to protect from competitors such as Novartis and now GSK, Sanofi would do well to eventually "lock-in" any potential disruptive technology.

For more information about this research please visit [www.vacZine-analytics.com](http://www.vacZine-analytics.com)  
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**About VacZine Analytics:**

VacZine Analytics is a new strategic research agency based in the United Kingdom. Its aim is to provide disease and commercial analysis for the vaccine industry and help build the case for developing new vaccines.

