

GSK Biologicals and AFFiRiS – are therapeutic vaccines back in fashion?

LONDON, UK----24 October 2008----ExpertREACT. Large vaccine companies have historically focused on “tried and tested” prophylactic vaccines preventing diseases caused by infectious pathogens. However, with new product opportunities becoming limited, especially in the West, the recent investment by GSK Biologicals may signal an increase move by the established players into the therapeutic space.

Recently vaccine giant GSK Biologicals announced it had acquired exclusive rights to the beta-amyloid vaccine (Alzheimer’s disease) programs of AFFiRiS GmbH based in Vienna, Austria (1). AFFiRiS founded in 2003, has a management team with connections to Intercell AG, another Austria company with a successful track record of attracting investment from larger vaccine players. For an upfront payment of £17.5 million, GSK will acquire disease vaccine candidates that are based on the AFFiRiS AFFiTOPE technology and are currently in Phase I clinical development. Other preclinical projects based on the same technology are also involved in the arrangement. If the programs are developed successfully AFFiRiS could receive payments totaling £334 million.

According to AFFiRiS, AFFiTOPEs induce a relevant immune response by mimicking “self” antigens but do not induce pathological auto-immunity. This potentially avoids downstream safety concerns and allows their potential application in vaccines against conditions such as Alzheimer’s where “rogue” versions of intrinsic proteins form the basis of disease pathogenesis. Because Alzheimer’s disease commonly affects the elderly population and is without effective modifying treatments, a vaccine based approach with any proven clinical benefit could be a lucrative opportunity for GSK, albeit with high risk. Moreover, the AFFiTOPE platform could eventually allow GSK Biologicals to begin addressing other chronic diseases through a vaccine based approach.

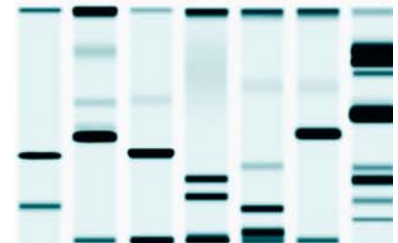
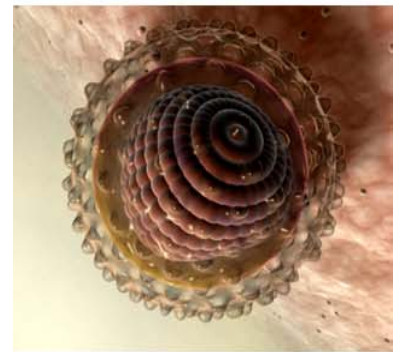
GSK Biological’s move to acquire the AFFiRiS programs signals the company’s intention to build further a diversified balanced vaccine pipeline, combining traditional prophylactic approaches against common infectious pathogens e.g. *Streptococcus pneumoniae* and novel vaccines with therapeutic applications. The company is already progressing development of its MAGE-A3 ASCI cancer immunotherapeutic programs for the treatment of melanoma and non small-cell lung cancer (Phase II and III respectively) (2). For GSK Biologicals, the AFFiRiS deal would appear exploratory and no doubt forms part of a longer-term plan to build a higher value vaccine portfolio. Under new leadership this is critical especially in light of fierce competition directed to Cervarix (HPV), Rotarix (rotavirus) and Synflorix (*S.pneumoniae*/NTHi). Furthermore, some observers doubt the near-term approvability of GSK’s novel MPL-based adjuvant systems in the largest US market, meaning the company must continue to build new options.

In recent years other major companies with vaccines divisions have also experimented with the idea of developing therapeutic vaccines, with marginal clinical trial success to date and no firm product approvals. Notable examples are the multimillion dollar investment by Sanofi Aventis in Oxford Biomedica’s Trovax (March 2007) (3). Trovax is currently being studied in various forms of cancer with the most advanced Phase III TRIST study in renal cancer recently undergoing a number of study amendments in response to FDA guidance. A range of perceived setbacks and delays caused the stock price of Oxford Biomedica to fall sharply in October, 2007 with the company overall value still remaining low a year later.

Pfizer, a relative newcomer the vaccine business, with little significant leverage within the prophylactic vaccine space apart from mainly its DNA-based influenza programs acquired from Powdermed, UK, has made investments in the therapeutic vaccine area as well as complimentary novel adjuvant technologies with Coley Pharma. In April 2008, the company was granted an exclusive worldwide license by Avant/Celldex to a therapeutic cancer vaccine candidate, CDX-110, in Phase II development for the treatment of glioblastoma multiforme (GBM). Pfizer also gained right to the use of EGFRvIII which is a validated target in various other cancer indications. Pfizer has also made investments in Swiss-based Cytos (August 2008) (4) for a number of indications based on the Immunodrug™ technology (5). Novartis Pharma also made an investment in the Cytos nicotine vaccine program.

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As time passes **VacZine Analytics** believes many of the major vaccine companies will make selected investments in therapeutic vaccine technologies, especially after the new GSK move. Indeed, there are very few unpartnered programs in the prophylactic space that can be acquired and easily commercialized, at least in the Western economies (6). To begin fueling future growth through early stage product development vaccine companies can either look at technologies being developed in emerging economies e.g. LATAM and SE Asia or turn their attention to therapeutic vaccines. Both are associated with different kinds of risk. In the therapeutic space, for the size of the upfront payments and deal structures currently being made, it is a risk worth taking to stay ahead. But with some many therapeutic vaccines underdevelopment and generally a more complex mechanism of action, it will remain challenging to select the most promising.

References:

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- 6) Vaccine Pipeline Review (CAT No: VAVS011) published by VacZine Analytics. October 2008

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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.

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