

Summary of VaxInnate's Influenza Program

VaxInnate is developing novel, proprietary vaccines for both pandemic and seasonal influenza. These breakthrough vaccines utilize the company's technology platform that substantially improves vaccine immunogenicity and efficacy. This technology physically links a natural component of microbes, known as flagellin, to vaccine antigens helping our immune system to recognize the vaccine as foreign and responded with a strong protective immune response. This boost in the immune response should overcome the poor potency of pandemic influenza vaccines, and of seasonal vaccines in individuals with less than robust immune responses, notably the elderly, the immunocompromised and children.

Physical linkage of flagellin to vaccine antigens allows VaxInnate to use efficient, low cost recombinant protein methodologies. The recombinant expression of VaxInnate's vaccines alleviates the manufacturing constraints that have restricted influenza vaccine availability. These products can be efficiently produced at a national and global scale for pandemic and seasonal influenza needs.

VaxInnate's influenza vaccines use two influenza components, the hemagglutinin and M2 proteins. Hemagglutinin (HA) has been the key component in influenza vaccines for the last forty years and is well characterized. For current vaccines, the greatest limitations of HA have been that it changes yearly and it is manufactured by old processes. HA changes each year in an attempt to evade previous immune responses against influenza. These annual changes in HA require manufacturers to change the HA antigens used in each year's formulation. Furthermore, its production is dependent upon egg-based manufacturing. Egg-based manufacturing has limited manufacturing capacity.

Improvements in influenza vaccine production by the industry have recently focused on the production of influenza vaccine in cell culture. This approach alleviates the need for eggs but also has limited manufacturing efficiency. The focus on cell culture production stems from the historical view that protective forms of HA antigens must be manufactured using cells from animals like humans and chickens. VaxInnate has developed the proprietary insights and methods needed to produce protective forms of HA in bacterial expression systems. Our evaluations indicate that these HA-based vaccines, including those for H5 influenza, can be efficiently produced to meet national needs in a period of several months without excessive investments in manufacturing infrastructure.

To address the ever changing nature of HA-based vaccines, VaxInnate's second vaccine candidate uses the stable antigen, M2. M2 has remained unchanged across influenza strains and has mutated only slightly over the last century. Although the M2 antigen by itself is poorly immunogenic, the company's

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Influenza Backgrounder

technology platform stimulates the immune system to take specific notice of it, resulting in a rapid and robust immune response far beyond what would be possible using standard vaccine methods. The M2-based vaccine does not require the advance identification of specific influenza strains and this allows for the stockpiling of vaccine or potentially for the prophylactic vaccination of populations ahead of the emergence of a threat.

VaxInnate's influenza vaccines are entering clinical development. The company has validated manufacturing processes and the M2 based vaccine is scheduled to enter Phase I trials in the first half of 2007. VaxInnate is rapidly developing the HA-based vaccines and expects to file an IND for our HA product in late 2007.