

# VAXINNATE

## **VaxInnate's technology platform: A novel, highly competitive approach to efficient and fast supply of unlimited quantities of vaccines**

VaxInnate, a biotech company based in Cranbury, NJ, produces highly immunogenic vaccines by utilizing its unique technology platform based on the specific and controlled activation of Toll-like Receptors (TLRs). TLRs are a key component of the innate immune system that recognize molecular patterns of microbes and trigger a first line, unspecific immune response against invading pathogens. At the same time, the cells expressing TLRs on their surface also prompt the body to mount an adaptive (specific) immune response (reactive T-cells and antibodies) against foreign antigens that are present when they get stimulated.

The company's genetically engineered vaccines fuse antigens of interest with the bacterial protein, flagellin, a potent stimulator of TLR-5, resulting in *one* pure recombinant protein that contains both components, creating a highly potent vaccine that leverages both the innate and the adaptive immune system.

The company has developed proprietary variants of flagellin fused with various vaccine antigens, including the Hemagglutinin A (HA) component of pandemic (H1N1 and H5N1) and seasonal influenza viruses that are efficiently expressed in bacteria. These recombinant vaccine products have been shown in relevant animal models to be highly immunogenic and protective. Phase I trials in volunteers have confirmed that the influenza vaccines are effective at about one tenth of the dose of a standard commercial influenza vaccine and have good tolerability. The vaccines have also proven highly effective in elderly subjects who typically react only poorly to standard influenza vaccines, resulting in higher seroconversion rates and antibody titers.

The 2009-H1N1 flu epidemic has clearly demonstrated how difficult it is for public health authorities to predict the origin and nature of a pandemic, making it impossible to effectively stockpile or pre-vaccinate proactively. To effectively prepare and respond to an influenza epidemic/pandemic, time- and cost-efficient surge capacities are needed that do not negatively impact the manufacturing capacities for seasonal flu as has been the case in 2009.

VaxInnate's clinical trial and cGMP production experience has demonstrated that tens of millions of doses of human influenza vaccine doses can be manufactured within two weeks from a single manufacturing run per component, using a 1000 liter fermenter. In contrast to

egg-based and even cell culture manufacturing, the VaxInnate process can be readily transferred and scaled-up to the required volumes.

The total amount of vaccine needed for global needs can be made in a few months using existing, standard bacterial fermentation capacity and thus eliminating the need for costly capital investments into new facilities and the significant time needed to build and validate them.

**Key advantages** of VaxInnate's approach are:

**Speed:**

It took only 15 days from obtaining the synthetic gene for novel H1N1-HA to delivery of the first batch of recombinant vaccine product. Generally, first doses of vaccine for use in humans can be available within 10-12 weeks and the total national supply only a few weeks later – a capability to meet surge demand in a pandemic/epidemic situation unmatched by any other technology.

**High potency and good tolerability:**

Adequate immune response levels can be achieved with about one tenth of a standard human dose, and VaxInnate's proprietary methods to modify the flagellin component result in well-tolerated vaccines. VaxInnate's prototype influenza vaccines have been clinically tested in more than 400 healthy volunteers and proved safe and potent in both young and elderly adults. Elderly adults are the most at risk population for influenza disease and have poor response levels to the existing, standard influenza vaccines.

**Unlimited supply with low investment:**

Since the vaccine product is a recombinant protein made in *E.coli* with high efficiency, production can be performed in medium-scale prokaryotic facilities that are already available in many countries, thus avoiding the large capital investment and long lead-time required for new egg-based or cell-culture capacities. This makes the technology highly portable, an advantage especially in emerging markets.