



ASX ANNOUNCEMENT

Imugene avian influenza vaccine success in US trials

- *avian influenza vaccine achieves proof of concept*
- *broiler vaccine progresses to product development*

29 January 2007, Sydney, Australia: Imugene Limited (IMU) has received positive preliminary results from trials of its orally administered poultry avian influenza vaccine candidates. The lead broiler vaccine candidate has achieved proof of concept and will now progress to the product development phase.

The broiler bird vaccine provided protection for two thirds of vaccinated birds (7 survivors from 11 challenged) against a very high dose of a highly pathogenic Asian strain of the H5N1 avian influenza virus. All 9 control birds (not vaccinated) died.

Imugene Managing Director Dr Warwick Lamb said, "these are very positive results from a first proof of concept trial. The best vaccine candidate performed very well for this type of trial. We must emphasize that the virus challenge dose was many times more severe than bird flu outbreaks in the field."

For the first time protection for birds has been achieved with oral administration of a vaccine. As we develop these vaccines we expect to achieve higher levels of protection due to

- further refinement of the vaccine candidates,
- adjustments to the dose and timing of administration, and
- lower virus challenges seen in the naturally occurring disease.

"This trial was a very tough test of the vaccine candidates. For example, the final challenge dose we used in this trial was 200 times higher than was used in Imugene's 2004 Australian based trial in which all birds died within 48 hours. Additionally, the challenge virus strain was different from virus strain used to make the vaccine (heterologous challenge) as we also wanted to document protection across virus strains. It is normal for protection to be lower in this type of challenge model than if the challenge virus and vaccine come from the same strain of the virus (homologous challenge).

Future challenge trials will be at much lower doses to more closely simulate field conditions."

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The successful vaccine candidate has met the efficacy requirements to progress to the next phase of product development. This will involve vaccine construction optimisation followed by dose and timing optimisation studies. These will improve the effectiveness of the vaccine, including increasing the rate of birds protected and the timing for the onset of immunity. Planning of the next phases will depend partly on the information gained from the full trial results report expected within the next two months. The next stages in developing a commercial vaccine is being partially funded by the recently awarded \$880,000 Australian Government Commercial Ready Grant.

The advantages of Imugene's vaccines are effectiveness, low cost mass administration and speed of treatment. Existing methods of dealing with at-risk birds are mass extermination or people going into flocks administering individual injections.

Imugene's successful vaccine candidate is based on the Fowl Adenoviral Delivery Vector that delivers benign genetic material into a bird's bloodstream to boost the immune system to protect against the bird flu virus.

The US based trial on a total of 60 birds commenced in November 2006 with Benchmark Biolabs initially validating the challenge model through to chickens receiving Imugene's vaccine and being challenged with avian influenza virus.

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About the Imugene Avian Influenza vaccines

Imugene is developing two vaccines – one for broiler (meat producing) birds and the other for breeding and egg layer birds. The two vaccine candidates differ as the commercial requirements for broilers and breeders or layers vary. The primary aim for a commercial bird flu vaccine for broilers is to provide immunity early in a bird's life but the protection need only be short term as broiler birds typically reach market weight by 42-49 days of age. Layer birds and birds used for breeding stock for the broiler market require longer lasting immunity. The vaccine designed for layers and breeders uses two antigens (rather than the single antigen used in the broiler vaccine) to elicit both antibody and cell mediated immunity.

The Imugene vaccine candidates have been thoroughly verified by a series of in-house and external tests.

Value of Imugene's vaccines

An effective vaccine could be used to protect the world's poultry industry from further avian influenza outbreaks and halt the spread towards Australia, Europe and the US.

A viable vaccine to control outbreaks must be safe, effective and able to be quickly and easily administered on a large scale.

The Imugene vaccine candidates:

use technology that allows authorities to differentiate between infected and vaccinated birds, a vital consideration for the international poultry industry.

deliver only a portion of the flu genetic material instead of the whole virus. This makes the Imugene vaccines safe by preventing mutations or recombination with human flu viruses.

have been generated using the Imugene delivery system are very cost effective for mass administration to entire poultry sheds and do not require injection of each bird.

are specific to the H5N1 strain of avian influenza, but can be easily and quickly adapted to protect against other strains of influenza

The advantages of the Imugene vaccine solve the limitations of existing vaccines and treatments.

About Imugene

Imugene specialises in commercialising animal health products for production animals including pigs and poultry.

Imugene owns the worldwide rights to the Fowl Adenoviral Vector Delivery System for poultry and the Porcine Adenoviral Vector Delivery System for pigs. Imugene has successfully licensed the first product based on the Fowl Adenoviral Vector Delivery System – the Poultry Productivity Enhancer.

Imugene's poultry and pig portfolio is targeting a worldwide US\$3 billion annual market with four lead vaccine products under development and a strong product pipeline. Consumer demands for disease free and residue free food will bolster Imugene's prospects.

Imugene's products safely prevent disease and reduce or eliminate antibiotics and harmful chemicals in animals. Animal antibiotics and chemicals in the human food chain have been linked to the emergence of dangerous resistant bacteria in people and food residues.

For more information please visit the Imugene Website www.imugene.com

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