



ASX ANNOUNCEMENT

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Imugene's Poultry Growth Product Safety Trial Achieves All Endpoints

Imugene's Poultry Productivity Enhancer easily passes all safety tests

Results from the recently completed Poultry Productivity Enhancer trial have re-confirmed the safety of the vaccine. The Poultry Productivity Enhancer satisfied all the safety trial design endpoints.

The Poultry Productivity Enhancer improves bird health by boosting the chicken's immune system to prevent diseases. The improvement in bird health results in greater weight gains, improved feed conversion and other producer efficiencies.

The trial was undertaken to document certain product safety parameters to enable additional regulatory approvals from the Office of Gene Technology Regulator (OGTR) and Australian Pesticides & Veterinary Medicines Association (APVMA). In particular, the trial was designed to:

1. Detect the duration of shedding for the vaccine following treatment in chickens
2. Detect any spread from treated chickens to untreated chickens in close contact
3. Confirm the vaccine does not infect bird species that may be found in close proximity to commercial chickens (sparrows and starlings)
4. Confirm other bird species (sparrows and starlings) cannot be infected with the vaccine when housed with treated chickens
5. Confirm other bird species (sparrows and starlings) cannot be infected with the vaccine when housed outside the shed of treated chickens
6. Provide information on the lowest vaccine dose at which an effect is seen in chickens
7. Monitor for any vaccine in the flooring material (litter)
8. Check for any residual vaccine on shed surfaces after normal cleaning

Abridged trial results are included at Appendix 1. In summary, the trial results showed:

1. Confirmation of vaccine shedding times shown in previous trials.

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2. No spread from treated chickens to untreated chickens in the same pen
3. No infection of sparrows or starlings when directly treated with a chicken dose of the vaccine
4. No spread to sparrows or starlings housed with treated chickens
5. No spread to sparrows or starlings housed outside the shed of treated chickens
6. A minimum dose at which no significant beneficial effects were seen in chickens
7. No vaccine in floor litter material
8. No detectable vaccine on surfaces after normal shed cleaning

The trial results have been forwarded to Merial Limited, the sublicensee of the Poultry Productivity Enhancer.

Imugene will, pursuant to an OGTR request, conduct one further safety trial to document the vaccine does not infect pigeons. This short trial is awaiting external Ethics Committee approval.

Imugene has commenced preparation of the final submission dossier to the OGTR. Further approvals from the APVMA will be required to allow product sales in Australia. These regulatory approvals focus on the product claims and manufacturing processes. When these approvals are obtained, the Poultry Productivity Enhancer can be sold to commercial growers.

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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Appendix 1

Abridged Trial Results

1. Detection in directly inoculated chickens

Chickens in three groups of ten were treated with the Poultry Productivity Enhancer at varying doses. Swabs were collected to test for the presence of any live vaccine. Of the 322 samples tested over a 36 day period, 8 samples were found to be positive. All 8 positive samples came from 3 birds in the same group and confirmed the presence of shedding of the vaccine at days 6, 7 and/or 8. This result is consistent with previous data submitted to the OGTR which has shown shedding of the vaccine virus from treated birds for up to 10 days after treatment.

2. Detection in sentinel chickens

5 untreated sentinel chickens were allocated to each of the three treatment groups to assess possible spread of the vaccine from treated to untreated in-contact chickens. Swabs were collected to test for the presence of any live vaccine. Of the 154 samples tested over a 36 day period, none were found to be positive. This result confirms that at the doses administered, there is no spread from treated chickens to untreated chickens in close contact.

3. Detection in directly inoculated pest birds

Four house sparrows and four starlings were treated with the Poultry Productivity Enhancer via drinking water at the same dose given to chickens. Fecal samples were collected from each cage every second day to test for the presence of any live vaccine. Of the 44 samples tested over a 41 day period after inoculation, no samples were found to be positive. This confirms the vaccine does not infect pest birds and is therefore not shed in the faeces.

4. Detection in sentinel pest birds

Sparrows and starlings were housed in separate cages, each containing 4 birds of the same species. Two cages each containing four birds of each species were housed within the shed above the floor over a section of the room not containing chickens. Two cages each containing four birds of each species were located against the outside of the shed, adjacent to the wire mesh, above the ground.

Fecal samples were collected from each cage every second day to test for the presence of the live vaccine. Of the 88 samples tested over a 41 day period, none were found to be positive. These results confirm the vaccine does not spread from chickens to other bird species either housed in the shed with treated chickens or outside a shed containing treated chickens.

5. Dose Ranging

Eight groups each of ten chickens were given different doses of the Poultry Productivity Enhancer at different time intervals of between one and three doses to provide information on minimum effective doses. From the results of these eight groups, a dose which has little or no effect on chickens was found, effectively establishing the minimum dose and providing further information for commercial dose regimes.

6. Detection in floor litter

Samples of the floor litter from the shed housing the treated birds were obtained daily for 14 days after treatment. The samples were tested for the presence of any live vaccine. Of the 42 samples tested, none tested positive.

7. Detection in shed after cleaning

Samples were obtained from four separate surface locations in the shed at Day 7 and Day 14 after normal shed cleaning. The samples were tested for the presence of any residual live vaccine. Of the 8 samples tested, none tested positive.

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