

final report

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Development of a single dose bovine immunocontraceptive vaccine

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Abstract

The project was terminated prior to completion by mutual agreement between MLA and Zoetis Australia Research & Manufacturing Pty Ltd in August 2017. At the time of termination, an efficacy study had been completed with four formulations of the anti-GnRF vaccine. Overdose/repeat dose and field efficacy and safety trials had been completed. Three of the formulations resulted in antibody responses, but there was no significant reduction in serum progesterone levels in any of the vaccinated groups.

Executive summary

Zoetis Australia Research & Manufacturing Pty Ltd had been investigating and developing an anti-GnRF (gonadotropin-releasing factor) vaccine in cattle for a number of years. Previous studies showed that heifers vaccinated twice with a four-week interval demonstrated a reduction in oestrus behaviour, suppressed levels of serum progesterone, and increased levels of anti-GnRF antibody. But such a vaccination regime does not fit with husbandry practices in northern Australia, or in beef feedlots. This project was to test a single dose immunocontraceptive vaccine to satisfy registration requirements. An efficacy study was performed with four formulations of the anti-GnRF vaccine. Overdose/repeat dose and field efficacy and safety trials were also performed. Three of the formulations resulted in antibody responses, but there was no significant reduction in serum progesterone levels in any of the vaccinated groups. The project was terminated prior to completion by mutual agreement between MLA and Zoetis in August 2017.

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1 Background

Zoetis had been investigating and developing an anti-GnRF (gonadotrophin releasing factor) vaccine in cattle for a number of years. Previous studies conducted with a vaccine formulations given as two doses with a four week dosage interval, showed that vaccinated heifers demonstrated a reduction in activities associated with oestrus behaviour, suppression of levels of serum progesterone and increases in the levels of anti-GnRF antibody.

The current Bovine anti-GnRF 2 dose vaccine does not fit in with all market applications, for example:

- Pasture reared heifers and culled cows in Northern Australia where animals are mustered infrequently
- Feedlots where cattle are fed for more than 5 months.

Contraception in the above situations could be satisfied by a product that delivers similar efficacy but with longer duration of hormone suppression after a single handling. Zoetis has been examining the VacciMax single dose technology, licensed from ImmunoVaccine Inc, Halifax, Canada. This technology has given long lasting immune responses to GnRF. By inference and with experience in other species it was presumed that these anti-GnRF antibodies would closely correlate with suppression of ovarian activity including folliculogenesis, effectively spaying the heifers. But these manifestations of efficacy, still needed to be proven especially under field conditions.

The aim of this project was to field test a single dose immunocontraceptive vaccine for female cattle and complete studies needed for registration. The availability of this vaccine would allow beef operators to make an informed decision in the management of fertility of female cattle in Northern Australia.

2 Project objectives

Evaluation of the safety and efficacy of an anti-GnRf vaccine under Australian conditions. Registration of an anti-GnRf vaccine for the temporary suppression of fertility in non-pregnant heifers and cows from a minimum 6 months of age. Drafting of a business plan, agreed between the parties and implemented seeking strong adoption within the Australian red meat industry. Successful adoption of the vaccine, resulting in improved female herd management and reduced mortality and welfare concerns that are currently associated with spaying.

3 Methodology

Three delayed release encapsulation versions and one liquid formulation of the vaccine were examined for the temporary prevention of oestrus and pregnancy, and compared to an unvaccinated control group.

A single 2x overdose anti-GnRF vaccine was administered to minimum age heifers, and safety assessed by observation of general health, measurement of rectal temperature and injection site evaluation.

The safety, efficacy and performance of preliminary formulations of a single dose anti-GnRF vaccine in *Bos indicus* x heifers were assessed for the temporary prevention of oestrus and pregnancy in the field, including use of a safety vaccinator.

4 Results

Three of the formulations resulted in antibody responses, but there was no significant reduction in serum progesterone levels in any of the vaccinated groups. The project was terminated prior to completion by mutual agreement between MLA and Zoetis in August 2017.