

ASX Release

Anatara Reports Successful Detach™ Trial Results

Key points:

- Anatara's Detach™ reduced piglet mortality by 47.8%
- Detach™ increased weaning weight of piglets by 5.2%
- Data is consistent with earlier registration trials on commercial pig farms and supports renewed registration

BRISBANE, 18th February 2015: Anatara Lifesciences (ASX:ANR) is pleased to announce positive results from the first Australian field trial of its lead product Detach™, a non-antibiotic natural product to prevent and treat diarrhoea in piglets.

The trial was conducted on a commercial pig farm in Northern Victoria, and the data obtained will be used to support Anatara's application to register Detach™ for sale in Australia with the Australian Pesticides and Veterinary Medicines Authority (APVMA).

The farm had a history of problems with pre-weaning diarrhoea, otherwise known as scour. Current approaches such as vaccines as well as antibiotics had failed to adequately control the problem.

There were 21 litters treated with Detach™ (233 piglets), while 23 litters were administered a placebo (229 piglets) in a randomised and blinded study. The trial investigated the incidence of death and scour, morbidity (or piglet clinical condition), antibiotic use as well as weight gains and found:

- Detach™ significantly reduced piglet mortality by 47.8%. There were 19 piglets treated with Detach™ that died compared with 36 control piglets.
- Detach™ reduced severe morbidity, or life threatening disease. In the control group, there were 38 morbid piglets, of which 36 died, compared with 28 morbid Detach™ piglets of which 19 died.
- Detach™ increased the average weight of each piglet at weaning by 210g (or 5.2%). The increase in average daily weight gain to weaning was 5.3%. More detail on this trial is in the attached Appendix.

Anatara Chief Scientific Officer, Dr Tracey Mynott said: "The results from this trial reproduces our findings from our earlier registration trials where Detach™ was proven to be safe and effective in several thousand piglets on commercial pig farms. In these early trials, as in the current trial, Detach™ significantly reduced mortality, and improved piglet weight gains which provides an economic benefit to the farmer."

Anatara will now focus on completing additional registration trials, as well as scaling up its activities for registration of Detach™ in Europe and the USA. Subject to successful field trials and regulatory approval, Anatara plans to launch Detach™ in Australia in 2016, and then launch in the EU and USA in 2017.

Dr Roger Campbell, CEO of the government supported Cooperative Research Centre for High Integrity Australian Pork (Pork CRC) commented, "The results of this trial are encouraging and support our view that Detach™ could provide a significant benefit to Australian pork producers. The Pork CRC remains keen to work closely with Anatara in investigating Detach™ in Pork CRC supported studies".

Dr Mel Bridges, Chairman said "We are excited that the latest Detach™ field trials reinforce what earlier trials found. This is an important milestone for Anatara and validates our belief that Detach™ will become a valuable tool in producing healthy pigs and generating significant economic returns for farmers".

"Since listing in October 2014 the Anatara team has worked diligently on delivering its key milestones. We are confident in our ability and capability to scale up manufacturing to meet with both the Australian and global demands," Dr Bridges added.

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About Anatara Lifesciences

Anatara Lifesciences is developing therapeutics for gastrointestinal diseases in production animals and humans. Its lead product Detach™ is a natural plant based product that will help address global concerns around the overuse of antibiotics in production animals that is contributing to the rise of so-called "super bugs" that make infectious diseases harder to treat. The Anatara team has a strong track record in biological science as well as building and growing international biotech companies.

Appendix:

Study Description:

This trial was the first of three trials designed to support Anataara's application to re-register and launch Detach™ in Australia. These data will also be used to support Anataara's plans to register and launch Detach™ globally.

The study was conducted on a commercial piggery located in Northern Victoria. This farm has a history of problems with pre-weaning scour usually occurring at 3-4 days following birth.

Study Goals:

The objective of this study was to investigate the efficacy of Detach™ in reducing piglet mortality and morbidity on an Australian farm with a history of pre-weaning scour.

Design:

This study was a blinded, controlled, randomised field trial comparing two parallel groups of piglets. The farmer and farm workers were blinded to the treatments.

Group 1 piglets (21 litters; 233 piglets) were administered Detach™ at 2 days of age.

Group 2 piglets (23 litters; 229 piglets) received a placebo at 2 days of age.

Each group contained equal gilt litters (or first time mothers).

The usual management routines of the farm were allowed to continue, including usual medications such as sow vaccinations and antibiotics, as well as cross fostering of piglets, where small piglets or those of ill health may be moved to another sow.

The trial was conducted by independent veterinarians and investigators from the Pig Specialist Centre, Victorian Department of Economic Development, Jobs, Transport and Resources. The appropriate statistical analysis was determined and applied by an independent biometrician.

Results:

The study was designed as a prophylactic study, where Detach™ was to be administered to piglets prior to the expected onset of scour. However, prior to product administration, scour was evident in 59 of 462 piglets (12.8%). Despite the earlier than expected onset of scour, all piglets were included in the study, and there were no exclusions.

Table 1 shows the number of pre-weaning mortalities in both groups due to all causes. There were significantly fewer piglet deaths ($p < 0.02$) in the Detach™ treated group.

Table 1 – Pre-weaning mortality (all causes)

Treatment	No. Pigs per group	No. pigs	% mortality
Detach	233	19	8.2%
Untreated	229	36	15.7%
% reduction			47.8%

The predominant cause of death in this study was identified as scour and ill thrift in the piglets.

Of the piglets that had life threatening disease, or were considered moribund, 36 of 38 control piglets died, compared with 19 of 28 piglets that were moribund in the Detach™ group.

Table 2 shows the mean and range of weight gains (from day of treatment, Day 2 to weaning) and the average daily weight gain (ADG) for both groups.

Table 2 – Weight gains and ADG from Day 2 to weaning at 21 days.

Treatment	No. Pens	Litter size (weaned)	Average Weight Gain (g) (min – max)	Average ADG (g/day) (min – max)
Detach™	21	10.19	4,188 (2,511 to 5,279)	199 (120 to 251)
Control	23	8.48	3,978 (939 to 5,204)	189 (45 to 248)
% increase			5.3%	5.2%

Detach™ increased litter weights by 5.3% or 210g per piglet. Detach™ also improved the average daily weight gain to weaning of litters by 5.2%. However, these gains were not statistically significant (p=0.49).

Discussion:

Detach™ significantly reduced death in this study, and overall improved piglet health. Although not statistically significant, the increase in piglet weight of 210g per piglet and ADG, as well as the reduction in morbidity and mortality are consistent with previous results obtained from previous challenge studies¹ and field trials conducted on other Australian commercial farms^{2,3}.

Weights of piglets are a quantitative indication of overall piglet health. So together with the observed reduction in morbidity and mortality, Detach™ improved the overall health status of the piglets.

The much higher mortality than expected of nearly 16% observed on this farm, led to the widespread use of antibiotics for welfare reasons. More antibiotics were used in the Detach™ group only because of the larger number of piglets surviving compared with the control group.

¹Chandler and Mynott. 1998. Detach protects piglets from diarrhoea caused by oral challenge with K88 positive enterotoxigenic Escherichia coli. *Gut* 43:196-202.

² Chandler DS, Spicer EM. Fixed or flexible dose regimes for Detach. Manipulating pig production III. Proceedings of the Inaugural Conference of the Australian Pig Science Association. Werribee, Victoria, Australia: Australian Pig Science Association, 1991:146.

³ Ciba Geigy Detach Trial summary, 1991.