

ASX Release

## Anatara Market Update

### Key points:

- **Third Australian field trial commences on commercial pig farm**
- **Target Animal Safety Study commences**
- **APVMA Dossier preparation well advanced**
- **Potential to quickly move into major Asian markets post APVMA approval**
- **Company pursues additional growth opportunities**
- **Research and Development program initiated with La Trobe University**

BRISBANE, 16<sup>th</sup> June 2016: Anatara Lifesciences (ASX:ANR) is pleased to announce significant progress towards registration of its lead product Detach™, a non-antibiotic, natural therapeutic to prevent and treat diarrhoea, in piglets.

Anatara has commenced two new trials that will support its application to register Detach™ for sale in Australia with the Australian Pesticides and Veterinary Medicines Authority (APVMA) and overseas. Approval for sale of Detach™ in Australia will open the opportunity to quickly register it for sale in major Asian markets. The first trial is an efficacy study in unweaned piglets (“suckers”). The second trial is a GLP target animal safety (TAS) study, also in suckers, in compliance with the VICH GL43 international guidelines.

Anatara is also pleased to announce that it has commenced a research and development collaboration with researchers at La Trobe University in Melbourne, exploring Detach™ product extensions and new opportunities for the core active components of Detach™.

### **Efficacy Study on a Commercial Pig Farm**

The objective of this study is to expand the dosing instructions for the final registration label. This expanded label will provide the farmer the option to administer either a single Detach™ dose, or a multiple (x 2) dosing regimen depending on a particular farm’s problem.

This third Australian field trial is being conducted on a major commercial piggery. A minimum of 450 two day old sucker piglets have been enrolled and have been treated with Detach™ in a placebo controlled, parallel group, randomised and blinded study. The results are expected within the third quarter 2016.

The farm has a history of problems with pre-weaning scour (diarrhoea) and current approaches such as antibiotics have failed to control the problem. The trial will investigate the ability of Detach™ to reduce mortality, the incidence, severity and duration of scour compared to placebo. Scour and overall piglet health up to weaning will be assessed by a scoring system that measures the incidence and severity of scour as well as overall piglet demeanour and clinical condition. Other trial endpoints include increases in average daily weight gain as well as need for antibiotic treatments.

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## **Target Animal Safety Study**

The objective of this study is to provide detailed safety data on Detach™ when administered orally to piglets at dose rates higher than the recommended single dose, commencing at two days of age. The effect of re-dosing piglets after three-to-four day intervals over a three week period will also be examined.

This study is being conducted in accordance with VICH<sup>1</sup>, a trilateral (EU-Japan-USA) program aimed at harmonising the technical requirements for veterinary product registration, and will further support the global rollout of Detach™.

Although Detach™ has already been shown to be safe in previous trials, a formal safety assessment is a requirement for registration of new active ingredients and new veterinary formulations in Australia, Europe and the USA. The margin of safety of Detach™ will be determined when it is administered at larger doses (up to five times), and for a longer than intended duration (up to three weeks). This is in the case of accidental overdosing, or repeated administration of Detach™.

Anatara Chief Scientific Officer, Dr Tracey Mynott, said, “All piglets have now received their first dose of Detach™ and I am pleased to report that no adverse effects have been observed in piglets receiving the highest dose, which is five times the recommended dose rate.”

Anatara Chairman, Dr Mel Bridges, said, “These studies will complete the clinical trial requirements for the Australian Dossier. Anatara still expects approval and product launch in Australia in 2017.”

## **Research and Development Collaboration with La Trobe University**

Anatara is also pleased to announce it has entered into a research and development collaboration with The La Trobe Institute for Molecular Science, at La Trobe University in Melbourne to develop active components within Detach™ for the treatment of inflammatory diseases in humans and in companion animals.

The La Trobe Institute for Molecular Science (LIMS) brings together leading scientists in protease chemistry, biochemistry, molecular biology, and structural biology who have a strong focus on infection and immunity, as well as molecular design.

Dr Mynott said, “Now that Anatara’s lead product is nearing APVMA submission, the company has commenced advancing Anatara’s pipeline of novel products. The Agreement is for the production, validation and pre-clinical evaluation of a specific active component called ANA0019 isolated from the active ingredient in Detach™. Earlier work has shown that ANA0019 displays anti-inflammatory activity by blocking MAP kinase pathways, and the production of pro-inflammatory cytokines, well validated targets for anti-inflammatory drugs.”

Dr Mynott added, “The program aims to generate a data package demonstrating ANA0019’s efficacy, potency, stability and pre-clinical safety. This pre-clinical R&D program will provide

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<sup>1</sup> VICH – International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

the data package Anataara needs to pursue ANA0019's development and partnering activities in both animals and humans.”

Anatara Chairman, Dr Mel Bridges said, “Since listing in October 2014 Anatara continues to execute on its business plan and deliver on its key milestones. Anatara expects Detach™ to be on sale in Australia in 2017, with launch into a number of Asian markets also targeted shortly after the Australian launch.”

The Anatara team plans a further market update and investor roadshow in July.

**For more information please contact:**

**Investor and Media inquiries**

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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.

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