ASX Release

Anatara Successfully Completes Target Safety Study

Key points:

- **Successful completion of pivotal safety study for Detach™**
- **Detach™ proven to be safe in fully GLP compliant study, conducted to the highest international standards**
- **Dossier for registration of Detach™ with Australian Pesticides and Veterinary Medicines Authority (APVMA) now in final stages of preparation in readiness for submission in Q3 2016**
- **Australian launch for Detach™ remains on track for 2017**

BRISBANE, 8 September 2016: Anatara Lifesciences (ASX: ANR) is pleased to announce the successful completion of its pivotal Target Animal Safety (TAS) Study for Detach™, the Company's lead product for the control of diarrhoea in piglets.

The objective of the study was to provide detailed safety data on Detach™ when administered to piglets at dose rates higher and more frequent than the recommended dose. For example, in the case of accidental overdosing, or repeated administration of Detach™.

The study involved 40 piglets and Detach™ was found to be safe when administered orally at the recommended dose rate (2 mL) and also at three times (6 mL) and five times (10 mL) the recommended dose. Detach™ was dosed on six occasions (at 2, 5, 9, 12, 15 and 18 days of age) throughout the study, a frequency which far exceeds the recommended dosing regimen. There were no differences between placebo-control piglets in any of the parameters studied, including body weight gain, tissue weights, tissue histopathology examination, haematology, serum chemistry, and urine analysis.

The study was a fully GLP[1] compliant, randomised, controlled, parallel group study conducted in accordance with the US Food and Drug Administration's Center for Veterinary Medicine's Guideline 185, VICH[2] Topic GL43 guideline. It was contracted to a leading international contract research organisation (CRO) that provides pre-clinical and clinical services to the global animal health industry.

Anatara CSO, Dr Tracey Mynott commented, "These studies complete the clinical trials component of the APVMA Dossier".

"Although Detach™ had already been proven 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 results confirm that Detach™ is safe, consistent with the large safety database already generated on the product," finished Dr Mynott.

[1] Good Laboratory Practice
[2] VICH – International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.

Anatara Lifesciences Ltd
433 Logan Road, Stones Corner
Brisbane QLD 4120 Australia
info@anataralifesciences.com
www.anataralifesciences.com

Anatara CEO and Chairman, Dr Mel Bridges, said, "The results of this study, are as we expected, and are a significant milestone achieved in the Detach™ development program. We continue to make good progress towards the approval of this important product."

"The TAS study was conducted to the highest international standard acceptable in major commercial territories and may reduce the need for separate TAS studies in each jurisdictional registration application. Long term this strategy presents the most efficient and cost effective way to prepare for the global roll out of Detach™." said Dr Bridges.

This TAS report will now be incorporated into the APVMA regulatory approval application Dossier, along with the other Dossier requirements[3] which include data and reports on,

- Occupational Health and Safety
- Environmental Risk Assessments
- Metabolism and kinetics
- Chemistry and Manufacture
- Toxicology assessment
- Residues and metabolism
- Efficacy and safety

The only outstanding item required to complete the Dossier Application is receipt of a validation report from Anatara's manufacturing partner, which is part of the Chemistry and Manufacturing requirements. This is only a procedural matter.

For more information please contact:

General inquiries	**Media inquiries**
Mel Bridges CEO and Chairman, Anatara Lifesciences +61 (0) 413 051 600 mbridges@anataralifesciences.com	Jane Lowe IR department +61 (0) 411117774 jane.lowe@irdepartment.com.au

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.

[3] http://apvma.gov.au/registrations-and-permits/data-guidelines?qt-data_guideline_tabs=1#qt-data_guideline_tabs