ANATARA LIFESCIENCES

ASX Release

Anatara achieves a major US FDA milestone in the registration of Detach® with approval of the Human Food Safety Dossier

Key points:

- **Significant milestone achieved in the United States with the receipt of a "complete" letter for the technical section of the human food safety submission for Detach®**
- **Letter confirms that the US Food and Drug Administration is satisfied that food products from animals treated using Detach® will be safe for human consumption**
- **Human food safety dossier forms one part of the application required to register Detach® for sale in the United States; approved ahead of time expectations**

BRISBANE, 5 February 2018: Anatara Lifesciences (ASX:ANR) has achieved a significant milestone in the United States of America after receiving a "complete" letter from the US Food and Drug Administration (FDA) for the Technical Section of its Human Food Safety (HFS) submission. The HFS is a major component of a New Animal Drug Application (NADA) which is currently underway and is necessary for enabling the marketing of Detach® in the US.

The complete letter confirms that the FDA's Office of New Animal Drug Evaluation, Center for Veterinary Medicine, is satisfied that the human food safety requirements for Detach® have been met and that food products from animals treated using Detach® are considered safe for human consumption.

The HFS Technical Section includes an assessment as to whether Detach® will contribute to antimicrobial resistance (drug resistance).

Anatara's Chairman and CEO, Dr Mel Bridges commented, "Safety of edible products from drug-treated, food-producing animals is a critical part of the US drug approval process, so receipt of the complete letter is a core step for the entry of Detach® into world markets.

The efficacy, overall safety and manufacturing information required for the approval of human and animal drugs is very similar, but the safety of a drug targeted at food-producing animals must undergo an additional level of stringent review to ensure that there are no residual safety issues for the human consumer.

The Human Food Safety section of the registration process can alone take from three to six years to complete, and can represent 50 to 70 percent (or between $5 to $8 million) of expenditure for a new drug[1]. The fact that Anatara has achieved an outcome within three

[1] Committee on Drug Use in Food Animals, Panel on Animal Health, Food Safety, and Public Health, National Research Council, 1999. The Use of Drugs in Food Animals: Benefits and Risks. ISBN: 0-309-52536-5

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years of opening our Investigational New Animal Drug application is an outstanding result and speaks to the strong safety profile we've seen for Detach® in our trials.

Registering Detach® in the US will be key to the safe sale of the product in that market for Antara or a commercial partner."

For more information please contact:

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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 aids in the control of diarrhoea and 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.