

ASX Release

Anatara Milestone and Market Update

Key points:

- **Lead product Detach™ shipped to Zoetis under Option Agreement with the non-refundable Option payment expected in April**
- **Receipt of Detach™ by Zoetis triggers start of evaluation period**
- **Anatara to conduct Target Animal Safety Study offshore to higher standards, delaying submission of the APVMA approval dossier**
- **Detach™ still on track for 2017 approval and product launch in Australia**
- **Ongoing media reports highlight growing global awareness and action on the need to reduce antibiotic use in livestock thereby supporting Anatara's natural based product Detach™**

BRISBANE, 1st April 2016: Anatara Lifesciences (ASX:ANR) is pleased to advise confirmation of shipment of its lead product Detach™ to Zoetis Inc. under their exclusive global Evaluation and Licence Option Agreement (ASX release Jan. 18, 2016). Receipt of the shipment of Detach™ will allow Zoetis, a multinational animal health company, to begin an aggressive and comprehensive evaluation program using Detach™ in multifaceted trials across a range of livestock species.

An invoice has been issued to Zoetis for the first upfront payment due following signing of the agreement.

Anatara Managing Director and CEO, Dr Paul Schober said the Detach™ consignment was manufactured under strict GMP compliance and labelled to conform to US standards.

Dr Schober said, “We now have in place the ability to manufacture and supply large quantities of Detach™ which are sufficient to meet global demand. The shipment of product to the US marks a significant milestone for the company.”

As Zoetis conducts its evaluation program, Anatara will now conduct a full GLP target animal safety (TAS) study in piglets in compliance with the VICH GL43 international guidelines.



VICH¹ is a trilateral (EU-Japan-USA) program aimed at harmonizing the technical requirements for veterinary product registration, and may reduce the need for separate TAS studies in each registration application, and in the long term reduce the costs of product development. The study will further support the global rollout of Detach™.

Whilst completion of this TAS study, and its inclusion in the APVMA dossier, will delay submission of the Detach™ dossier by several months, the study will significantly strengthen the Australian dossier and aid in its passage through the approval process. Importantly Anatarra still expects approval and product launch in Australia in 2017.

“The TAS study will be conducted to the highest International standard acceptable in major commercial territories and long term presents the most efficient and cost effective way to complete roll out of Detach™ globally,” said Dr Schober. “Given Anatarra has demonstrated safety of Detach™ previously to Australian standards in numerous trials, we expect the study to go smoothly,” he added.

Anatarra Chief Scientific Officer and co-founder Dr Tracey Mynott said an additional trial of Detach™ in piglets in Australia was ready to proceed and would be used to further support applications for regulatory approvals.

She also noted that Anatarra’s intellectual property position has been strengthened by a recent positive International Searching Report (ISR) on the key Detach™ patent. The ISR identifies possible prior art which may have an influence on the patentability of products. “We were delighted with the report recently received,” Dr Mynott added.

Anatarra is also pleased to note growing global awareness and action on the need to reduce the use of antibiotics in production animals.

The antibiotic-free food movement continues to gain momentum with large food chains such as In-N-Out Burger, Subway and Chipotle having declared they will only use antibiotic-free meats in their products while the European Parliament has voted to further tighten laws on the veterinary use of antimicrobial medicines. There is now clear and significant global industry support for efforts to combat antimicrobial resistance and its associated impact on humans.

At the recent World Economic Forum, more than 80 leading international pharmaceutical and biotechnology companies issued a joint declaration calling on governments to work in parallel with industry to implement a comprehensive global action plan against “super bugs”.

¹ VICH – International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

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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.