

ASX Release

Manufacturing, clinical trial and European SME status update

Highlights

- First manufacturing run of Detach™ completed, ready for use in the treatment of pigs during field trials
- Trial site selection underway, with Australian Detach™ trials expected to commence in November
- Registration of SME status approved in Europe, enabling a 90% fee reduction on the cost of seeking advice from the European Medicines Agency

BRISBANE, 17 October 2014: Gastrointestinal therapeutic company, Anatara Lifesciences (ASX: ANR) is pleased to announce it has completed its first pilot manufacturing runs of Detach™ and will now initiate manufacture required for registration purposes under the Australian Pesticides and Veterinary Medicines Authority's (AVPMA's) product registration approval process.

The Detach™ product, used for the treatment of scour (diarrhea), is being manufactured using Good Manufacturing Practice (GMP) standards, and will be used in Anatara's Australian field trials, where it will be used to treat diarrhea in pigs. Diarrhea is a major issue that affects the weight of pigs and profitability of pig farms.

In parallel with manufacturing the product, Anatara is working with Australian pig farmers to select appropriate sites for the Australian clinical trials, which are expected to commence in November. The purpose of the clinical trials will be to reconfirm the safety and efficacy of Detach™ in an Australian setting.

Anatara Chairman, Dr Mel Bridges said "While we know from recent field trials in other countries that Detach™ has been proven safe and efficacious, running these Australian trials are an important box for Anatara to tick as we move towards registration of the product with the AVPMA. Completion of our first manufacturing run and trial site selection are two key steps for Anatara on the path to delivering our strategy of getting Detach™ on the market in Australia by 2016."

Alongside the work being undertaken in Australia, in order to accelerate the regulatory acceptance of Detach in Europe, Anatara has submitted and received acceptance on its application for micro-, small- and medium-sized-enterprise (SME) status in Europe.



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With the granting of SME status by the European regulatory body, European Medicines Agency (EMA), Anatara stands to benefit from the incentives offered under the scheme. Under the SME initiative, a substantial 90% fee reduction is applied where registered companies seek advice from the EMA on all issues relating to the development of new medicinal products. The purpose of the scheme is to maximise the chances of a successful marketing authorization for companies like Anatara.

Other financial incentives include a 90% fee reduction for any good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP), or pharmacovigilance inspections requested by the EMA. For Anatara's veterinary medicines, there are several areas of support that will be necessary in gaining European product approval and there is the possibility to request a 90% fee reduction for establishment of maximum residue limits. Full fee exemptions are also offered for administrative services from the EMA (eg. EMA certificates for medicinal products).

"It is significant that Anatara has gained SME status as a non-European company. The overwhelming majority of companies to gain this status are based in Europe. The granting of this status will greatly support our move into the important European market. Our plan is to leverage off Australian and European approval to launch our products into other global markets," Dr Bridges added.

Health authorities around the world are moving to limit the use of antibiotics in animal production as their overuse contributes to the rise of antibiotic-resistant bacteria, so-called superbugs that threaten human health.

The Company's lead product, Detach™, is a non-antibiotic therapy to treat and prevent diarrhoea. Anatara is focused on commercialising Detach™, initially for use in pigs, ahead of expanding its use to other livestock, and then developing it for use in humans.

Anatara looks forward to updating shareholders as progress is made to launch Detach™ into the market.

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About Anatara Lifesciences

Anatara Lifesciences (ASX: ANR) 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 concern about 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. For more information visit www.anataralifesciences.com.