



**PEPTECH**  
LIMITED

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## **ASX / MEDIA ANNOUNCEMENT**

### **Suprelorin<sup>®</sup> recommendation clears path for sales in Europe**

#### Key points

- Suprelorin<sup>®</sup> receives recommendation for approval in Europe
- Significant regulatory step completed
- One procedural step required for marketing authorisation
- Sales in Europe expected in second half of 2007

Peptech Limited (ASX:PTD; AIM:PTDx), the Australian biotechnology company announced today that its wholly-owned subsidiary Peptech Animal Health Pty Limited (PAH), has received a recommendation to grant approval in Europe for Suprelorin<sup>®</sup>, a veterinary contraceptive product.

PAH has been informed by the European Medicines Agency (EMA) that the Committee for Medicinal Products for Veterinary Use (CVMP) has recommended the grant of a European Marketing Authorisation for Suprelorin<sup>®</sup>.

Cyton Biosciences, PAH's regulatory partner in Europe for Suprelorin<sup>®</sup> said that a positive opinion from the CVMP provides an almost certain indication that a European Marketing Authorisation, granted by the European Commission, will follow within the next three months. With this opinion, the CVMP has reached a positive conclusion on the safety and efficacy of Suprelorin<sup>®</sup> for rendering healthy, non-castrated, sexually mature male dogs as temporarily infertile for a period of six months.

Suprelorin<sup>®</sup> is anticipated to become commercially available throughout Europe during the second half of 2007

The product has been successfully marketed in Australia since December 2004 and New Zealand since September 2005. In addition, PAH is currently pursuing a registration application with regulatory authorities in the US.

Dr John Chiplin, CEO of Peptech said: "The European market for Suprelorin<sup>®</sup> offers considerable growth opportunities for sales of the product with the canine population estimated to be over 60 million, more than fifteen times the size of the Australian market but with a much lower rate of surgical castration".

“Importantly, the European attitude towards castration of pets is far more polarised compared with Australia. An illustration is that surgical castration for reproductive control in dogs is banned in Norway. As a result, we anticipate an enthusiastic response to the launch of Suprelorin® in Europe.”

“We are confident that our search for a suitable European marketing partner will gather increased momentum in recognition of this recommendation for approval. Furthermore the recommendation also makes the Animal Health business much more attractive to prospective acquirers as it gives more certainty to the business’s potential”.

## **ENDS**

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### **About Peptech:**

Peptech Limited focuses on the research and development of peptides and proteins in the areas of human pharmaceuticals and animal health. The company is positioned to become a globally recognised leader in biopharmaceutical development.

For further information: [www.peptech.com](http://www.peptech.com)

### **About EMEA**

The European Medicines Agency (EMA) is a decentralised body of the European Union with headquarters in London, and is responsible for the scientific evaluation of applications for European marketing authorisation for medicinal products (centralised procedure). Under the centralised procedure, companies submit one single marketing authorisation application to the EMA and obtain one single, pan-European marketing authorisation.

### **About Suprelorin®**

The active agent in Suprelorin® is a synthetic analogue of a naturally occurring hormone (LHRH). When this analogue is given over a sustained period of time the chemical message to product steroid hormones from the pituitary gland to the gonads is impaired.

The drug delivery platform for Suprelorin® a subcutaneous, slow-release, lecithin-based, biocompatible implant - is unique in the market and has wide potential applications. Peptech is a world leader in this type of slow-release implantable technology. Trials of up to five consecutive treatments over three years of Suprelorin® have shown that fertility

returns when treatment is stopped, making the treatment reversible, which is a major bonus for breeders.

Suprelorin<sup>®</sup> (as a 2.3x12mm cylindrical dose) is inserted between the dog's shoulders. The disposable implanter is no larger than that used to implant microchips in dogs and is a highly cost-effective way to deliver the drug. No anaesthetic is required and there is none of the discomfort, recovery or potential risks that would be associated with surgery.

Suprelorin<sup>®</sup> also has the potential to improve the health of many species of animals on a number of fronts. It is already indicated for benign prostatic hyperplasia and behaviour in Australia and New Zealand and recent studies show that Suprelorin<sup>®</sup> is also effective in treating incontinence in spayed bitches. This would provide dog owners with a convenient, long-term treatment option, preferable to the current therapies that not only require frequent medicating, but can also be associated with side-effects.

Suprelorin<sup>®</sup> is currently being used in wildlife parks and zoos for population control on a number of different species including lions, cheetahs, monkeys, dolphins, seals and other mammals.

Patent applications are being expanded to cover repeat usage, use in females, use for other indications and in other animal species.

Further information is available on Peptech's website: [www.peptech.com](http://www.peptech.com)