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ASX / MEDIA ANNOUNCEMENT

Peptech advances anti-TNF dAb following completion of successful preclinical trial

Key points

- Anti-TNF dAb about three times more potent than a leading blockbuster anti-TNF drug against rheumatoid arthritis in an industry standard model
- Drug candidate engineered to improve acceptability in humans and to enhance commercial potential
- The anti-TNF dAb is targeted at a market with 2004 product sales in excess of \$US6 billion
- The drug candidate has now entered the initial phase for quantity production under the stringent conditions of Good Manufacturing Practice (GMP), to enable further preclinical and clinical testing.

Australian biotechnology company Peptech Limited today announced significant preclinical trial results for its human domain antibody (dAb) therapeutic, with the candidate recording potency levels approximately three times higher than a leading blockbuster anti-TNF drug against rheumatoid arthritis in an industry standard model.

Peptech's domain antibody against tumour necrosis factor- α (TNF) — used for the treatment of multiple inflammatory diseases such as rheumatoid arthritis and Crohn's disease — successfully and dose- dependently suppressed disease development.

Peptech Executive Chairman Mr Mel Bridges said Peptech had completed extensive work over the past year in improving the acceptability of the anti-TNF dAb as a potential drug in humans and increasing its commercial potential.

"We have advanced our anti-TNF dAb considerably over the past 12 months through further engineering and preclinical development. Our current work is at the forefront in the development of effective treatments for a wide range of inflammatory diseases," he said.

Peptech R&D Director Dr Phil Jennings said the strong performance of the anti-TNF dAb in preclinical studies conducted to date gave Peptech strong confidence the drug candidate could be successfully commercialised.

“The model used in the preclinical trial was the same model used in the commercialisation of marketed blockbuster anti-TNF drugs, which reinforces our conviction that this candidate has the potential to become one of the next generation in anti-inflammatory treatments,” he said.

Dr Jennings said the drug candidate had now entered the initial phase for quantity production under the stringent conditions of Good Manufacturing Practice (GMP), to enable quality and quantity suitable for further preclinical and clinical testing.

“Our focus is on continuing to advance the preclinical development of the anti-TNF dAb, with an expectation of reaching the clinic in 2007,” he said.

“Our recent move to new premises has enabled us to undertake early stages of production, reducing the company’s reliance on outsourcing and resulting in ongoing cost savings.”

Following the successful completion of work under a research agreement between Peptech and the UK company Domantis Limited, the anti-TNF dAb was transferred to Peptech by Domantis in April 2005. Peptech has since further engineered the dAb based therapeutic protein to enhance its characteristics as a human therapeutic.

Mr Bridges said therapeutic biologicals represented a major commercial opportunity, with the company’s anti-TNF dAb targeted at a market with 2004 product sales in excess of \$US6 billion.

“We hold a very strong intellectual property position in anti-TNF’s, and are in the enviable position of receiving ongoing strong revenue streams from our existing TNF licence agreements with Abbott and Centocor,” he said.

“Peptech has never been better positioned — we have a spread of risk, ongoing revenue streams and a promising development pipeline with products directed at two of the world’s largest markets; cancer and inflammation.”

ENDS

Further information:

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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. Peptech holds a 36.1 per cent shareholding in Domantis, a UK-based drug development company. The company is positioned to become a globally recognised leader in biopharmaceutical development.

About anti-TNF biologicals

Anti-TNF biologicals already constitute an expanding market and the domain antibody provides an opportunity to develop a product to treat important clinical conditions using the anti-TNF therapeutic approach. The worldwide antibody market continues to provide strong growth, with 2004 sales exceeding US\$9 billion. The sales of anti-TNF's alone exceeded US\$6.4 billion in the 2004, with revenue growth continuing resulting in sales of US\$1.9 billion in the first quarter of 2005.

Tumour Necrosis Factor (TNF)

TNF is a normal protein hormone produced by white blood cells that is important as a regulator of the immune system. In its normal role it contributes to protection against infection and cancer. However excess TNF is associated with inflammatory diseases e.g. rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis and Crohn's disease (an inflammatory bowel disease).

Inflammatory diseases characterised by excess TNF can be treated by effectively reducing the excess TNF through antibodies and other molecules which block or neutralize TNF. Successful agents which have been used to reduce excess TNF include Remicade® (Centocor), Humira® (Abbott) and Enbrel® (Amgen).

Glossary

- Anti-TNF= molecule that negates the biological activity of TNF
- Domain antibody = a class of biological molecules that can be engineered for a range of applications including neutralising the effects of TNF in patients. The technology used here for initially generating the anti-TNF dAb is proprietary to the UK company, Domantis.