

ASX ANNOUNCEMENT

Benitec Biopharma welcomes European Regulator's Landmark Gene Therapy Decision

Highly significant for Benitec Biopharma's gene silencing programs

Sydney Australia 23 July 2012: Benitec Biopharma Limited (ASX:BLT), a world leader in RNA-based gene silencing for human therapeutics, today welcomed news of the landmark decision by the European Medicines Agency to recommend approval of uniQure's gene therapy to treat a rare genetic disease.

When formally approved, this will be the first gene therapy product to be approved in the EU or United States. "The implications of this decision for Benitec Biopharma's technology and programs is enormous," Benitec Biopharma's CEO, Dr Peter French said. "I believe that a major reason why big pharmaceutical companies have been slow to invest in the gene therapy field is because, until now, there have been no approved products in the major markets. Now there is a precedent for approaches using gene therapy delivery to gain marketing approval, meaning that they can be used to treat patients, and enter the standard revenue/reimbursement model of pharmaceuticals. This takes the valuation of our programs out of the theoretical arena and into a realistic scenario of market size and penetration. Our shareholders, along with current and potential licensing partners can now be confident that, should our programs pass the clinical stage testing in terms of safety and efficacy, they have a realistic probability of reaching the market. We are now no longer seen as ground-breakers, and therefore high risk. We have a precedent to follow."

Although the therapy does not utilise Benitec Biopharma's gene silencing technology, it is a critical decision for Benitec as it utilises a very similar (viral) delivery method to take the gene silencing DNA to target cells and tissues, and therefore this approach is regarded as a form of gene therapy by the regulators.

Dr French had an encouraging preliminary meeting with the EMA in May regarding the design of Benitec Biopharma's pain program, and the company sees the EMA's decision as validating its focus on the European market as the first jurisdiction to enter.

The therapy recommended for approval in Europe, called Glybera, was developed by uniQure, formerly Amsterdam Molecular Therapeutics, a Dutch company. It treats lipoprotein lipase deficiency, a disease that affects only several hundred people in the European Union and a similar number in North America. uniQure and Benitec Biopharma are in early stage discussions regarding potential collaborative approaches.



For Further Information

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About Benitec Biopharma

Benitec Biopharma Limited is developing novel treatments for chronic and life-threatening conditions based on targeted gene silencing activity using a transformational technology: DNA-directed RNA interference (ddRNAi) - sometimes called expressed RNAi. The technology's potential to address unmet medical needs and to cure disease results from its demonstrated ability to permanently silence genes which cause the condition. Importantly, this technology's target gene and related gene pathways will rarely have presented as a therapeutic avenue for research for the traditional small molecule agents, currently accounting for the majority of today's pharmaceutical products.

Founded in 1997 and trading publicly since 2001, Benitec Biopharma is listed on the Australian Securities Exchange (ASX) under the symbol "BLT". Benitec Biopharma aims to deliver a range of novel ddRNAi-based therapeutics to the clinic in partnership with the pharmaceutical industry. Besides a focused R&D strategy in infectious diseases, cancer and chronic cancer-associated pain, Benitec Biopharma is pursuing programs with licensees that have advanced to pre-clinical and/or clinical trials.

Benitec Biopharma videos can be viewed at www.youtube.com/user/BenitecNews