



BioPharmica Limited

PRESS RELEASE

Successful Lung Disease Genechip Trial

Perth, Australia, February 1 - BioPharmica Ltd (ASX: BPH) today announced that the lung disease genechip trial was an outstanding success, surpassing all goals and objectives.

The new lung disease test is being developed in conjunction with Diagnostic Array Systems at RMIT University. An international pathology company participated in a blind study to determine the accuracy of the test. The study involved approximately 500 clinical sputum samples from patients with suspected lung disease.

Key Outcomes:

- (1) DNA from the clinical samples was isolated in batch, high throughput conditions with 100% efficiency. PCR amplification from these DNA samples was obtained for 92% of the clinical samples tested.
- (2) The genechip was able to test for all 23 species of bacteria simultaneously.
- (3) The genechip performed in a quantitative, specific and robust manner.
- (4) Discussions have commenced with third party providers in terms of supply/manufacture/ licensing.
- (5) The company is seeking to further validate the test through trials in hospital pathology settings.

Importantly the results also showed that:

- (1) The genechip was able to detect atypical organisms, which can be very important causes of pneumonia, especially in children and the elderly. Atypical bacteria are extremely hard to detect with conventional culturing methods and are often misdiagnosed or the samples are determined as 'no pathogen isolated' through the culture technique.
- (2) Extraction and amplification of DNA from clinical sputum samples could be performed in high throughput under commercial pathology laboratory conditions.
- (3) The technology enabled the identification of an array of bacteria in a clinical sample in a matter of hours instead of testing for each bacterium individually over a period of several days, or even weeks.

The system did not require special conditions to be set for each species of bacteria, or a judgment concerning the infection prior to testing whereas the traditional testing approach relies on the GP predicting which bacteria may be causing symptoms.



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The traditional culture test conducted on the samples was able to identify individual bacterial species only when a specific pathogen could be isolated (only in approximately 29% of the samples).

The genechip was shown to be capable of producing a fingerprint of bacterial flora in a given sputum sample in over 90 % of the patient samples. This provides potentially important information concerning the natural or background flora of a patients lungs as well as pathological identification and quantification.

The Genechip indicated pathogen positive in 52 % of the samples, the traditional culture techniques indicated pathogen positive in less than 30 %. The Genechip was also very specific about the species of bacteria detected as it relies on DNA signatures, and not on an individual operator's judgement.

Dr Gallagher said "Obviously, we are very pleased with the results of the trial. The lung disease test has moved from the research bench to clinical testing conditions with no hitches."

"We have also been able to identify further enhancements to the test from our study of the pathology laboratory samples which may further improve the product to meet the needs of the end user."

"Resolving manufacturing and distribution issues to gain market entry is the next area of focus and we are starting to attract some interest in this area."

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BioPharmica is dedicated to the ideals of Personalized Medicine through the applied development of discoveries made through fundamental research coming from leading Australian biomedical researchers. Projects undergoing pre-clinical and clinical development are in the production of diagnostic arrays, nanoprobe, biomarkers and therapeutics for diseases including cancer, neurodegenerative, and infectious diseases.

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