BioPharmica Limited

BioPharmica Cancer Gene Pilot Trial

- HLS5 gene fault found in over 50% of breast cancer cell lines
- 70 sample pre-clinical trial commenced at WAIMR
- Preliminary HLS5 gene trial results expected within 4-6 weeks

ASX Announcement – 17 February 2005

BioPharmica Ltd (ASX: BPH) and the Western Australian Institute for Medical Research (WAIMR) today announced that the parties have commenced potentially groundbreaking trials to detect cancer with an HLS5 gene marker due to outstanding pilot study results.

A pilot study of 20 breast cancer cell lines found that **more than 50% tested had a fault in the HLS5 gene.**

Sales of marker tests associated with just 10% -20% of cancers target markets in excess of hundreds of millions of dollars, which reflects the tremendous commercial potential of HLS5.

The pilot study indicated that cancer cells are able to grow when the HLS5 gene becomes faulty and that a fault in the HLS5 gene may be associated with a *majority* of breast cancers.

Repeated testing by WAIMR researchers also confirmed that other cancer cell lines, including ovarian, colon and lung cancers also demonstrated a fault in the HLS5 gene. There is vast potential for wide reaching HLS5 commercial applications.

BioPharmica and WAIMR have now commenced a pre-clinical trial of the HLS5 marker. This trial involves a 70-sample study of the HLS5 cancer marker in normal and confirmed breast, ovarian, lung and colon tissue.

Completion of this trial is anticipated within 2 months, with **preliminary results in 4-6 weeks.**

An HLS5 marker test is being developed to diagnose the fault (called a marker) and thereby detect cancer earlier and more accurately than existing methods. The goal of the trial is to confirm pilot study results and directly correlate the presence of the HLS5 molecular marker to cancer in humans. The trial program will assist in developing a robust test for detecting cancer with the HLS5 marker.

A further trial is anticipated to commence May 2005 that would increase sample numbers and complete validation of the HLS5 marker. Such evidence will assist regulatory approval and marketing of the HLS5 marker test by BioPharmica, or a strategic partner, to specialist diagnostic laboratories.

Led by Professor Peter Klinken, a team of scientists discovered the tumor suppressor gene known as HLS5 at the University of Western Australia. Professor Klinken said the gene acted like a brake in a car to keep cell growth at a normal rate.

"If that brake is faulty, then the gene can't do its job and cell growth can't be controlled. We intend to confirm a method of detecting the faulty brake through trials of cancer patient samples."

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WAIMR researchers believe the work could also lead to the development of a drug, which could slow cancer progression by mimicking the action of HLS5. Techniques may also be possible to reactivate HLS5 through gene therapy.

"It is very encouraging to have such a potentially important, and valuable, discovery in our portfolio," said BioPharmica Managing Director David Breeze. We now have two of our projects in trials, have recently engaged further international expertise in commercializing diagnostics and are assessing an applicant Director with substantial multinational biotech experience and networks.

In recognition of the potential of the HLS5 gene, it has received over $1M in funding from leading bodies including the Cancer Council, National Breast Cancer Foundation, Royal Perth Hospital and the Federal Government's NHMRC, among others.

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About BioPharmica
BioPharmica is working to commercialise a portfolio of Australian biomedical research discovered by Australian universities, medical institutes and hospitals targeting large global markets. The Company has several projects currently undergoing trials in Australian hospitals.

In conjunction with the University of Western Australia and the Western Australian Institute for Medical Research, the Company is commercialising a molecular marker for early and accurate cancer detection. The HLS5 genetic marker is currently undergoing trials at Royal Perth Hospital and is a potential therapeutic and gene therapy target.

In partnership with Cortical Dynamics Pty Ltd, the Company is commercialising the BAR Monitor, a device that measures a patient's brain electrical activity (EEG) to indicate the response to drugs administered during surgery. The BAR Monitor assists doctors to ensure patients do not wake up unexpectedly during an operation, and minimizes associated side effects from post-operative recall of surgical procedures. The BAR Monitor is currently undergoing trials at Royal Melbourne Hospital.

Together with the Royal Melbourne Institute of Technology University and Diagnostic Array Systems, the Company is commercialising faster and more effective methods of detecting infectious diseases using the genetic structure (DNA) of bacteria. Founders Dr Benjamin Fry and Dr Viraj Nawagamuwa are both world leaders in the genetic structure of bacteria.

In conjunction with Swinburne University of Technology and Dr Paul Stoddart, BioPharmica is commercialising the SERS Probe, a fibre optic probe to be used in biosensors for diagnostic testing and drug development. The probe enables the microscopic tip of an optical fibre to be used in biosensors to detect and monitor biological and chemical targets. Biosensor manufacturers have seen rapid growth with the 2003 worldwide market for biosensors at US $ 7.3 billion.