BioPharmica Limited

PRESS RELEASE

Successful Brain Function Monitor Results

Perth, Australia, May 16 - BioPharmica Ltd (ASX: BPH) today announced that the brain function monitor clinical study at Royal Melbourne Hospital was an outstanding success.

The Company is pleased to announce that results of the clinical study have been presented today at the 2006 Annual Scientific Meeting of the Australian and New Zealand College of Anaesthetists.

The **Bar Index** brain function monitoring system is being developed in conjunction with Cortical Dynamics Pty Ltd and Swinburne University of Technology. Royal Melbourne Hospital also participated in the clinical study which involved approximately 60 elective surgery patients with a 2 Stage anaesthetic induction.

Key Outcomes:

(1) The results from this study indicate that the BAR index, is superior in a number of respects to other approaches to quantify brain function.

(2) In a critical discovery it was determined that the Bar Index was able to measure two very separate brain activities:

(a) brain state - whether the patient is in a state of consciousness, hypnosis and amnesia.

(b) brain input - whether the patient is capable of receiving external input such as sound or touch.

Other brain function monitors are not able to separately measure these brain activities, and thus can only provide a result which combines brain state and brain input into a single measure.

Therefore, the ability of the BAR Index to measure these separate brain activities has the potential to provide a very strong competitive advantage.

(3) The BAR Index was able to show clear and identifiable changes in the brain of patients being administered *nitrous oxide*.

(a) The BAR Index exhibited clear trends in patients who were going in and coming out of anaesthesia.

(b) The leading competitors monitor was unable to detect changes at any inhaled or effect site nitrous oxide concentration. Other monitoring methods are relatively insensitive in detecting *nitrous oxide and opioids*, commonly used agents in anaesthesia.

(4) Upon the completion of a further trial involving *opioids*, the Company will be in strong position to provide a select group of leading international companies with sufficient data to initiate licensing discussions, facilitate collaboration on development related to anaesthesia, as well as making a case for development of other areas involving drugs, brain state and function.

Importantly the results also showed that:

(1) Unlike previous approaches for the quantification of brain function, the Bar Index produces two separate measures of brain activity by incorporating a detailed knowledge of the physiological principles underlying the generation of brain activity.

(2) Thus by quantifying both brain state and brain input the Bar Index may be able to assist in monitoring the effectiveness of novel pharmaceutical agents designed to treat certain neurological diseases or to optimally ameliorate their symptoms. For example in multiple sclerosis there is evidence to suggest that the cognitive impairment observed may be due to the loss of subcortical white matter.

(3) Because this subcortical white matter connects regions of cortex to each other it thus provides one source of input (the major) to cortex. The Bar Index may be able to provide an important measure of how this input changes as a function of the diseases natural history and in response to specific therapeutic (pharmacological) intervention.

(4) The Bar Index holds promise to aid the management of and detection of neurodegenerative diseases in clinical settings and to accelerate the development of drug therapies.

Further Details on the Clinical Study

The study applied a new physiologically motivated mode of data received from electroencephalogram (EEG) output, the BAR index, derived by Dr David Liley and his team of researchers at Swinburne University of Technology.

The study involved 60 elective surgery patients with a 2 Stage anaesthetic induction. The first stage was randomised to one of:

4% sevoflurane + 100% O2

4% sevoflurane + 33% N2O

4% sevoflurane + 66% N2O

At the start of the first induction, loss of verbal response and loss of eyelash reflex were accurately determined. Raw EEG and BIS data were recorded, together with all event markers corresponding to assessed levels of consciousness; these were digitally recorded for later analysis.

The physiologically based, patent pending algorithm developed by Liley and his team was applied to the output data and the results compared to the leading competitor derived data.

The results from this study indicate that the BAR index, is superior in a number of respects to other approaches to quantify brain function. Unlike previous heuristically based approaches for the quantification of brain function, the method incorporates a detailed knowledge of the physiological principles underlying the generation of brain activity to produce the two separate measures of brain activity.

The clinical study found that the Bar Index method of EEG analysis was able to distinguish drug induced changes in cortical brain state and cortical brain input. N2O was shown to significantly reduce cortical input at moderate inhaled and effect site concentrations. The leading competitors monitor was unable to detect changes at any inhaled or effect site N2O concentration.

Commercial Application

The administration of any drug to the system has potential consequences in the form of unwanted side effects, the anaesthetic agents are no different in this respect.

In the modern age of personalized medicine, one drug or drug dosage does not fit all. It is important to monitor anaesthesia to maximise the loss of consciousness whilst minimizing the use of these potent drugs.

The appropriate dosage regime tailored to an individual therefore has the potential to reduce post-operative complications in at risk patients, reduce the incidence of intra-operative awareness with subsequent recall, reduce the incidence of litigation and post-operative costs.

The accurate monitoring or appropriate modelling also enables the clinical outcomes from different anaesthetic procedures to be meaningfully compared by ensuring that identical levels of anaesthesia are induced.

There are 40 million surgical interventions performed annually in the U.S. under general anaesthesia. The number of surgical and anaesthesia-based interventions both therapeutic and diagnostic is expected to increase as the population ages. **There is more than double that number worldwide**.

Changes in neurological functions are an early indicator for a number of degenerative diseases. Monitoring such functions, critical for preventive diagnoses, is spurring demand for EEG diagnostic and monitoring equipment. The proliferation of specialized facilities such as EEG labs and sleep centres, which utilize EEGs to chart neurological activity and detect/document disturbances in the brain, is also driving the market.

Digital EEG equipment allows sophisticated seizure detection algorithms, high precision abilities, and greater ease of use, facilitating screening of a wider range of patients. Total worldwide markets for EEG processor and sensors for both surgical and intensive care markets were US$51.4 million in 2002 are expected to reach US$734.9 by 2008.

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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, nanoprobes, biomarkers and therapeutics for diseases including cancer, neurodegenerative, and infectious diseases.