ASX Announcement

New peer reviewed journal article validates safety of lead diagnostic product ThromboView® for pulmonary embolism

Melbourne, Australia, 14 June 2011; China-focused drug and diagnostic company Agenix (ASX: AGX) today said the results of its Phase 1b study confirming the safety of its lead diagnostic product for the detection of pulmonary embolism, ThromboView®, had been accepted for publication in peer reviewed medical literature.

Pulmonary embolism (PE) is a blockage in a main artery or one of its branches in the lungs. It is the third most common cause of death among hospitalised patients in the USA.

ThromboView® has been developed as a more accurate way to test for pulmonary embolism and other forms of thrombosis without exposing patients to pulmonary angiography contrast agents that can be toxic to the kidneys, nor to the high radiation dosages associated with a CT scan.

Agenix recently engaged the respected international business development firm Partner International Inc. to work on a partnering and divestment program to develop a competitive process with the aim to obtain a number of solid, financially beneficial opportunities with global medical and pharmaceutical partner organisations to help expedite the final clinical phase for the US and European regulatory approval of ThromboView®.

The results of the Phase 1b study to be published in *Heart, Lung and Circulation,* the official journal of the Australasian Society of Cardiac and Thoracic Surgeons, and the Cardiac Society of Australia and New Zealand. The journal article, *Pulmonary Emboli Imaging with ^{99m}Tc-labelled Anti-D-dimer (DI-80B3) Fab' Followed by SPECT*, concluded that ThromboView "is well-tolerated in patients with acute PE and does not induce an immune response. (ThromboView®) may offer a novel approach to imaging PE in a clinically acceptable timeframe without exposure to potentially nephrotoxic radiographic contrast agents."

The 16-patient, multi-centre, single arm, prospective open-label Phase 1b study conducted in Australia confirmed evidence from two earlier studies that established ThromboView® is "safe in patients with acute pulmonary embolism" and shows promise as a "safe, useful and accurate diagnostic for detecting pulmonary embolism."

The study found pulmonary embolisms could be accurately imaged in a clinical setting using a standard hospital gamma ray scan after ThromboView® had been administered. Current procedures involve the use of a large CT scanner.

Importantly, the investigators found none of the patients measured displayed an immune response or side effects from exposure to the radioactive diagnostic drug during a 90-day follow-up period. All were suffering from the onset of acute pulmonary embolism.

The lack of an immune response indicates the test has the potential to be used more than once in the same patient. The study also revealed that images could be read at a relatively short interval after administration of ThromboView® and that considering it was the first ThromboView® PE study, the ease of reading ThromboView® was encouraging. Further, the article independently validates ThromboView®'s ability to bind to thrombi in patients despite the presence of anticoagulants.

Agenix Chairman & CEO Nicholas Weston said, "This new peer reviewed article detailing the Phase 1b study conducted by prominent physicians provides timely validation that ThromboView® affords a number of benefits to both patients and the medical professionals who currently have limited options available".

"It also supports our strategy for a diagnostic such as ThromboView® to meet the significant demand in the anticoagulation market if it could be shown that new clots or clots that "remain hot" (persistently contain 'active' fibrin for the agent to bind to) require ongoing anticoagulation treatment beyond the standard three month time course. This could be a considerable market, since the optimal duration of anticoagulation after unprovoked venous thromboembolisms (VTE) is still very controversial," Mr Weston added.

At present, diagnosis of VTE involves a physical exam and potentially a range of complex diagnostic tests. Current technologies detect VTE as "filling defects" with clot activity being irrelevant. The least informative in locating VTE is called a D-dimer test, which is used to screen out VTE. High levels of D-dimer in the blood indicate the possible presence of an active clot. Use of an ultrasound is the least invasive and most common test worldwide but is not accurate in the chest or upper extremities.

The current standard for diagnosing pulmonary embolism is a procedure called computed tomography pulmonary angiography (CTPA). It delivers a substantial radiation dose and involves the injection of a contrast agent, through the patient's leg or arm. A CAT scanner then takes a series of images of the lungs from different angles.

ThromboView requires only a standard hospital gamma camera to take a single photon emission tomography (SPECT) image from which the reader can easily identify the presence, absence and location of a blood clot.

The Phase Ib study was led by Dr David Macfarlane, Deputy Director & Clinical Director (PET), Royal Brisbane Hospital and authored by Dr Timothy Morris, head of Pulmonary and Critical Care Medicine at the University of California San Diego. Medical Director of the Respiratory Care and the Pulmonary Function Laboratories. It was conducted at seven Australian hospitals during 2005 and 2006.

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