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SEC#82-5258

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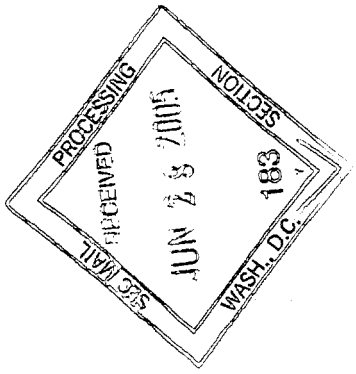
17 June 2005



US Securities and Exchange Commission
Attention: Filing Desk
450 Fifth Street NW
WASHINGTON DC 20549
USA

Dear Sir

Re: Submission Under Rule 12g3-2(b) - Agenix Limited

We refer to the attached announcement that was made to the Australian Stock Exchange on 17 June 2005.

We are providing a copy of the announcement by virtue of our requirements under Rule 12g3-2(b).

Yours sincerely

PROCESSED
JUN 30 2005
THOMSON
FINANCIAL

Neil Leggett
Company Secretary

17 June 2005

AGENIX OBTAINS POSITIVE RESULTS FROM PHASE Ib DVT SAFETY STUDY

Agenix [ASX: AGX; OTC (NASDAQ): AGXLY] today announced the release of positive results from its ThromboView® Phase Ib DVT (deep vein thrombosis, or blood clots in the legs) safety study.

The Phase Ib DVT study confirms the previously announced results of the interim safety analysis that the administration of ThromboView® was safe and was not associated with an immune response. The interim analysis had previously supported the strategy to move ThromboView® forward into larger Phase II trials. A summary of the study results is contained in the Appendix.

Whilst this was a safety trial and not a trial designed to assess image quality, the following information regarding the DVT images was ascertained and will be applied to Phase II and Phase III trial designs:

- 96.2% of images were judged to be of either "good" or "fair" quality (the rating alternatives were "good", "fair" or "poor").
- For the 3.8% of images judged to be of "poor" quality, the most frequent reason given was insufficient radioactivity counts in the image. Image counts are more important than time taken to image.
- There was no evidence that any one dose level of ThromboView® (0.5 mg, 1.0mg or 2.0mg) provided an advantage over others, confirming the decision to initially evaluate only the lowest dose in subsequent clinical trials.

Whilst this was a DVT study, DVTs may break off to form pulmonary emboli, that is, blood clots in the lungs (PE). Therefore, all 16 evaluable patients had an image taken of the chest at 4 hours (either a Planar or a SPECT image - a three-dimensional image using a dual-headed gamma camera), with 2 of the patients having both Planar and SPECT images taken. These images were reviewed, with the binding of ThromboView® to a clot and the corresponding visual signal or "hot spot" being described as *"increased and focal uptake"*.

Most encouragingly, ***50% of all patients showed "increased and focal uptake" in one or more quadrants of the lungs***. In addition, **16 of 18 lung images were judged to be of "good" quality.** Allowing for the lack of reference images at this stage in development, there was good agreement between the readers with final consensus for all patient images.

Although the diagnosis of PE was not part of the trial protocol, symptoms of dyspnoea and pleurisy (commonly seen in patients with PE) were documented for three subjects, with one of those subjects also recorded as suffering PE.

The current reference method for diagnosis of PE is pulmonary angiography. However, because of the high cost and invasive nature of this procedure most clinicians utilize lung ventilation/perfusion scanning or spiral CT scanning to diagnose PE. There are limitations both in terms of the accuracy of these modalities and their use in all patients with suspected PE. Accordingly, estimates by Agenix of market size recognize the unmet medical need in the diagnosis of this important life threatening illness.

US based drug development expert and Chairman of the Agenix Scientific Advisory Board, Professor Paul Eisenberg said: "The results from the Phase Ib DVT trial are very exciting and encouraging, especially for this stage of development. The DVT images showed that ThromboView® was able to specifically bind and visualize clots. Whilst we do not have a direct comparator for the chest images, we are confident that the Phase Ib PE trial currently underway in Australia will show images similar to those seen in this study."

Agenix is currently undertaking a Phase II DVT study in the USA and Canada to assess the accuracy of ThromboView® against the current "gold standard", contrast venography.

Recruitment for the Phase Ib PE safety study, to assess the safety of ThromboView® in patients with PE as determined by clinical assessment and CT scanning, has commenced.

ENDS

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Agenix Limited [ASX:AGX; OTC (NASDAQ): AGXLY] is a global health and biotechnology company based in Brisbane, Australia. The Company runs a suite of established businesses in human and animal health diagnostics, and is focused on growing its world-leading molecular diagnostic imaging R&D program. Agenix's lead candidate is its high-technology ThromboView® blood clot-imaging project, which is currently undergoing Phase II human trials in the United States and Canada. ThromboView® uses radiolabelled antibodies to locate blood clots in the body, and could revolutionise the US $3 billion global clot diagnostic imaging market. ThromboView® is being developed with the assistance of the Federal Government through its START scheme. Agenix employs 110 staff and sells its products to more than 50 countries. ThromboView® is a registered trademark of wholly-owned subsidiary AGEN Biomedical Limited.

APPENDIX

Phase Ib DVT Study Results

Introduction

Deep vein thrombosis (DVT) is a common major complication in orthopaedic surgical patients as well as patients with cancer and other chronic illnesses. Venous thrombi, the cause of DVT, are intravascular deposits composed of fibrin, platelets, leucocytes and erythrocytes. They usually form in regions of slow or disturbed blood flow in large venous sinuses; in valve cusp pockets in the deep veins of the calf; and in venous segments that have been exposed to direct trauma. Venous thrombi may break off to form pulmonary emboli (PE).

There are several mechanisms involved in the formation of DVT and PE. These include activation of blood coagulation, venous stasis and vascular injury. Cross-linked fibrin is the major component of each DVT. Thrombi are formed when the enzyme thrombin, is activated in response to the abovementioned stimuli leading to the cleavage of fibrin peptides A and B from soluble plasma fibrinogen. The resulting sequence of events ends with the polymerisation of fibrinogen into insoluble fibrin. Ultimately, D domains of the rapidly forming polymer are covalently cross-linked. This form of fibrin has unique antigenic sites that are able to bind specifically to antibodies.

Since the D-dimer (DD) domain on cross-linked fibrin is unique, *murine* monoclonal antibodies (Mabs) with specificity for the DD domain on cross-linked fibrin have been previously used as diagnostic agents. Cross-linked fibrin is abundant in DVT and is accessible by intravenous (IV) administration of a labelled antibody.

ThromboView® (anti-fibrin Mab, DI-DD-3B6/22) has high affinity for the DD domain of cross-linked fibrin and does not cross react with fibrinogen, fibrinogen degradation products, or the fibrin monomer.

Initial studies using murine monoclonal anti-fibrin antibodies demonstrated that technetium labelled anti-fibrin antibodies, in the presence and absence of heparin, clearly visualised thrombi in rats, rabbits and baboons. The same labelled antibody studied in a human study in the early 1990s also demonstrated the ability to target thrombi *in vivo*. Localisation was observed using scintigraphy and no study subjects experienced any significant side effects.

This present study further explores the use, safety and tolerability of monoclonal anti-fibrin technetium labelled antibody protein fragment as a detection system for DVT in humans. In this study, the murine anti-fibrin DD3B6/22 antibody, has been humanised

by replacing the murine-specific sections of the antibody not involved in the antigen binding with the human equivalent (DI-DD-3B6/22-80B3 "ThromboView®"). Residual murine components have also been engineered to more closely resemble human proteins. The speed of antigen localisation and clearance of unbound tracer was improved by using Fab' fragments rather than the intact antibody.

Success of this protein fragment as a detection tool for DVT could potentially lead to improvement in the diagnosis of DVT. Diagnosis of DVT cannot be made on clinical grounds alone as the associated signs and symptoms are non-specific. Imaging tests are required to make a definitive diagnosis but are not always able to reliably diagnose clot in all patients. ThromboView® may meet important unmet medical needs in the diagnosis of DVT and PE.

Study Design

The Phase Ib ThromboView® DVT study was an open-label, dose-escalation multi-centre study evaluating the safety, pharmacokinetics and dosimetry profile of a single-dose of radiolabeled ThromboView® in patients with DVT confirmed by compression ultrasound.

Primary objective

- To evaluate the safety of increasing doses of ^{99m}Tc ThromboView® when administered as a single IV dose to subjects diagnosed with DVT.

Secondary objectives

- To assess and compare the PK and dosimetry profile of increasing doses of ^{99m}Tc ThromboView® when administered as a single IV dose to subjects diagnosed with DVT to that established in normal subjects from the Phase Ia study.

There were no comparator or placebo control groups recruited to this study.

Study Population

Twenty six (26) male and female subjects diagnosed with DVT, aged between 18 to 75 years of age were recruited to treatment in one of the following three (3) groups and twenty one (21) were administered [^{99m}Tc] ThromboView® (Table 1). 16 subjects were evaluable.

Table 1. Summary of treatment group and administered dose

Treatment Group	Single dose of [^{99m}Tc] ThromboView® (mg)	Number of Subjects Enrolled	Number of Subjects Dosed	Administered Activity of ^{99m}Tc (MBq)
A	0.5	8	6	750
B	1.0	12	9	750
C	2.0	6	6	750

Imaging Methods and Analysis

Study subjects were imaged using whole body planar scans at t = -60 to -30 minutes, 30 minutes, 120 +/- 30 minutes and 240 +/- 60 minutes where t is the time of the ThromboView® injection. The study subjects were also given the opportunity to have a 24 +/- 4 hour scan.

Even numbered study subjects were also imaged by Single Positron Emission Computerised Tomography (SPECT) in the thoracic region.

Image analysis was performed by three experienced readers not otherwise involved in the trial who were blinded to clinical information, administered protein dose and time of image acquisition after study protein administration. Images from normal subjects in the Phase Ia study served as negative controls.

Safety

Safety measurements utilised in this study included haematology, biochemistry, urinalysis, and vital signs (blood pressure, heart rate, respiratory rate and body temperature and ECGs). All of these measurements are considered to be standard safety assessments.

Human anti-human antibody (HAHA) levels, to determine the presence of an immune response to ThromboView®, were measured from collected blood samples.

The data indicates that administration of ^{99m}Tc ThromboView® at doses of 0.5, 1.0 and 2.0 mg, to subjects with DVT documented by clinical presentation and compression ultrasound is well tolerated. As expected, subjects with DVT often had symptoms during the study period that were reported as an adverse event (AE).

During this study there were 35 adverse events reported in 15 of the 21 subjects. From those 35 AEs, three (3) were reported as being "possibly" related to ^{99m}Tc ThromboView®. These three (3) events occurred in two subjects. All three (3) were mild to moderate in nature. One subject developed mild hypertension after administration of ^{99m}Tc ThromboView®. By two hours post-dose, the blood pressure had lowered to 130/90 mmHg and remained unremarkable. This subject had no history of hypertension. One subject experienced elevated levels of liver enzymes and as these were unexplained, were deemed "possibly" related to the study agent.

There was also one life-threatening or disabling AE (prostate cancer) and three serious adverse events reported (an increase in alkaline phosphatase, pneumonia and melaena). The elevation in alkaline phosphatase (ALP) was also reported as a dose-limiting toxicity. After review by the independent Data Safety Monitoring Board, the increase in ALP was deemed unlikely to be related to study protein. Both pneumonia and prostate cancer were reported by the investigator as unrelated to study protein and the melaena was reported to be unlikely to be related.

ECG analysis revealed that there were no significant changes in heart rate, standard ECG measures (PR interval, QRS duration or corrected QT interval) in any of the three dosage groups. A number of subjects had resting ECG abnormalities, but in general these did not change with study protein administration.

A specific focus in the safety evaluation of subjects participating in this study was monitoring for development of a HAHA response. To assess this, an assay was developed that had a sensitivity of 8 μg/mL for a murine anti-idiotype antibody prepared at AGEN Biomedical. The results did not suggest that ^{99m}Tc ThromboView® was strongly immunogenic.

Pharmacokinetics and Dosimetry

Pharmacokinetic evaluation took place to allow calculation of protein clearance, volume of distribution and half-life of ^{99m}Tc ThromboView®. Levels of ThromboView® were determined in plasma and urine utilising standard ELISA techniques. Plasma and urine radioactivity levels were also evaluated.

Dosimetry calculations were performed to define the biodistribution of ^{99m}Tc ThromboView® at multiple time-points and calculate organ-specific absorbed radiation doses. In addition, dosimetry calculations in this study were used to demonstrate comparability of the dosimetry profile of this agent in the subject population with the detailed analysis in healthy subjects. Data for these calculations comprised serial conjugate whole-body scintigraphic images and radioassay of multiple plasma and urine samples.

The biodistribution of ^{99m}Tc ThromboView® observed within this study was consistent with that observed in the Phase Ia study. Similarly there were no significant differences in the biodistribution between dose groups. There was rapid plasma clearance with significant urinary excretion and renal uptake.

The mean effective dose for males was 9.6 ±0.9 mSv/GBq. For an administered activity of 750 MBq this gave an effective dose of 7.2 ±0.7 mSv. The mean effective dose for females was 11.4 ±0.6 mSv/MBq. For an administered activity of 750 MBq this gave an effective dose of 8.5 ±0.5 mSv. The effective doses were consistent with the Phase Ia study in healthy subjects.

Pharmacokinetic analysis determined that up to four hours after a dose, the concentrations of Fab' fragment in plasma increased in direct proportion to dose across a four-fold range of doses. The levels of radioactivity increased in direct proportion to dose. The concentrations of ThromboView® and levels of radioactivity in plasma were comparable to those reported in the Phase Ia normal subjects.

DVT Imaging Results

All DVTs had been pre-determined by compression ultrasound. Most images (96.2%) were judged to be of either 'good' or 'fair' quality. For the images judged to be of poor quality by one or more reviewers, the most frequent reason given was insufficient counts in the image. The other occasional reasons included subject body habitus (presumably large size), and interference in image assessment by transplanted kidney and surface contamination. Unblinded review confirmed comments by blinded reviewers that adequate duration of image acquisition was of great importance.

When blinded review results were stratified according to dose level (0.5 mg, 1.0 mg and 2.0 mg), there was no evidence to suggest that any one dose level provided an advantage over the others. The unblinded image review supported this conclusion.

Implications on the Safety of ThromboView®

The study has provided important information about the safety, dosimetry and pharmacokinetics of ThromboView® in patients with thromboembolic disease. In summary, ThromboView® was well tolerated and did not cause an immune response, was rapidly cleared from the circulation primarily by the kidney, and had comparable dosimetry to other diagnostic antibody fragments.

These are characteristics well suited to a potential thrombus imaging agent. The results of this study support the decision to move ThromboView® into later phase clinical trials which are specifically designed to test efficacy against a gold standard comparator.

Lung Imaging Results

Although this study was not designed nor implemented to assess efficacy of ^{99m}Tc ThromboView® for the diagnosis of pulmonary thromboembolism, at entry to the study subjects were allocated to undergo either single photon emission computed tomography (SPECT) or planar imaging of the thorax at four (4) hours following the injection of ^{99m}Tc ThromboView®. Two patients underwent both planar and SPECT imaging, resulting in a total of 18 images for the 16 evaluable patients. All study images were then reviewed independently by the two principal investigators some months following closure of the trial, and without reference to clinical data. The aims of this purely qualitative review were to:

a. assess the patterns of distribution of ^{99m}Tc ThromboView® within the thorax;

b. explore agreement in image pattern recognition between experienced nuclear medicine physicians; and

c. trial the use of a data collection instrument (Attachment XX) proposed for subsequent studies.

For the purpose of image evaluation the left and right lungs were divided into upper and lower zones about a horizontal line drawn through the hilum. The readers assessed the image quality as 'good', 'fair', or 'poor'. Both readers were asked to assess the distribution of radioactivity within each zone, and describe it as 'decreased', 'normal' (i.e. expected blood pool activity), 'increased and diffuse', or 'increased and focal'. Allowing for the lack of reference images at this stage in development, there was agreement between the readers in 68 out of a total of 72 quadrants (4 quadrants for each of the 18 images) reviewed with final consensus for all image datasets.

Fifty percent (50%) of all patients showed 'increased and focal uptake' in one or more quadrants of the lung and 16 of 18 images were judged to be of 'good' quality. Although the diagnosis of pulmonary embolism was not determined as part of the protocol, symptoms of dyspnoea and pleurisy were documented for three patients, with the medical records of one of these documenting a pulmonary embolism.