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SEC#82-5258

21 June 2006

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

SUPPL

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 20 June 2006.

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

Yours sincerely

Tony Finn  
Joint Company Secretary

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## Company Announcement

20 June 2006



### **ThromboView Phase II DVT interim trial result supports advance of program towards registration trials**

Agenix Limited has today announced the results of the repeat interim analysis from the Phase II Deep Vein Thrombosis ("DVT") clinical trial, which support the advance of the program towards registration trials.

Results obtained when assessed against the FDA reference standard, venography as read by a central venography adjudication committee, included:

- ThromboView<sup>®</sup> achieved an overall accuracy of 77% compared with 77% for compression ultrasound read at the local trial sites and 87% for venography read at the local trial sites.
- Optimal ThromboView<sup>®</sup> sensitivity was 76% in all patients with DVT based on images taken 3 hours after injection.
- ThromboView<sup>®</sup> detected clots in 94% of patients with DVT above the calf (proximal clots) based on images taken 3 hours after injection.
- For patients pre-determined by venography as DVT negative, ThromboView<sup>®</sup> confirmed the absence of clots in 94% of patients (using a 3 hour and 15 minute paired set of images).

Compression ultrasound is the procedure most commonly used in clinical practice. Venography is far less used in clinical practice because it is an uncomfortable and invasive procedure.

Agenix Scientific Advisory Board ThromboView<sup>®</sup> Sub-Committee Chairman, Dr. Paul Eisenberg, stated: "Clinical trial results in Phase I and II studies with ThromboView<sup>®</sup> support a move to seek FDA consultation on design and approval of pivotal registration trials".

On 1 March 2006 Agenix advised that an external expert panel convened by it had ruled that the original image analysis yielded invalid results due to considerable variability in reader interpretation of images. The repeat image analysis was carried out by three new independent blinded reviewers of 21 patients predetermined by centrally-read venography as having initial onset DVT and 18 patients predetermined by venography as not having DVT. Compression ultrasound was completed for 16 patients with confirmed DVT and 11 patients confirmed negative for DVT.

Analysis of results from the repeat read highlighted the importance of improved training and improved reading procedures. Mr. Neil Leggett, CEO and Managing Director of Agenix, said: "It is not unusual in the development of new imaging agents to optimise training and reading procedures as data is collected. The process of image interpretation in controlled clinical trials is very unlike that undertaken in normal clinical surroundings. The repeat reading session by independent blinded reviewers yielded results which are marked by much greater consistency, giving us a high level of confidence in the data generated."

As a consequence of the results obtained, Agenix will now proceed with final data analysis from the remaining DVT image sets acquired in the study, which will assist in the positioning of ThromboView<sup>®</sup> for suspected recurrent disease and add further numbers to the dataset of results for initial onset DVT. This data will support an end of Phase II meeting request with the US Food and Drug Administration to seek approval to carry out Phase III pivotal trials.

These results follow on from the successful proof of concept study in the diagnosis of Pulmonary Embolism ("PE") announced on 1 March 2006. An independent analysis at the time confirmed that ThromboView<sup>®</sup> demonstrated a high sensitivity for detection of PE compared to CTPA (computed tomography pulmonary angiography).

From a partnering perspective, Agenix is continuing its focus on advancing ThromboView<sup>®</sup> towards late-stage clinical trials in PE as this is the indication characterised by the highest unmet medical need and the market application in which there is most interest in a new diagnostic modality.

Mr Leggett stated: "The PE and DVT results have provoked further interest from potential partners as we have demonstrably advanced the project from both a clinical and manufacturing perspective in the last several months. The program has achieved a number of critical milestones and we have added substantial value to our offering of a well-conducted, well-validated and compliant program ready to be partnered."

"It is also clear from recent discussions that, not only is there interest in ThromboView<sup>®</sup> as an imaging agent for venous-based clots associated with PE and DVT, there is additional interest in collaborations to explore the potential of ThromboView<sup>®</sup> in other indications (such as those associated with arterial-based clots) and with new modalities (such as Positron Emission Tomography or "PET")," Mr Leggett added.

Further information on the Phase II DVT trial protocol and safety, sensitivity and specificity results follows in the Appendix.

**END**

**For more information contact:**

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Agenix Limited  
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**Agenix Limited** [ASX: AGX, OTC (NASDAQ): AGXLY] is a biotechnology company based in Brisbane, Australia. The Company has a strategic focus of growing a pipeline of monoclonal antibody-based products.

Agenix's lead candidate is its high-technology blood clot-imaging agent, ThromboView<sup>®</sup>, which is currently undergoing human clinical trials in the United States, Canada and Australia. ThromboView<sup>®</sup> uses radiolabelled antibodies to locate blood clots in the body, and could revolutionise the global clot diagnostic imaging market. ThromboView<sup>®</sup> is being developed with the assistance of the Australian Federal Government through its START scheme. ThromboView<sup>®</sup> is a registered trademark of AGEN Biomedical Ltd, a wholly owned subsidiary of the ASX-listed Agenix Limited.

[www.agenix.com](http://www.agenix.com)

## APPENDIX

The following additional information is provided in accordance with the Code of Best Practice for reporting by Life Science Companies.

### Description of Trial

The trial (CAN/US-001-II-DVT) is a Phase II multi-centre prospective cohort trial to evaluate the accuracy of 0.5mg anti-fibrin humanized monoclonal antibody (DI-DD3B6/22-80B3) Fab' protein fragment (ThromboView<sup>®</sup>) conjugated with Technetium-99m in the detection of Deep Vein Thrombosis ("DVT").

The trial has a pre-planned interim analysis to review safety and estimates of sensitivity and specificity in a cohort of 25 patients with confirmed initial DVT and 25 patients with excluded initial DVT.

The diagnostic accuracy of [<sup>99m</sup>Tc] ThromboView<sup>®</sup> with confirmed or excluded DVT will be based on comparison with the reference standard, lower limb ascending venography.

Three sets of images, taken at specified time points, will be evaluated.

The study will have two independent adjudication committees: the Venography Central Adjudication Committee (VCAC) will review all lower limb ascending venography; the ThromboView<sup>®</sup> Central Adjudication Committee (TCAC) will review all ThromboView<sup>®</sup> images.

An independent Data Safety and Monitoring Board (DSMB) will review the safety data of [<sup>99m</sup>Tc] ThromboView<sup>®</sup>.

The Clinical Trials Methodology Group (CTMG) will prepare the findings from the VCAC and TCAC. The CTMG and DSMB will report to the Steering Committee on the accuracy and safety of [<sup>99m</sup>Tc] ThromboView<sup>®</sup>.

Compression ultrasound is optionally performed and read locally at individual trial sites, but not centrally read. Venography is also optionally read locally, in addition to the mandatory central read, the latter being the reference standard result. Data from the local reads of both compression ultrasound and venography is recorded and subjected to statistical review as an additional finding.

### Trial Subjects

Trial subjects are consecutive patients presenting with clinically suspected initial or recurrent DVT. Patients are 18yrs or older with initial onset of symptoms occurring within the preceding 7 days. Patients are not to have received prior anticoagulant therapy in excess of 3 days.

### Study Endpoints

Primary endpoints of the study are to assess sensitivity of [<sup>99m</sup>Tc] ThromboView<sup>®</sup> in detection of initial onset DVT (calf, popliteal, femoral, iliac) in venographically confirmed patients, and to assess specificity of ThromboView<sup>®</sup> in exclusion of initial onset DVT in patients without disease, as assessed by venography.

Secondary endpoints will examine the sensitivity and specificity of [<sup>99m</sup>Tc] ThromboView<sup>®</sup> in proximal (popliteal, femoral and iliac) and distal (calf) regions of the limb, as well as the diagnostic accuracy of different acquisition time points. Diagnostic accuracy of [<sup>99m</sup>Tc] ThromboView<sup>®</sup> in a cohort of suspected recurrent DVT patients will also be assessed.

### Method, Dose and Route of Administration

[<sup>99m</sup>Tc] ThromboView® will be administered into a peripheral vein (most often an antecubital vein) by hand injection over a period of 15 seconds. After injection, [<sup>99m</sup>Tc] ThromboView® binds specifically to the cross-linked "D" domains of human fibrin, a major constituent of acute venous thrombi. By linking the antibody fragment to a radiolabel [<sup>99m</sup>Tc], binding of the antibody fragment to the D-dimer region of fibrin can be visualised by gamma scintigraphy and the extent and location of acute DVT can be determined

### Results of the Interim Analysis

An interim analysis was conducted in the first quarter of 2006 following the recruitment of 50 patients to the first cohort with suspected initial disease.

Of 50 image sets, 39 were considered evaluable for the analysis. 7 image sets were assessed as being non-evaluable by venography by the Venography Central Adjudication Committee (VCAC) and 7 cases were deemed to be non-evaluable for [<sup>99m</sup>Tc] ThromboView® image reading (3 of these are also included in the 7 VCAC exclusions above). Reasons for exclusion included acquisition of images using the wrong energy window, poor uniformity of flood images, [<sup>99m</sup>Tc] ThromboView not injected and lack of adherence to imaging protocol. Therefore, a total of 11 cases were excluded leaving 39 patients available for the analysis.

The results of the interim safety report indicate that the administration of radiolabelled ThromboView® to patients with suspected deep vein thrombosis is well tolerated. Of the adverse events experienced, most were mild in nature and from abnormal liver function tests related to their therapy with unfractionated heparin or low molecular weight heparin. All assessments of HAHA were negative suggesting that the administration of ThromboView® did not induce an immune response.

### **ThromboView® Accuracy – All DVT All Time Points**

Presentation Set	Sensitivity		Specificity	
	Estimate	95% CI	Estimate	95% CI
1h	9/21 = 42.9%	24.4 to 63.4%	14/18 = 77.8%	54.8 to 91.0%
3h	16/21 = <b>76.2%</b>	54.9 to 89.4%	11/18 = 61.1%	38.6 to 80.0%
0.25h + 1h	3/21 = 14.3%	5.0 to 34.6%	18/18 = 100 %	82.4 to 100 %
0.25h + 3h	13/21 = 61.9%	40.9 to 79.3%	17/18 = <b>94.4%</b>	74.2 to 99.1%

### **ThromboView® Accuracy – Proximal Clots Only (Calf clots removed from analysis) All Time Points**

Presentation Set	Sensitivity		Specificity ( <i>no change</i> )	
	Estimate	95% CI	Estimate	95% CI
1h	8/16 = 50.0%	28.0 to 72.0%	14/18 = 77.8%	54.8 to 91.0%
3h	15/16 = <b>93.8%</b>	71.7 to 98.9%	11/18 = 61.1%	38.6 to 80.0%
0.25h + 1h	3/16 = 18.8%	6.6 to 43.0%	18/18 = 100 %	82.4 to 100 %
0.25h + 3h	12/16 = <b>75.0%</b>	50.5 to 89.8%	17/18 = <b>94.4%</b>	74.2 to 99.1%

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### **Interpretation of Results**

The 3-hour imaging time point was most appropriate for diagnostic assessment.

Calf clots (distal) did not appear to image unambiguously which may be due to a number of reasons (currently under review) relating to clot biology, inherent patient factors (e.g. length of symptoms, impact of anticoagulation), image interpretation factors or product factors. Further data is required to assess these issues.

Isolated or single images gave the best sensitivity for detection of confirmed disease, whilst paired image sets offered the best specificity for excluding confirmed absence of disease.