Company Announcement

13 February 2007

Final ThromboView® Phase II DVT Report Confirms Strong Efficacy

Agenix has today announced final safety and efficacy results for its *in vivo* imaging agent ThromboView® from the Phase II Diagnostic Accuracy in Deep Vein Thrombosis (DVT) study.

These results are highly promising and show strong signs of efficacy, both for ruling-in and ruling-out thrombotic disease in patients with signs and symptoms of proximal DVT (clots in the thigh).

In brief:

- With regard to sensitivity, ThromboView® was able to detect clots in the thigh in 89% of cases when read at the 3 hour timepoint.
- Concerning specificity, for patients who were symptomatic but DVT negative, ThromboView® confirmed the absence of clots in >95% of all patients at the 3 hour timepoint.
- Overall accuracy for proximal DVT was 92% and 77% for any DVT (thigh and calf combined).
- ThromboView® was well-tolerated with no attributable serious adverse events.
- Further optimization of imaging protocols is proposed, particularly relating to the blood pool acquisition, which may allow greater identification of clot in all regions of the leg, including the calf.
- The results met pre-determined corporate criteria for ongoing product commercialisation.

The study, which recruited 91 patients, was conducted at 11 sites throughout Canada and the USA and led by Principal Investigators, Drs. Jeff Ginsberg and Jim Douketis from McMaster University, Hamilton.

The results will be reported in full at the upcoming International Society of Thrombosis and Haemostasis meeting in Geneva, July 6-12, 2007. Interim results have previously been announced.

Mr. Neil Leggett, CEO and Managing Director of Agenix, stated: "The analysis of the full results from this study has confirmed the positive results we reported at the interim analysis. Combined with our recent Phase Ib Pulmonary Emboli (PE) data, we have now shown that ThromboView® can image clots in both the legs and lungs. We plan to take the learnings from this study and apply them to later stage studies in the indication in which potential partners have most interest, PE."

"Whilst potential partners have most commercial interest in the imaging of PE, the results of the DVT study are extremely important, as a product which can image both PE and DVT is attractive to them," he said.

"We are currently working on a clinical trial design for a Phase II PE study, which, subject to FDA approval, will commence patient recruitment mid-year. We will provide further details as the trial design is completed", Mr Leggett continued.

Imaging protocols used in the DVT study allowed an assessment of efficacy at different imaging time points (60 mins and 180 mins), with or without reference to a blood-pool image (taken at 15 mins). The comparator used in the study, a radiographic technique known as contrast venography, is no longer in common use but is the designated reference method required by FDA.

Study results showed that ThromboView® had highest diagnostic accuracy when images were read at the later timepoint (3 hours) and these images were better able to identify clot located in the thigh (see table).

Image Set	**Any DVT** (distal & proximal) **Sensitivity (%)**	**Any DVT** (distal & proximal) **Specificity (%)**	**Proximal DVT** **Sensitivity** (%)	**Proximal DVT** **Specificity (%)**
180 min	72.0	66.7	88.9	72.0
15 + 180 min	59.3	96.2	84.2	96.7

More detailed information about the trial is provided in the summary attached.

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Agenix Limited [ASX: **AGX,** OTC (NASDAQ): **AGXLY**] is a biotechnology company based in Brisbane, Australia. Through its wholly owned subsidiary, Agen Biomedical Ltd, the company has a strategic goal of building and developing a pipeline of therapeutic protein/monoclonal antibody-based products.

Agen Biomedical's lead candidate is its high-technology blood clot-imaging agent, ThromboView®,which has been undergoing human clinical trials in the United States, Canada and Australia. ThromboView® uses radio-labelled antibodies to locate blood clots in the body, and could revolutionise the global clot diagnostic imaging market. ThromboView® is being developed with the assistance of the Australian Federal Government through its START scheme. ThromboView® is a registered trademark of Agen Biomedical Ltd.

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TRIAL SUMMARY

About the trial

Name of Trial	CAN/US-001-II-DVT
Trial Design	Multi-center, phase 2, prospective cohort trial investigating the accuracy of ThromboView® (0.5 mg protein dose) in patients with suspected initial/recurrent DVT and a moderate/high clinical likelihood for DVT
Study Population	18 yrs and older presenting with suspected DVT, evaluable venography, completed 7-day safety visit
Blinding	Images were read by trained readers (venography and ThromboView) blinded to the clinical outcome of the patientComparator Contrast venography
No of Subjects	91 enrolled, 82 imaged, 66 evaluable
Trial location	11 sites in USA and Canada
Primary Endpoints	Estimates of sensitivity and specificity of ThromboView® in confirmed and excluded initial DVT
Secondary Endpoints	Estimates of sensitivity and specificity of ThromboView® in confirmed and excluded recurrent DVT Sensitivity and specificity at 1 and 3 hr imaging timepoints Sensitivity and specificity for distal and proximal disease

The DVT study was primarily designed to assess the diagnostic accuracy of radiolabeled ThromboView® in detection of proximal DVT (clot in the thigh), distal DVT (clot in the calf), and all DVT (thigh and calf combined). The analysis was conducted by leg region in order to assess the efficacy of ThromboView® in patients with different risk profiles for clot embolisation (precursor to pulmonary embolism). Clots located in the calf are usually much smaller and less prone to embolisation than clots located in the thigh. Although about 15% of calf clots will propagate and become proximal DVT, current management of small clots in the calf does not routinely involve anticoagulation therapy, as these clots will often spontaneously lyse. It is therefore important to fully understand the imaging capability and diagnostic accuracy where clinical management is most likely to be affected i.e. in proximal DVT.

Trial Results

Of 82 image sets, 66 were considered evaluable for the analysis. 16 image sets were assessed as non-evaluable by venography, 9 were assessed as non-evaluable by ThromboView® (4 of these included in the venography exclusions above). Poor

intraluminal filling of veins with contrast agent rendered many leg segments non-evaluable, leading to a relatively high proportion of excluded venograms. Non-adherence to the prescribed imaging protocol was responsible for most non-evaluable ThromboView® cases. Of 71 evaluable ThromboView® image sets, 86% were rated as either good or fair by readers for image quality assessment.

ThromboView® Sensitivity and Specificity
All time points
Any DVT/Proximal DVT

Image Set	**Any DVT** (distal & proximal) **Sensitivity (%)**	**Any DVT** (distal & proximal) **Specificity (%)**	**Proximal DVT** **Sensitivity** (%)	**Proximal DVT** **Specificity (%)**
60 min	37 (22-56)	77 (58-89)	42 (23-64)	86 (69-95)
180 min	**72** (52-86)	67 (45-83)	**89 (67-97)**	72 (52-86)
15 + 60 min	11 (3.9-28)	100 (87-100)	16 (5.5-38)	100 (88-100)
15 + 180 min	59 (41-76)	**96** (81-99)	84 (62-95)	**97 (83-99)**

Insufficient patients with suspected recurrent disease were recruited to the study prior to closure to make a confident prediction of efficacy.

The 3 hour imaging timepoint was the most appropriate for diagnostic assessment.

Isolated or single images gave the best estimate of sensitivity for detection of any DVT, but particularly proximal DVT, whilst paired image reads offered the best estimate of specificity for excluding any DVT or proximal DVT.

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