



## Company Announcement

### **AGEN Biomedical secures worldwide distribution partnership with Inverness Medical Innovations**

11 June 2004

Brisbane-based biotechnology company Agenix Limited [ASX: AGX, NASDAQ OTC: AGXLY] today announced that its wholly owned subsidiary AGEN Biomedical Limited had signed an exclusive worldwide distribution agreement with US based Inverness Medical Innovations Inc (Amex: IMA) for its *Simplify*<sup>™</sup> D-dimer test.

Under the partnership, Inverness Medical — one of the world's largest and leading manufacturers and marketers of rapid diagnostic products — will have worldwide exclusive rights to distribute the test kit through its two wholly owned subsidiaries, Wampole Laboratories and Unipath.

Agenix Limited Managing Director Mr Don Home said the distribution agreement was a major breakthrough for AGEN in serving the acute phase thrombosis market globally.

"This collaboration is a significant commercial coup for AGEN. Importantly, it provides the best partner to take *Simplify*<sup>™</sup> to the growing market," Mr Home said.

"Through Inverness, we can get *Simplify*<sup>™</sup> directly into the hands of the hospitals, hospital buyer groups and doctors who are demanding this type of diagnostic test.

"The Wampole and Unipath networks give us access to up to 1,000 representatives to market our product."

AGEN has been executing its strategic plan for D-dimer globally over the past several years by positioning itself as the gold standard for D-dimer testing based around the 3B6 antibody. It has now secured global alliances with some of the largest and best multinational diagnostic companies representing all the key diagnostic disciplines:

1. Immunodiagnostics based – Dade Behring, Diagnostic Products Corporation
2. Coagulation market – Diagnostica Stago, Instrument Laboratories, bioMerieux
3. Point of care instrument based with Biosite
4. Point of care – rapid assays with Inverness.

"With the addition of Inverness, we've got all the key market sectors covered," Mr Home said.

"Inverness is in an extremely powerful position in the marketplace –it dominates the international rapid point of care testing market, and has outstanding sales and marketing capability around the world."

Agenix is forecasting growth in sales volume of the *Simplify*<sup>™</sup> D-dimer test by up to four times in the first 12 months to \$2.5 million. Sales projections for the following two years also anticipate increases by a minimum of 100 percent per annum.

"These are conservative forecasts and in the next few months we expect these will be upgraded once further training is conducted with the Inverness team," Mr Home said.

The *Simplify*<sup>™</sup> D-dimer test, based on AGEN's patented specific monoclonal antibody for D-dimer, DD3B6/22, delivers a rapid D-dimer measurement for a whole blood or plasma sample using a simple lateral flow self performing assay format. This format is ideally suited for near patient testing allowing a positive result to be available in one to two minutes particularly in critical care settings such as Emergency Departments and doctors offices where the speed of information can significantly improve patient outcome.

D-dimer is one of the smallest proteins arising directly from the body's natural mechanism to break down blood clots. Elevated levels of D-dimer in a patient's blood are indicative of abnormal rates of clotting. AGEN Biomedical's *Simplify*<sup>™</sup> tests for D-dimer aid practitioners in diagnosing blood clot conditions.

AGEN Biomedical Vice President Human Health Gregg Mastroianni said the signing of the five year distribution agreement (with automatic annual renewals) was one of the most important milestones in the history of AGEN's unique D-dimer tests since the 3B6 antibody was patented in 1982.

"This arrangement provides us with an excellent partner to maximise the penetration of *Simplify*<sup>™</sup> into these markets," he said.

"D-dimer demand continues to grow throughout the world as a result of increased public and medical community awareness. Through this global distribution agreement, we can leverage our portfolio of D-dimer intellectual property to capitalise on this anticipated increased demand."

Distribution of the *Simplify*<sup>™</sup> D-dimer test by Inverness Medical will commence next month, when the product will also be showcased to the international medical community at the American Association of Clinical Chemists meeting in Los Angeles (July 26). This meeting is the largest annual gathering of pathologists and medical scientists in the world.

## **ENDS**

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**Agenix Limited [ASX:AGX, NASDAQ: AGXLY]** is a listed company based in Brisbane, Australia. It manufactures, distributes and markets human and veterinary diagnostic test kits, over-the-counter pharmaceuticals and infant-care products via its wholly-owned subsidiaries AGEN Biomedical and Milton Pharmaceuticals. Agenix focuses on developing a horizontally-integrated product portfolio to service the needs of the acute phase thrombosis market. Agenix's lead candidate is its high-technology ThromboView<sup>®</sup> blood clot-imaging project, which is currently undergoing human trials. ThromboView<sup>®</sup> uses radiolabelled antibodies to locate blood clots in the body. It could revolutionise the US \$3 billion global clot diagnostic imaging market. ThromboView<sup>®</sup> is being developed with the assistance of the Federal Government through its START scheme. Agenix employs 200 staff and sells its products to more than 50 countries. ThromboView<sup>®</sup> is a registered trademark of AGEN Biomedical.

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

**Inverness Medical Innovations [AMEX:IMA]** is a leading global developer of advanced diagnostic devices and is presently exploring new opportunities for its proprietary electrochemical and other technologies in a variety of professional diagnostic and consumer-oriented applications including immuno-diagnostics with a focus on women's health, cardiology and infectious disease. The Company's new product development efforts, as well as its position as a leading supplier of consumer pregnancy and fertility/ovulation tests and rapid point-of-care diagnostics, are supported by the strength of its intellectual property portfolio. The Company is headquartered in Waltham, Massachusetts.

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

**Deep Vein Thrombosis** is a common condition that can be extremely painful and life threatening and if left undiagnosed can result in pulmonary embolism. Accurate and early diagnosis of blood clots is important, because it minimises the risk of complications and averts the exposure of patients without thrombosis to the dangers of anticoagulant therapy.

However, accurate detection of blood clots is a major problem for the medical community. Blood clot symptoms can be very vague and only around one-quarter of all patients presenting with symptoms have the disease confirmed. Diagnosis of clots is predominantly undertaken by radiologists who use imaging tests to confirm or rule-out disease. Current imaging tests are expensive and time-consuming and may not deliver an accurate result in certain types of patients. Therefore, a rapid, inexpensive, non-invasive and sensitive blood test, such as AGEN Biomedical's *Simplify*<sup>™</sup> D-dimer test, is of great interest to the medical community to reduce the burden on radiology resources, improve quality of patient care and improve diagnostic accuracy.