

# News Release

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**InGen BioSciences Group, exclusive distributor for Cylex Incorporated in France, reinforces its translational medicine positioning.**

**Chilly-Mazarin, June 13, 2012** — InGen BioSciences, specialised in the development and commercialisation of mono and multiparametric *in vitro* diagnostic tests announced a new exclusive partnership with Cylex Incorporated (Columbia, Maryland, US), a global life sciences company focused on *in vitro* diagnostic products intended to illuminate immunity.

With this exclusive partnership with Cylex, InGen BioSciences will provide to the French medical community the only FDA-cleared, CE marked and IVDD compliant assay that detects changes in global immune function over time in patients undergoing immunosuppressive therapy for organ transplant: ImmuKnow®.

Organ transplantation is an effective therapy for end-stage organ failure and is widely practised around the world. Global Observatory on Donation and Transplantation (GODT) 2010 data (produced by the WHO-ONT collaboration) report 106879 total solid organ transplants per year of which 73179 kidney transplants, 21 602 liver transplants and 5 582 heart transplants<sup>(1)</sup>.

Studies show that long-term use of immunosuppressants is associated with significant morbidity and mortality in transplant recipients and current monitoring systems of immunosuppression in those patients are typically focused on prevention of clinical toxicities of immunosuppressive drugs. Minimising the risk of infection and rejection in post-transplant patients is therefore crucial and challenging for clinicians.<sup>(2-5)</sup> Unfortunately, these strategies are often not tailored to the individual and do not determine the optimal level of immunosuppression for these patients.<sup>(3)</sup>

ImmuKnow, is an innovative platform, using a small blood sample, to simply and reproducibly assess immune cell function, providing medical professionals with crucial insight for individualised allograft transplant patient management allowing them to better tailor immunosuppressant drug regimens to prevent organ rejection while avoiding infection.

“Cylex is a global life sciences company leading *in vitro* diagnostic assays that measure cellular immune function and ImmuKnow is an established, accepted technology that is critical to providing better patient care” says Brad L. Stewart, President and CEO of Cylex. “This distribution partnership with InGen BioSciences represents an exciting opportunity for offering the best possible services to French transplant professionals seeking to provide individualised management for their patients.”

“We are very proud of this exclusive partnership with Cylex which reinforces our innovative offerings in immunology, complements our HLA IVD portfolio and strengthens our positioning in integrated, concrete best-in-class solutions for present and future needs of healthcare professionals in the rapidly evolving field of diagnostics”, comments Isabelle Buckle, CEO of InGen BioSciences. “With our partners ONE LAMBDA and now CYLEX, we respond to transplant specialists needs of diagnostic tools for assessing donor-recipient matching as well as a personalised monitoring of transplanted patients.”

Since its foundation in 2001, InGen BioSciences has experienced 19 percent compound growth (CAGR) and counts 65 employees (of whom 15% are dedicated to R&D). Its first proprietary product,

BJI InoPlex™, a non-invasive and easy to use tool for detection of infections in pre-and post-operative implants for orthopaedic surgeons, infectious diseases specialists and other healthcare professionals, was launched in 2011.

1. 2010 Estimates from the Global Observatory on Donation and Transplantation. [www.transplant-observatory.org/Pages/Uses-of-Data.aspx](http://www.transplant-observatory.org/Pages/Uses-of-Data.aspx) last visited May 30th 2012. 2. Fishman J A. Infection in solid-organ transplant recipients. *N Engl J Med.* 2007;357:2601-2614. 3. Cainelli F., Vento S. Infections and solid organ transplant rejection: a cause-and-effect relationship? *The Lancet Infectious Diseases*, 2002 ; 2: Issue 9, : 539-549 4. Kowalski, R J.; Post, Diane R.; Mannon, Roslyn B. et al. Assessing Relative Risks of Infection and Rejection: A Meta-analysis using an Immune Function Assay. *Transplantation* 2006 ; 82 - Issue 5: 663-668. 5. Cabrera R, Ararat M, Soldevila-Pico C, et al. Using an immune functional assay to differentiate acute cellular rejection from recurrent hepatitis C in liver transplant patients. *Liver Transpl.* 2009;15:216- 222.

## Notes to Editors

### About the InGen BioSciences Group

#### *The ambition of excellence.*

**The InGen BioSciences Group, a flexible, reactive, client centric company striving for optimum innovation (products and services) to meet the needs of biologists for their patients - develops and markets (proprietary or licensed) advanced *in vitro* diagnostic kits and automats for clinical use.**

- The company's primary focus is on infectious diseases, transplant diagnostics, auto-immunity, quality control products and rapid tests including its proprietary product Tétanos Quick Stick®.
- Turnover reached 23.3 M€ in 2011.
- InGen Biosciences supplies with seamless services a large selection of high-performing reagents combined with platform analysis to roughly 750 European customers. Its current customers are hospitals, private laboratories, blood transfusion services and research laboratories.
- InGen, the distribution part of the Group, has historical footprint in France, Italy, Belgium, Switzerland and strong brand recognition in Europe with 25 longstanding partnerships.
- The Group's R&D arm, IBS, specialises in the development of mono and multiparametric tests using proteomics technologies - IBS brings to market clinically relevant , innovative, CE marked and IVDD compliant assays that are minimally invasive, fast, cost-effective. Over 15 patent families, 39 patent applications are currently registered.
- The group is ISO 9001 (2008) and 13485 (2004) certified.
- Sustainable strategic alliances are keys for InGen BioSciences Group to pursue its mission in delivering innovative solutions to unsolved matters worldwide with IVD companies for product distribution, acquisitions & geographic expansion or with academics, biotech and pharma for companion tests, in-licensing, co-development & in-house development of proprietary technologies.

For more information please visit: <http://www.ingenbiosciences.com>

### About Cylex

Originally founded in 1992, Cylex is a venture-backed global life sciences company based in Columbia, MD USA. Cylex develops, manufactures and commercializes *in vitro* diagnostic products intended to illuminate immunity. The Company received certification to ISO 13485:2003 and 9001:2000, signifying compliance with internationally recognized standards in design, development and manufacturing of medical products. Cylex experienced exponential growth in recent years and holds a robust portfolio of patents issued in North America, Europe and Asia.

Cylex's first FDA-cleared product, ImmuKnow, represents patented technology designed to give clinical researchers insight for individualized patient management. Combined with individual patients' clinical factors and other routine monitoring tests, the ImmuKnow assay results help guide decisions in therapy to avoid over- or under-immunosuppression. ImmuKnow is currently sold in 18 countries.

*For more information, visit [www.cylex.net](http://www.cylex.net).*

### **About ImmuKnow®**

The Cylex ImmuKnow assay uses only 1 ml blood to provide rapid assessment of global immune function in organ transplant patients.

The ImmuKnow assay defines three immunological response zones: strong, moderate and weak. These zones can guide physicians in patient management.

ImmuKnow detects intracellular ATP synthesis in stimulated CD4+ cells selected from whole blood by monoclonal antibody coated magnetic beads. The amount of ATP produced reflects global T cell function. The measurement of CD4+ activation reflects cellular immunity because the CD4+ lymphocytes orchestrate cell-mediated immunity through immunoregulatory signalling.

The utility of the ImmuKnow assay has been well characterized and validated:

- Over 650,000 assays run
- 25 prospective and interventional studies in more than 1000 transplant recipients
- More than 120 clinical studies

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