

**For immediate release**

**TcLand Expression, a global leader in the field of gene expression biomarkers in immunology, launches an international, multicenter clinical validation study on its K-RejX diagnostic blood test for the identification of kidney transplant recipients at risk of chronic rejection**

- *The in vitro K-RejX diagnostic blood test to be launched by 2011*
- *TcLand Expression receives 2 prestigious awards from Frost & Sullivan*

**Nantes, France, October 13, 2009** - TcLand Expression SA, a global leader in the field of gene expression biomarkers in immunology, today announced the launch of the KARE study (**K**idney **A**llograft **R**Ejection). This will be the international, multicentre, prospective clinical validation study for TcLand Expression's K-RejX qPCR blood test, as a multi-gene molecular diagnostic tool to help in the identification of kidney transplant recipients at risk of chronic antibody-mediated rejection (CAMR). The KARE study will enroll 450 patients from over 30 European and North American large transplantation centers.

*"The K-RejX diagnostic blood test will be a great step forward in the management of CAMR, this form of late-onset kidney transplant rejection. It will address some of the limitations of graft biopsies (notably by precluding non-contributive biopsies), as well as of the detection of circulating DSA and will also have a positive impact on the healthcare system in terms of overall cost efficiency and quality of care",* commented Patrick Larcier, PharmD, TcLand Expression's Vice-President of Regulatory and Clinical Affairs.

K-RejX is a non-invasive, gene expression diagnostic blood test that has been designed to be performed as a Laboratory Designed Test (LDT) solely in TcLand Expression's ISO 17025-accredited laboratory in Nantes, France. The KARE study will meet the most stringent regulatory requirements for complex & high-value diagnostic and TcLand Expression expects to launch the K-RejX test by 2011.

Early prediction of the long-term post-transplantation prognosis is a major issue, since it enables therapy to be adapted to match the risk of graft rejection in a given recipient. The K-RejX test's ease of use is positioning it as a diagnostic blood test that should be systematically performed for monitoring patients more accurately and more frequently and thus improving the overall management of the transplant recipient.

## Transplantation<sup>1</sup>

Today, more than 350,000 patients live with a transplanted organ and more than 150,000 are on a transplantation waiting list. Given that early diagnostic of a graft rejection enables rapid and effective patient management and the avoidance of graft rejection, improving transplantation outcomes (i.e. increasing the graft's lifetime and diminishing the morbimortality due to chronic exposure to immunosuppressants) is a major challenge in public health.

## TcLand Expression's biomarker programs

With the KARE Study, TcLand Expression has two gene expression biomarkers in transplantation, K-RejX (in kidney) and L-TolX (in liver) currently in late-stage clinical validation. The L-TolX blood test is also a multigene molecular diagnostic tool for helping identify liver transplant recipients with stable allograft function for whom immunosuppression withdrawal is being considered. The L-TolX blood test started its international, multicentre, clinical validation phase in September 2007.

## The Frost & Sullivan awards

On October 8<sup>th</sup>, TcLand Expression received 2 prestigious awards at the *Frost & Sullivan Excellence in Healthcare Awards* event in London:

- the “*Entrepreneurial Company of the Year Award 2009*” in recognition of TcLand Expression's biomarker discovery and development work
- the “*Technology Innovation Award*”, validating the company's gene expression biomarker platform.

## **About TcLand Expression SA**

TcLand Expression SA is a recognized pioneer in the discovery, monitoring and interpretation of gene expression biomarkers for unmet medical needs in transplantation and auto-immune disease. The company benefits from an exceptional scientific and clinical environment. For more information, please visit our website [www.tcland-expression.com/](http://www.tcland-expression.com/)

## **About Frost & Sullivan Best Practices Awards**

Frost & Sullivan Best Practices Awards recognize companies in a variety of regional and global markets for demonstrating outstanding achievement and superior performance in areas such as leadership, technological innovation, customer service, and strategic product development. Industry analysts compare market participants and measure performance through in-depth interviews, analysis, and extensive secondary research in order to identify best practices in the industry.

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*This press release may contain forward-looking statements. As such, they do not guarantee future performance; there are risks and uncertainties. Future scientific, preclinical, clinical, regulatory, manufacturing, financial, commercial, business outcomes may be substantially different from those suggested by the forward-looking statements. The forward-looking statements are effective only as per the date at the top of this press release.*

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<sup>1</sup> In appendix, Allograft rejection in kidney transplantation

## Appendix

### Allograft rejection in kidney transplantation

Improvements in immunosuppressive strategies and the management of kidney transplant patients over the last few decades have led to a significant reduction in acute allograft rejection rates and thus an overall improvement in graft survival. However, long-term graft loss remains the bane of kidney transplantation. Evidence for the involvement of a humoral component in the immune response to allografts has come from (i) analysis of the impact of anti-HLA antibodies on graft outcome and (ii) evidence of complement cascade activation within kidney grafts (as shown by intra-graft deposits of the complement split product C4d). These data were recently reinforced when the definition of CAMR was introduced into the Banff classification of kidney graft injury. In fact, CAMR is defined by the diagnostic combination of (i) specific histological lesions associated with diffuse C4d deposits in peritubular capillaries and (ii) circulating, donor-specific, anti-Human Leukocyte Antigen (HLA) antibodies (DSAs). The diagnosis of CAMR requires both an invasive biopsy (to detect any histological lesions and C4d deposition) and a non-invasive blood test for anti-HLA DSAs. Since each of these tests has its own limitations, TcLand Expression SA is currently identifying a transcriptional signature of the immunological risk of CAMR in transplant patients with a view to overcoming the limitations of graft biopsies and of the detection of circulating DSA.