



Harnessing the power of T cell measurement

Press Release

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T-SPOT[®].TB GAINS FDA PREMARKET APPROVAL

Oxford, UK [Marlborough, MA]; 01 August 2008 – Oxford Immunotec, the global T-cell diagnostic company, today announced that the U.S. Food and Drug Administration (FDA) has approved a premarket approval application (PMA) for the T-SPOT.TB test. The T-SPOT.TB test is a laboratory-based cellular blood test that is intended for use as an aid in the diagnosis of *Mycobacterium tuberculosis* infection and disease. T-SPOT.TB improves accuracy and eliminates the logistical challenges found with the current tuberculin skin test.

The T-SPOT.TB test has been tested in patient groups indicated for screening for TB infection according to current American Thoracic Society and Center for Disease Control Guidance; such as, human immunodeficiency virus (HIV) positive persons, recent contacts of TB case patients, patients with chronic renal failure, children, and immunosuppressed patients¹. T-SPOT.TB is the only blood test that has demonstrated in a pivotal clinical study both sensitivity and specificity exceeding ninety-five percent and reliability in all targeted patient groups.

“This approval represents a significant milestone for the company”, said Peter Wrighton-Smith, CEO of Oxford Immunotec Ltd. “We have been pleased by the success of T-SPOT.TB in Europe and look forward to achieving continued success in the United States.”

Jeff Schroeder, President of North America commented that “Healthcare providers have told us that TB is a serious disease that requires a more accurate diagnostic test like T-SPOT.TB. We are looking forward to working with clinicians and laboratories so that they may offer their patients and employees the unique benefits of the T-SPOT.TB test.”

According to the World Health Organization (WHO) there were an estimated 8.8 million new cases of tuberculosis and 1.6 million deaths attributed to the disease worldwide in 2007. In the United States there is an estimated 10-15 million individuals infected with latent TB.

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Notes to editors:

About Oxford Immunotec

www.oxfordimmunotec.com

Oxford Immunotec, the T cell measurement company, is headquartered near Marlborough, MA and Oxford, UK. The Company develops and sells clinical diagnostic products based on its patented T-SPOT[®] technology, the first regulatory approved method for directly quantifying antigen-specific T cells.

T-SPOT is a simple and extremely accurate method of studying a person's cellular immune response to infection and can be applied to diagnose and monitor any major disease driven by a T cell response.

About T-SPOT[®].TB

T-SPOT.TB is an in vitro T cell measurement assay used for diagnosing TB disease and latent TB infection and the first product from Oxford Immunotec using the T-SPOT technology. The product is extremely robust in that it gives a result every time and offers unrivalled and maintained sensitivity in high risk and immunocompromised patient groups. T-SPOT.TB is approved for sale in Europe, Canada & over 40 other countries worldwide and is designed to replace the 115 year old Tuberculin Skin Test. As such it offers a substantially more accurate and effective tool for controlling the spread of TB, addressing a market opportunity exceeding \$1bn.

T-SPOT[®] is a trademark of Oxford Immunotec.

References

¹CDC. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis. MMWR weekly, June 09, 2000; 49(RR06): 1 – 54.

²Global tuberculosis control: surveillance, planning, financing. WHO report 2007. Geneva, World Health Organization (WHO/HTM/TB/2007.376)