

LISA TRACKER® CHOSEN BY JANSSEN BIOTECH FOR ITS PROGRAM TO MONITOR PATIENTS TREATED WITH REMICADE® IN THE USA

CROISSY-BEAUBOURG and MONTPELLIER - THERADIAG (ISIN: FR0004197747, Ticker: ALTER, PEA-PME eligible), a company specialized in in vitro diagnostics and theranostics, reports that, on August 29, Janssen Biotech Inc. announced the launch of a program to offer free monitoring tests to help healthcare professionals (HCP) better use Remicade® in treating patients with inflammatory bowel disease (IBD).

According to the terms of an agreement between Janssen Biotech and Miraca Life Sciences, the InformTx™ therapeutic drug monitoring tests will be provided within the framework of the Janssen2Inform program [1]. Based on the licensing agreement signed in November 2015 [2] between Miraca Life Sciences and Theradiag, Theradiag supplies raw materials and has provided an exclusive “know-how” license to Miraca Life Sciences.

“We are delighted to be contributing to this unprecedented new program launched by Janssen Biotech, Inc. with Miraca Life Sciences. This initiative will help increase the use of drug monitoring tests by healthcare professionals in the United States”, comments Michel Finance, CEO of Theradiag. “Sales of raw material to Miraca Life Sciences and royalties on Miraca’ sales represent a substantial growth potential in the United States for Theradiag”.

With the help of the Janssen 2Inform program, therapeutic drug monitoring test results will help HCPs evaluate how a patient is responding to treatment with REMICADE® and, in turn, identify necessary dosing regimen adjustments to optimize the patient’s response.

The Janssen 2Inform program consists of giving healthcare professionals access to two free Remicade® monitoring tests per patient per year.

About Theradiag

Capitalizing on its expertise in the distribution, development and manufacturing of in vitro diagnostic tests, Theradiag innovates and develops theranostics tests (combining treatment and diagnosis) that measure the efficiency of biotherapies in the treatment of autoimmune diseases, cancer and AIDS. Theradiag notably markets the Lisa Tracker® range (CE marked), which is a comprehensive multiparameter theranostic solution for patients with autoimmune diseases treated with biotherapies. With its subsidiary Prestizia, Theradiag is developing new biomarkers based on

microRNAs for the diagnosis and monitoring of rectal cancer, auto-immune and inflammatory diseases and HIV/AIDS. Theradiag is thus participating in the development of customized treatment, which favors the individualization of treatments, the evaluation of their efficacy and the prevention of drug resistance. The Company is based in Marne-la-Vallée, near Paris, and in Montpellier, and has over 75 employees.

For more information about Theradiag, please visit our website: www.theradiag.com

INVENDO MEDICAL ANNOUNCES FDA CLEARANCE OF THE INVENDOSCOPY E200 SYSTEM – INCLUDING THE FIRST AND ONLY STERILE, SINGLE-USE ENDOSCOPE FOR COLONOSCOPIES

A Simple, Safe and Effective Solution to the Challenges of Cross-Contamination and Infection Control



NEW YORK and KISSING, Germany (GLOBE NEWSWIRE) – invendo medical GmbH, a leading developer and distributor of sterile, single-use and robotically-assisted HD endoscopy products in the field of gastroenterology and GI surgery, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the invendoscopy E200 System, which includes the invendoscope SC200 – the first and only sterile, single-use colonoscope.

The invendoscope SC200 is a simple, safe and effective solution to clinical and hygienic challenges, ensuring that a new colonoscope is always ready for physicians to use and that each patient receives his or her own device. The new advanced invendoscopy technology leads endoscopy ergonomics into the 21st

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century with robotic assistance for tip control and a new design to offer gastroenterologists (GIs) greater control and enhanced comfort while performing procedures.

The invendoscopy E200 System has been cleared by the FDA to provide visualization and diagnostic / therapeutic access to the adult lower gastrointestinal tract (including but not limited to, the anus, rectum, sigmoid colon, colon, cecum and ileocecal valve) for endoscopy and endoscopic surgery. The colonoscope component of the invendoscopy E200 System, the invendoscope SC200, is a sterile single-use disposable device.

“Our one-of-a-kind technology provides a platform specifically tailored to address the need for device sterility during endoscopies, the importance of which has been underscored by various recent ‘superbug’ outbreaks in multiple U.S. hospitals,” said Timo Hercegfi, Chief Executive Officer of invendo medical. “The FDA clearance of the invendoscopy E200 System continues its pathway of validation, enabling our company to now provide endoscopists in the U.S. with a revolutionary technology that will allow them to perform colonoscopies with a system that significantly improves medical staff and patient safety while enhancing physician comfort during procedures.”

A colonoscopy is widely regarded as the gold standard for colon cancer screening. Colon cancer is the second most common cause of cancer-related deaths in the U.S.¹ but may be prevented through proper screening, such as colonoscopy. The sterile, single-use invendoscope SC200 delivers a technology that improves the current colonoscopy experience by providing advanced ergonomics for the physician, enhancing safety through the elimination of risky manual cleaning processes, easing financial burden on institutions and ensuring that each patient receives a new, sterile colonoscope.

As part of the invendoscopy E200 System, the invendoscope SC200 is a sterile and single-use colonoscope that eliminates the main challenge of gastrointestinal endoscopy: the complex reprocessing of endoscopes, which is costly, overly challenging, manual-labor intensive and increases patients’ risk for cross-contamination. In addition, the invendoscope SC200 fits seamlessly into any existing clinical practice, with a low associated startup cost. The technology also improves practice efficiency by eliminating the need for scope cleaning, reprocessing and repairs; and the

invendoscope SC200’s simplified setup allows for ease of use and fast turnaround.

The CDC estimates that at least 1 in 276,000 GI procedures places a patient at risk of endoscopy-associated infection (EAI) – a six-fold increase over the initial estimate.² More than 55 million procedures were performed with GI endoscopic devices in 2009, nearly 50 percent of them colonoscopies, and the number is increasing annually.³

Current infection control guidelines require that GI flexible endoscopes, such as colonoscopes, only be high-level disinfected, as these devices are unable to withstand the heat of high-temperature sterilization. More healthcare-associated infection outbreaks have been linked to contaminated endoscopes than to any other medical device.⁴ The alternative available option of prolonged gas sterilization creates a financial burden on GI practices, necessitating the purchase of additional units to ensure device availability at all times.

“In addition to the clinical benefits associated with reducing potential cross-contamination, the ergonomic design of the invendoscope SC200 offers a ScopeController that contours to the physician’s hand and can be used attached or detached to the endoscope. This unique control body coupled with the lightweight of the colonoscope provides a more comfortable and less tiring procedure for the healthcare provider. The invendoscope SC200 also includes a unique tip for full retroflexion in various segments of the colon, enabling inspection behind colonic folds, which is key to a comprehensive diagnosis during colonoscopies,” said John Cifarelli, Chief Commercial Officer of invendo medical.

About Invendo Medical

Based in New York, U.S.A. and Kissing (near Munich), Germany, invendo medical is a leading developer of sterile and single use endoscopy products in the field of gastroenterology that are hygienically safe and employ robotic assisted controls and sterile packaging.

1. <http://www.cancer.org/research/cancerfactsstatistics/>
2. Rutala WA, Weber DJ, and the Healthcare Control Practices Advisory Committee (HICPAC). CDC. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Available at: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
3. Becker’s GI and Endoscopy. Available at: <http://www.beckersasc.com/gastroenterology-and-endoscopy/35-statistics-about-giendoscopy-in-asc.html>
4. Kenters N, Huijskens EGW, Meier C, Voss A. Infectious diseases linked to cross-contamination of flexible endoscopes. *Endoscopy International Open*. 2015;3(4):E259-E265. doi:10.1055/s-0034-1392099.