



OraSure Technologies and Roche Announce FDA 510(k) Clearance for Four Fully Automated Oral Fluid Drugs of Abuse Assays

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PCP, Cocaine, Opiates and Methamphetamine Assays to be Used Exclusively as Part of OraSure's Intercept(R) Oral Fluid Drug Testing System

BETHLEHEM, Pa., Mar 3, 2011 (GlobeNewswire via COMTEX) -- OraSure Technologies, Inc. (Nasdaq:OSUR) and Roche announced today that the U.S. Food and Drug Administration ("FDA") has granted the Companies 510(k) clearance on four homogeneous fully automated oral fluid drugs of abuse assays developed to be used exclusively as part of OraSure's Intercept(R) Oral Fluid Drug Testing System. The cleared oral fluid assays include Phencyclidine (PCP), Cocaine, Opiates and Methamphetamine.

The oral fluid assays use Roche's KIMS (kinetic interaction of micro-particles in solution) technology and were jointly developed under an agreement previously signed by the parties. These assays are designed to run on various clinical chemistry automated analyzers, which are intended to allow oral fluid samples to be processed with the same efficiency as current fully automated urine-based drug tests.

"We are very pleased to announce this significant milestone in our joint effort with Roche to develop and market these important drugs of abuse assays," said Douglas A. Michels, President and CEO of OraSure Technologies. "The combination of Roche's industry leadership in lab instrumentation and reagent chemistry and our leadership in oral fluid technology and sample collection devices has enabled us to bring to market a breakthrough system that will have an immediate and positive impact on laboratory efficiency for drugs of abuse testing."

"The approval of this first set of fully automated oral fluid drugs of abuse assays demonstrates the strengths and experience of both companies," said Frank G. Sieben, SVP and Life Cycle Leader of Roche Professional Diagnostics. "Specifically the technologies and expertise of our collective research and development teams will enable us to provide novel high throughput oral fluid drug testing solutions."

The Companies anticipate the first four assays to be available for sale later this year. Several additional assays are also in development and are currently in varying stages of submission with the FDA.

Developed and manufactured by OraSure Technologies, the Intercept(R) Drug Testing System is the only FDA-cleared in vitro diagnostic laboratory-based oral fluid testing system used for detecting commonly abused drugs such as marijuana, cocaine, opiates, PCP and amphetamines (including methamphetamine and ecstasy) and for detecting barbiturates, methadone and benzodiazepines. All of these drugs of abuse assays are currently processed in laboratories using microplate technology. In collaboration with Roche, four of these assays -- PCP, cocaine, opiates and methamphetamine -- can now be processed efficiently using automated analyzers. Intercept(R) is primarily used in workplace, drug treatment and criminal justice testing markets, as well as in public school systems.

A global leader in diagnostics, Roche has been providing testing solutions for the drugs of abuse market for more than 25 years. Roche offers a broad test menu, integrated analyzer platforms and automation solutions to help a wide variety of labs increase revenue, improve efficiency and enhance patient care.

About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other in vitro diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities.

OraSure Technologies is the leading supplier of oral-fluid testing solutions for drugs of abuse and for the detection of antibodies to HIV.

For more information on the Company, please go to www.orasure.com.

The OraSure Technologies, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=6440>

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2010, Roche had over 80,000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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