



Walter Reed Evaluation Concludes OraQuick(R) HCV Test is Preferred Over Other Rapid Tests

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OraQuick(R) HCV Test Found to Have Higher Sensitivity and Specificity Than Other Rapid HCV Tests

BETHLEHEM, Pa.--(BUSINESS WIRE)--Sept. 2, 2008--OraSure Technologies, Inc. (NASDAQ:OSUR), a market leader in oral fluid diagnostics, today announced that an evaluation by the Walter Reed Army Institute of Research of the OraQuick(R) HCV Test, currently in clinical development by OraSure Technologies, was recently released at the Advanced Technology Applications for Combat Casualty Care meeting, sponsored by the Department of Defense. The purpose of the evaluation, entitled "Laboratory Evaluation of Hepatitis C Rapid Test for Use in Screening Walking Blood Bank Donors," was to determine the best rapid HCV test to use for screening blood donors for hepatitis C ("HCV") in the theater of war. The OraQuick(R) HCV test was selected as the preferred test based on all facets of the evaluation.

Blood that is donated to commercial or hospital blood banks is subjected to extensive testing for blood-borne pathogens before it is released to be used in transfusions. However, emergency battlefield conditions sometimes dictate that an available soldier, or Walking Blood Bank, donate without this normal lab-based testing being available. A rapid assay such as the OraQuick(R) HCV test can add a measure of safety against this important blood borne virus.

Five rapid tests were initially selected from the rapid HCV tests available worldwide, based on an evaluation of published claims and sensitivity testing using HCV positive samples. The tests were then compared in a comprehensive evaluation of test performance using plasma and blood specimens. The study indicated that the OraQuick(R) HCV test had the highest sensitivity (99.4%) and the highest specificity (99.7%) among the tests evaluated. In addition, the evaluation indicated that the OraQuick(R) HCV test detected HCV antibodies approximately three days sooner than available laboratory-based enzyme immunoassays and approximately sixteen days earlier than the next most sensitive rapid HCV test. Early detection of seroconversion is an important measure of the sensitivity of a test and means that hepatitis C infection can be identified even with relatively recent exposure.

"We are very pleased with the results of the Walter Reed evaluation," said Stephen R. Lee, Ph.D., Chief Science Officer of OraSure Technologies. "We are eager to complete our clinical trials for the OraQuick(R) HCV test and submit our applications for both FDA approval and CE registration for this product. Based on the performance data generated to date, we believe this test will play an important future role in identifying new HCV infections and enabling infected individuals to receive the care and treatment they need."

The study was conducted at The Walter Reed Army Institute of Research and involved investigators from the Walter Reed Army Institute of Research Division of Retrovirology, The U.S. Military HIV Research Program, Walter Reed Army Institute of Research Division of Military Casualty Research, the U.S. Army Blood Program, the Army Medical Department Center and School, the Robertson Blood Center and the American Red Cross. Conference information may be obtained at <https://www.usacc.org/ATACCC/index.htm>

The OraQuick(R) HCV rapid test is not currently approved by the U.S. Food and Drug Administration ("FDA") for use or sale in the United States. OraSure Technologies is currently conducting clinical trials to obtain FDA approval for the test utilizing multiple specimen types including oral fluid, finger-stick and venous whole blood, plasma and serum. The clinical studies are nearing completion and a pre-market application is expected to be submitted to the FDA in the near future. An application for CE mark approval, which is required to sell the test in the European Union, is expected to be filed shortly after the FDA submission.

Approximately 170 million people are chronically infected with hepatitis C worldwide, and there are approximately three to four million new HCV infections each year on a global basis. Chronic hepatitis C can cause cirrhosis, liver failure and liver cancer. About half of all cases of primary liver cancer in the developed world are caused by hepatitis C, and hepatitis C-related liver disease is now the leading cause for liver transplants. Most people who develop chronic hepatitis C infection are not aware that they have the disease. Identification and treatment of occult infections could significantly reduce future morbidity and mortality associated with HCV infection.

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 collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV. In addition, the Company supplies oral-fluid testing solutions for drugs of abuse testing. For more information on the Company, please go to www.orasure.com.

About the Walter Reed Army Institute of Research

Walter Reed Army Institute of Research (WRAIR) is the largest, most diverse, and oldest laboratory in the US Army Medical Research and Materiel Command. It conducts research on a range of militarily relevant issues, including naturally occurring infectious diseases, combat casualty care, operational health hazards, and medical defense against biological and chemical weapons. WRAIR is the Department of Defense's lead agency for infectious disease research and a crucial source of research support for medical product development.

About the United States Military HIV Research Program

The U.S. Military HIV Research Program (USMHRP) is dedicated to HIV vaccine development, prevention, disease surveillance and care and treatment for HIV. This program builds on the strength of the U.S. military medical research community, and addresses specific HIV research requirements to meet its mission: prevention of HIV-1 disease in the active force and, by extension, the global community at risk of infection. USMHRP's extensive diagnostics expertise including familiarity with HIV rapid tests led the U.S. Army Blood Program to engage with USMHRP for this HCV rapid test evaluation. USMHRP information may be found at <http://www.hivresearch.org/index.html>

Important Information

This press release contains certain forward-looking statements, including with respect to products, product performance, clinical studies, and regulatory submissions and approvals. Actual results could be significantly different. Factors that could affect results include the ability to market and sell products; changes in relationships, including disputes or disagreements, with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; impact of replacing distributors; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties or products required for use of our products; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including changes in international funding sources; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to patent infringement, product liability, and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission ("SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2007, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. Although forward-looking statements help to provide complete information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

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