



OraSure Technologies Receives FDA Approval for OraQuick(R) HCV Rapid Test, the First Rapid HCV Test Approved for Sale in the U.S.

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BETHLEHEM, Pa., Jun 25, 2010 (GlobeNewswire via COMTEX) --OraSure Technologies, Inc. (Nasdaq:OSUR) announced today that its OraQuick(R) Hepatitis C ("HCV") Rapid Antibody Test has been approved by the U.S. Food and Drug Administration ("FDA") for use in detecting HCV antibodies in venous whole blood specimens, making it the first rapid HCV test approved by the FDA for use in the United States.

"The OraQuick HCV test efficiently identifies previously undiagnosed HCV infected individuals who are at risk," said Eugene R. Schiff, MD, MACP, FRCP, MACG, AGAF, University of Miami School of Medicine. "We at the University of Miami found this test to be user-friendly, practical and an important tool for rapid HCV antibody detection."

"We believe that the OraQuick(R) HCV Rapid Antibody Test, with its simplicity and speed, will be a critical tool in identifying more at risk individuals infected with hepatitis C in the U.S., and thus represents a significant market opportunity," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "Obtaining FDA approval of our OraQuick(R) HCV Rapid Antibody Test for venous whole blood represents a major milestone for our Company."

OraQuick(R) HCV is the only rapid, point-of-care test for the detection of antibodies to the hepatitis C virus in venous whole blood specimens that is approved by the FDA. The test, which utilizes the OraQuick(R) technology platform, provides results in 20 minutes. The OraQuick(R) HCV Rapid Antibody Test is the latest rapid test manufactured by OraSure to receive FDA approval. OraSure had previously received FDA approval for its OraQuick ADVANCE(R) Rapid HIV-1/2 Antibody Test for use with oral fluid, fingerstick and venous whole blood and plasma samples.

In the U.S., there are an estimated 4.1 million Americans, or 1.6 percent of the population, that are or have been infected with HCV. According to the Centers for Disease Control and Prevention ("CDC"), new infections in the U.S. are estimated at approximately 20,000 per year. On a worldwide basis, there are an estimated 180 million people who are chronically infected with HCV, with an estimated 3 to 4 million individuals newly infected each year.

According to the World Health Organization, most cases of HCV infection are currently undiagnosed and up to 80 percent of HCV-positive individuals show no signs or symptoms.

In December 2009, the Company received the CE mark for its OraQuick HCV Rapid Antibody Test for use with oral fluid, whole blood, serum and plasma specimens. The CE mark was required in order to sell the product in the European Union.

As previously announced, OraSure has entered into agreements with Merck & Co. (through its predecessor Schering Plough Corporation) to collaborate on the development and promotion of the OraQuick(R) HCV test. Under the terms of these agreements, the Company has been and will be reimbursed by Merck for a portion of its costs to develop the test and obtain regulatory approvals. Additionally, Merck will provide promotional support, including detailing the test in the physicians' office market in those countries in which the Company has obtained approval.

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>

Important Information

This press release contains certain forward-looking statements, including with respect to product sales and registrations. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; changes in relationships, including disputes or disagreements, with strategic partners or other parties 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 and success of direct sales efforts; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; 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, extended shelf life or other factors; 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; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our 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 the impact of 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 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 Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 2009, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide 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 Note and OraSure Technologies undertakes no duty to update these statements.

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