OraSure Initiates Enrollment in Final Clinical Study for OraQuick(R) Rapid HIV Over-the-Counter Test

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FDA Approves 24-Month Shelf Life for OraQuick ADVANCE(R) Rapid HIV-1/2 Test

BETHLEHEM, Pa., Dec 13, 2010 (GlobeNewswire via COMTEX) -- OraSure Technologies, Inc. (Nasdaq:OSUR), the market leader in oral fluid diagnostics, announced today that it has enrolled the first subject in its final phase of clinical studies for United States Food and Drug Administration ("FDA") approval of the Company's OraQuick(R) Rapid HIV-1/2 test for sale in the U.S. consumer or over-the-counter ("OTC") market.

As previously announced in November, the FDA granted an Investigational Device Exemption ("IDE") which allowed OraSure to begin the final phase of clinical testing for the at home HIV test kit. This phase consists of an unobserved user study in which individuals will conduct unsupervised oral fluid self-testing using the investigational OTC version of the OraQuick ADVANCE (R) Rapid HIV-1/2 test.

OraSure also announced today that the FDA recently approved its request to extend product expiration dating to 24-months for its OraQuick ADVANCE (R) Rapid HIV-1/2 test which is currently available in the professional market. The FDA approval is based on prior enhancements made by OraSure to the manufacturing process for this product.

"We are extremely pleased to announce these two important milestones in our quest for FDA approval for an over-the-counter offering of our OraQuick(R) HIV test," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "We believe that the OraQuick(R) test, with its robust technology, ease of use, and oral fluid testing capability, is the best rapid HIV test available on the market, and is ideally suited for consumer self testing. We look forward to the successful completion of our clinical studies and the formal submission of our clinical data as we continue our work with the FDA to make an at home rapid HIV test kit available in the United States."

OraQuick ADVANCE (R) is the first and only FDA-approved and CLIA-waived rapid point-of-care test that can detect antibodies to both HIV-1 and HIV-2 in 20 minutes, using oral fluid, finger-stick or venipuncture whole blood or plasma specimens. As the market leader, OraQuick ADVANCE (R) is used extensively throughout the country in public health settings, hospitals, community-based organizations, and physician offices where HIV testing is conducted.

According to the Centers for Disease Control and Prevention, approximately 1.1 million individuals in the United States are infected with HIV, yet approximately one-quarter do not know they have the disease.

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. 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 expected clinical studies, markets, sales and regulatory approvals. 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 and testing algorithms; 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 press release and OraSure Technologies undertakes no duty to update these statements.

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