



OraSure Closes Enrollment in Final Clinical Study for Rapid HIV Over-the-Counter Test

August 9, 2011

BETHLEHEM, Pa., Aug 9, 2011 (GlobeNewswire via COMTEX) -- OraSure Technologies, Inc. (Nasdaq:OSUR), the market leader in oral fluid diagnostics, announced today that it has closed enrollment for its multi-site clinical study 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, OraSure initiated the final phase of clinical testing for an in-home HIV self-test kit in December 2010. This phase consists of a multi-visit, blinded, unobserved user study in which individuals conduct unsupervised oral fluid self-testing using the investigational OTC version of the OraQuick ADVANCE(R) Rapid HIV-1/2 test. Once all subject visits are completed and study results are un-blinded, the performance of the OraQuick ADVANCE(R) Rapid HIV-1/2 Antibody test in an OTC setting will be compared with FDA-approved blood-based assay performance. One of the study objectives specified by the FDA was to identify at least 100 HIV infected, but undiagnosed individuals. In order to meet this requirement, the Company enrolled approximately 5,700 participants in the study across 20 clinical sites nationwide.

In planning for its FDA submission, the Company has decided to split its filing into three separate parts or modules, the timing of which will be spaced to allow the FDA sufficient review time between modules. This is an accepted technique used to start the formal review process as early as possible. The first of the three modules is expected to be submitted to FDA in the third quarter; the last of the modules, containing the results of the final clinical study, is expected to be submitted around the end of the year.

"We are extremely pleased to have reached this very significant milestone in our clinical study. The ease of use and non-invasive nature of the collection process makes our oral fluid rapid HIV Test an ideal candidate device for in-home use by consumers," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "We anticipate the completion of the remainder of ongoing clinical study activities to occur sometime late in the third quarter, followed by data analyses in the fourth quarter. We look forward to continuing our work with the FDA and the healthcare community to make a home-use rapid HIV test available in the United States."

The Company also recently announced that the FDA and the Company's notified body in Europe have both granted an extension of shelf life to 30 months for the OraQuick HIV test. This is significant, not just for the professional market, but also for the over-the-counter market where the retail market typically requires a shelf life of 24 months or more.

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.

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of oral fluid diagnostic devices and other technologies designed to diagnose critical medical conditions and diseases. Its innovative products include rapid tests for the detection of antibodies to HIV and HCV at the point of care and testing solutions for detecting various drugs of abuse. These products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health. OraSure's products are sold globally 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 products, clinical studies and regulatory submissions. 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; 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; 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; ability to identify, complete, integrate, and realize the full benefits of potential future acquisitions, including the Company's acquisition of DNA Genotek; 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; 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; 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 refinance outstanding debt under expiring credit facilities on acceptable terms or at all; 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; 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, 2010, 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.

This news release was distributed by GlobeNewswire, www.globenewswire.com

SOURCE: OraSure Technologies, Inc.

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