# OraSure Makes Final FDA Submission for Approval of Over-the-Counter Rapid HIV Test

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BETHLEHEM, Pa., Jan 3, 2012 (GlobeNewswire via COMTEX) --OraSure Technologies, Inc. (Nasdaq:OSUR), a market leader in rapid point-of-care infectious disease diagnostics and biological sample collection, stabilization and preparation products, announced today that it has submitted the final of three modules in its application to the U. S. Food and Drug Administration (FDA) for the 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.

The third module contains the findings from the final phase of clinical testing, which involved the use of the OraQuick(R) Rapid HIV-1/2 test with subjects in an unobserved setting. Approximately 5,800 subjects were enrolled and tested in this phase across 20 sites nationwide, resulting in the identification of more than 100 previously undiagnosed individuals with HIV.

According to the Centers for Disease Control and Prevention (CDC), there are approximately 1.2 million people in the U.S. that have HIV and approximately 240,000 of them are unaware of their status, despite current HIV testing options. Not only is their own health at risk, they are also unknowingly responsible for up to 70 percent of the approximately 50,000 new HIV infections occurring each year in the U.S. The CDC recommends routine HIV screening for all people ages 13 to 64, with more frequent testing for people at higher risk.

"The latest CDC figures demonstrate the status quo for testing is inadequate and additional options to capture undiagnosed individuals infected with HIV must be brought to the market. We've been working closely with the community and FDA on the development of a powerful new HIV testing option for individuals. This submission was a major undertaking for OraSure and the culmination of years of hard work and financial commitment. An easy-to-use, private, and accurate in-home HIV test will enable more people to learn their presumptive HIV status so that they can receive necessary care and support," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "The completion of our submission to the FDA is a critical milestone in our efforts to secure approval and expand the tools available to combat the spread of HIV."

The final phase of clinical testing consisted of a multi-visit, blinded, unobserved user study in which individuals conducted unsupervised oral fluid self-testing using an investigational OTC version of the OraQuick ADVANCE(R) Rapid HIV-1/2 test. Once all subject tests were complete and study results unblinded, the performance of the OraQuick HIV test in the unobserved OTC setting was compared with FDA-approved laboratory HIV test results.

The Company intends to provide the necessary resources to ensure optimal support for individuals who, pending approval, would then be able to use the OraQuick HIV test in an OTC setting. In addition to a highly informative website, OraSure will offer "live" support and comprehensive referral services 24 hours a day, seven days a week, every day of the year, through a highly trained specialized toll-free call center, which was functional as part of the clinical trials. Detailed, easy-to-understand information on HIV and HIV testing was part of the clinical studies as well and will also be included in every test kit.

The first module for FDA review was submitted to the agency in the third quarter of 2011 and contained data from all studies performed prior to the final phase of testing. The second module was submitted to the FDA several weeks ago and included information about manufacturing and the customer care call center.

In the professional market, OraSure manufactures and sells the OraQuick ADVANCE(R) Rapid HIV 1/2 Test which 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 leading rapid HIV test with over 20 million tests sold, 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 rapid point-of-care infectious disease tests, collection devices and other technologies designed to detect or diagnose critical medical conditions. 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. In addition, through its wholly-owned subsidiary, DNA Genotek Inc., the Company also is a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, and commercial and industrial entities. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health. For more information on OraSure Technologies, please visit 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.



SOURCE: OraSure Technologies, Inc.

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