



OraQuick(R) In-Home HIV Test Receives Unanimous Positive Recommendation From FDA Advisory Committee

May 15, 2012

BETHLEHEM, Pa., May 15, 2012 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (Nasdaq:OSUR) today announced that the U.S. Food and Drug Administration (FDA) Blood Products Advisory Committee (BPAC) provided a unanimous positive recommendation for the Company's OraQuick® In-Home HIV Test. The BPAC provides advice to the FDA on issues related to the safety and effectiveness of biological products and medical devices seeking FDA approval.

The BPAC voted on two questions posed by FDA:

Do the projected benefits of the test outweigh the potential risks of false positive and false negative test results? The committee voted 17-0 in the affirmative to that question.

Do the available data provide reasonable assurance that the test is safe and effective for its intended use? The committee voted 17-0 in the affirmative to that question.

In addition to reviewing the Company's clinical data and performance, the BPAC considered data presented by the FDA and testimonies shared during the public comment session. The committee also discussed risk mitigation strategies that should be considered in addition to the current proposed labeling.

"We are pleased with the outcome of today's Blood Products Advisory Committee meeting," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "There was broad support expressed by the HIV community at today's meeting and we look forward to continuing our work with them in the fight against HIV. We believe the OraQuick® In-Home HIV Test will make a valuable contribution in this fight."

According to the Centers for Disease Control and Prevention, despite current testing options, 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. Those who do not know they are HIV positive are unknowingly responsible for up to 70 percent of the 50,000 new HIV infections that occur each year.

Data presented at the BPAC included findings from the final phase of clinical testing. The Company also presented a benefit analysis, using recently published research on HIV transmission rates from persons living with HIV who are aware and unaware of their infection¹. Assuming 1 million individuals tested with the OraQuick® In-Home HIV Test, the Company estimates that 9,087 HIV positive individuals would be identified with the added potential to prevent more than 700 onward transmissions annually. These would be in addition to those averted through current testing and intervention.

The OraQuick® In-Home HIV Test is an over-the-counter version of the OraQuick ADVANCE® Rapid HIV-1/2 Test which is currently sold into the professional market. The OraQuick ADVANCE® test 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 oral fluid in 20 minutes. As the market leading rapid HIV test with close to 25 million tests sold, OraQuick ADVANCE® is used extensively throughout the United States 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 and 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, the Company 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 and potential 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; 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 obtain FDA approval of the OraQuick® HIV test for use in the over-the-counter market; 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 integrate and realize the full benefits of the Company's acquisition of

DNA Genotek; ability to identify, complete, integrate and realize the full benefits of future acquisitions; 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; adverse movements in foreign currency exchange rates; 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, 2011, 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.

1 Hall HI, Holtgrave DR, Maulsby C., HIV transmission rates from persons living with HIV who are aware and unaware of their infection. AIDS. 2012 Apr 24;26(7):893-6.

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Image: company logo

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