



OraSure Receives Approval to Distribute OraQuick Rapid HIV-1 Antibody Test in Mexico; Approval Includes Oral Fluid Testing

July 29, 2003

BETHLEHEM, Pa., Jul 29, 2003 (BUSINESS WIRE) -- OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that it has received approval from the Ministry of Health in Mexico for its OraQuick (R)Rapid HIV-1 Antibody Test. Pursuant to this approval, the Company can distribute the OraQuick(R) test to healthcare professionals in Mexico for the detection of HIV-1 antibodies in both finger-stick whole blood and oral fluid samples.

The approval was received in response to an application filed by the Company's exclusive OraQuick(R) distributor in Mexico, Pro-Consulting S.A. de C.V. In addition, the approval is based on a technical evaluation of the OraQuick(R) test performed by the National Diagnostic Institute and Epidemiological Reference "INDRE", which demonstrated 100% specificity and 100% sensitivity when used on oral fluid samples. Sensitivity is a measure of the accuracy for detecting HIV-1 positive specimens, and specificity is a measure of the accuracy for identifying negative specimens.

"We are very pleased to have received the required regulatory approval to distribute OraQuick(R) into a market as important as Mexico," said Mike Gausling, OraSure's President and Chief Executive Officer. "This approval represents a significant step in an international strategy to extend our distribution network south of the United States into Mexico and ultimately into Central and South America and the Caribbean. Additionally, we are also thrilled, but not surprised, at the outstanding performance of the OraQuick(R) test, particularly in oral fluids, when tested by the Mexican Health Authorities."

Mexico has a current population of approximately 100 million people. According to a 2002 report by UNAIDS, approximately 150,000 people were reported to be infected with HIV-1 at the end of 2001. The Company expects that its OraQuick(R) test will ultimately be sold to the National Social Medicine Services, National Council for HIV/AIDS, State HIV programs, non-governmental organizations, hospitals, clinics, physicians and other members of the professional healthcare community in Mexico.

OraQuick(R) is the first FDA-approved rapid, point-of-care test designed to detect antibodies to HIV-1 in finger-stick whole blood within approximately 20 minutes. OraSure received FDA approval of the OraQuick(R) test on November 7, 2002. On January 31, 2003, OraSure received a CLIA (Clinical Laboratory Improvements Amendments of 1988) waiver for the test, permitting its use by more than 180,000 sites in the United States, including outreach clinics, community-based organizations and physicians' offices.

About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices and tests and other diagnostic products using its proprietary technologies, including immunoassays and other in vitro diagnostic tests and other medical devices. These products are sold in the United States and certain foreign countries to government agencies, clinical laboratories, physicians' offices, hospitals, commercial and industrial entities, and various distributors.

OraSure Technologies is the leading supplier of oral-fluid collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV-1. In addition, the Company supplies oral-fluid testing solutions for drugs of abuse testing. For more information on the Company, please go to www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to sales, markets and products. Actual results could be significantly different. Factors that could affect results include the ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain and timing of obtaining necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; 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; 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; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; 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 complete consolidation or restructuring activities; 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 Securities and Exchange Commission ("SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2002, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. Although forward-looking statements help to provide complete 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.

OraSure Technologies, Inc.

Financial/Investors:

Ronald H. Spair, 610-882-1820

Investorinfo@orasure.com

or

OraSure Technologies, Inc.

Media:

William E. Bruckner, 610-882-1820

Today's News On The Net - Business Wire's full file on the Internet with Hyperlinks to your home page.