



## OraSure Applies for CLIA Waiver on OraQuick Rapid HIV-1 Antibody Test

January 31, 2003

BETHLEHEM, Pa.--(BUSINESS WIRE)--Jan. 31, 2003--OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that it has submitted to the U.S. Food and Drug Administration (FDA) an application for a waiver under the Clinical Laboratory Improvements Amendments of 1988 (CLIA) for its OraQuick(R) Rapid HIV-1 Antibody Test. With an approved CLIA waiver, the OraQuick(R) test, which provides HIV-1 test results in just 20 minutes, would be available for use by sites in the United States that are CLIA-waived, including outreach clinics, community-based organizations and physicians' offices.

On November 7, 2002, the Company received FDA approval to manufacture and market the OraQuick(R) test in the United States for the detection of HIV-1 antibodies in finger-stick whole blood samples. Under that approval, the test is categorized as moderately complex and was restricted to use only in the nearly 40,000 laboratories in the United States certified under CLIA to perform moderately complex diagnostic tests. At the time of the approval, United States Health and Human Services Secretary, Tommy G. Thompson, strongly urged OraSure to submit an application for a CLIA waiver in order to expand the potential use of the test.

"We are very pleased to be able to quickly respond to Secretary Thompson's request and submit our application for a CLIA waiver for our OraQuick(R) Rapid HIV-1 Antibody Test," said Mike Gausling, Chief Executive Officer of OraSure Technologies. "I believe the study results in our application strongly support a CLIA waiver, and we look forward to working with the FDA once again as they review our submission."

The OraQuick(R) test has a sensitivity of 99.6% and specificity of 100% based on clinical studies performed by OraSure in support of its FDA approval. Sensitivity is a measure of the accuracy for detecting positive specimens, and specificity is a measure of the accuracy for identifying negative specimens.

### About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies and diagnostic products, 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](http://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 or other products; ability to fund research and development and other projects and operations; ability to obtain and timing of obtaining necessary regulatory approvals; ability to develop product distribution channels; uncertainty relating to patent protection and potential patent infringement claims; 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; 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 inventory practices and consolidations; equipment failures and ability to obtain needed raw materials and components; the impact of terrorism and civil unrest; and general business, political and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2001, and its most recent Quarterly Report on Form 10-Q. 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.

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