



OraSure Technologies, Inc.

## OraSure Receives FDA Approval for Test to Detect HIV-2 Antibodies

March 23, 2004

BETHLEHEM, Pa.--(BUSINESS WIRE)--March 23, 2004--OraSure Technologies, Inc. (Nasdaq NM:OSUR) announced today that the U.S. Food and Drug Administration ("FDA") has approved the Company's new OraQuick(R) Rapid HIV-1/2 Antibody Test. This approval will allow the simultaneous detection of antibodies to both the HIV-1 and HIV-2 viruses in finger stick and venipuncture whole blood specimens.

"Receiving FDA approval to test for HIV-2 is another significant milestone," said Mike Gausling, President and Chief Executive Officer of OraSure Technologies. "Our ability to offer a single rapid test for detecting antibodies to both HIV-1 and HIV-2 will allow for broader detection, treatment and prevention of HIV/AIDS. This is particularly important in the higher prevalence urban areas here in the United States where HIV-2 infection is more likely to occur and in many foreign countries where HIV-2 testing is required as part of the normal testing regimen."

The Company obtained FDA approval of an HIV-1/2 test in anticipation of receiving a worldwide, nonexclusive license to certain HIV-2 patents held by Bio-Rad Laboratories. The Company is cautiously optimistic that a license will be granted in the near future.

There are an estimated 40 million people in the world currently living with the HIV virus. Although the number of reported cases of HIV-2 infection in the United States is currently believed to be relatively low, the documented incidence of HIV-2 infection is much higher globally, as many foreign countries require testing for both HIV-1 and HIV-2.

The Company also has submissions pending with the FDA for approval of oral fluid and plasma claims for the OraQuick(R) Rapid HIV-1/2 Antibody Test. With these approvals, the Company believes it will have a significant market advantage by providing the most versatile rapid HIV test available in both the United States and around the world.

### About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other in vitro diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities.

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 products, regulatory approvals and markets. 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 (including our ability to implement a direct sales effort or other alternative distribution for OraQuick(R)); 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; ability to obtain licenses to patents (including HIV-2 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, 2003, 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.

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