



FDA Approves OraQuick HIV-1/2 Test to Detect HIV-2 in Oral Fluid

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BETHLEHEM, Pa.--(BUSINESS WIRE)--June 23, 2004--OraSure Technologies, Inc. (NASDAQ NM:OSUR), the market leader in oral fluid diagnostics, announced today that it has received U.S. Food and Drug Administration ("FDA") approval of its OraQuick(R) Rapid HIV-1/2 Antibody Test for use in detecting antibodies to the Human Immunodeficiency Virus Type 2, or HIV-2, in oral fluid samples. With this approval, the OraQuick(R) HIV-1/2 Test is the only rapid, point-of-care test approved by the FDA for use in detecting antibodies to both HIV-1 and HIV-2 in oral fluid, finger stick and venous whole blood, and plasma samples.

"We are extremely pleased to have obtained FDA approval of an oral fluid HIV-2 claim for our OraQuick(R) HIV-1/2 Test," said Ron Spair, Executive Vice President and Chief Financial Officer of OraSure Technologies. "This is another major milestone for the Company as we continue to build our leadership position in the oral fluid diagnostics market. The next step is to obtain a CLIA (Clinical Laboratory Improvements Amendment of 1988) waiver for our OraQuick(R) HIV-1/2 test, which will allow us to expand the availability of this product in the United States, especially in the public health market."

Now that the oral fluid HIV-2 approval has been received, OraSure will promptly submit an application for CLIA waiver of the OraQuick(R) HIV-1/2 test. Upon approval of this waiver, the OraQuick(R) HIV-1/2 test, which provides results in just 20 minutes, can be used by more than 180,000 sites in the United States, including outreach clinics, community-based organizations and physicians' offices.

In March 2004, OraSure announced FDA approval of the OraQuick(R) Rapid HIV-1/2 Antibody Test for use in detecting antibodies to HIV-1 in oral fluid and antibodies to both HIV-1 and HIV-2 in finger stick whole blood, venous whole blood and plasma samples. On June 21, 2004, OraSure announced that it had obtained a non-exclusive, worldwide sublicense to certain HIV-2 patents held by Bio-Rad Laboratories. With the receipt of an HIV-2 oral fluid approval and the HIV-2 patent sublicense, OraSure believes it is now positioned to pursue a global distribution strategy for its OraQuick(R) Rapid HIV-1/2 Antibody Test.

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 believed to be relatively low, the incidence of HIV-2 infection is much higher in certain other countries, and many foreign countries require testing for both HIV-1 and HIV-2.

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.

Important Information

This press release contains certain forward-looking statements, including with respect to products, regulatory submissions and 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 OraSure's 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 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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