



OraSure Begins Shipment of OraQuick Rapid HIV-1 Antibody Test; OraSure Fills Initial Stocking Order to Abbott Laboratories

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BETHLEHEM, Pa.--(BUSINESS WIRE)--Jan. 7, 2003--OraSure Technologies, Inc. (Nasdaq:OSUR), the market leader in oral fluid diagnostics, announced today that it has shipped more than 50,000 OraQuick(R) Rapid HIV-1 Antibody Tests to Abbott Laboratories.

This order was completed in late December 2002, and represents the first sale of OraQuick(R) tests under OraSure's agreement with Abbott, which is the Company's co-exclusive distributor of OraQuick(R) in the United States.

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.

"Following FDA approval, we focused on gearing up our manufacturing process to begin commercial production of the OraQuick(R) test," said Mike Formica, OraSure's Executive Vice President, Operations. "The initial production runs went well, with productivity exceeding our internal expectations. We will continue to fully scale up manufacturing in order to meet the expected increasing demand for this important product."

On June 17, 2002, OraSure announced that it had entered into an agreement with Abbott Laboratories for the co-exclusive distribution of the OraQuick(R) test in the United States. Abbott is the market leader for the distribution of infectious disease testing products, and is expected to focus its efforts on selling the OraQuick(R) test primarily to hospitals and physician's office laboratories.

The agreement with Abbott also permits OraSure to sell directly in the United States, and OraSure anticipates selling primarily in the public health market. Sales from OraSure to Abbott are expected to exceed \$4 million through the end of 2003.

Pursuant to its FDA approval, the OraQuick(R) test can be used by the nearly 40,000 qualified locations in the United States certified under CLIA (Clinical Laboratory Improvement Act of 1988) to perform moderately complex diagnostic tests. An estimated 17 million HIV tests are conducted annually in the United States at these locations.

In addition, the Company intends to seek a CLIA waiver for the OraQuick(R) test. If granted, this waiver is expected to substantially increase the market for OraQuick(R) to include entities such as public health outreach clinics that are not certified under CLIA.

"We are thrilled to have shipped OraQuick(R) devices by year-end," added Mike Gausling, OraSure's Chief Executive Officer. "Apart from producing commercial lots of OraQuick(R), we are now working closely with the FDA to finalize a protocol for seeking a CLIA waiver and obtain approval of an Investigational Device Exemption required to perform oral fluid clinical trials. We are also analyzing the potential use of our OraQuick(R) test as a screen for HIV-1 in conjunction with small pox vaccinations and evaluating our international distribution strategy for this important product."

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.

About Abbott Laboratories

Abbott is a leader in HIV testing, beginning with the licensure of the first HIV test in the United States in 1985. Since then, Abbott has continually improved the diagnostic effectiveness of its tests, targeting sensitivity to detect HIV infections earlier and developing advanced technology to automate HIV testing for patient diagnosis, managing therapy and screening donated blood.

Abbott also has developed important HIV therapeutics including Norvir, Abbott's first protease inhibitor, and Kaletra, an advanced-generation protease inhibitor, for the treatment of HIV/AIDS.

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals, nutritionals, and medical products, including devices and diagnostics. The company employs approximately 70,000 people and markets its products in more than 130 countries. For more information on Abbott, please go to www.abott.com.

Important Information

This press release contains certain forward-looking statements, including with respect to sales, markets, revenues, regulatory submissions 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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