CDC Selects OraSure Technologies' OraQuick as the Exclusive Rapid HIV Test for the MIRIAD Project

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BETHLEHEM, Pa., Aug 14, 2001 (BW HealthWire) -- OraSure Technologies, Inc. (Nasdaq NM:OSUR), announced that the Centers for Disease Control and Prevention (CDC) has selected the OraQuick(R) rapid HIV test to be used to provide results to pregnant women as part of the CDC funded clinical study, the Maternal Infant Rapid Intervention at Delivery (MIRIAD) Project.

Robert D. Thompson, Chief Executive Officer of OraSure Technologies, Inc., stated, "We are pleased to have been chosen once again for use in these important CDC projects. This is the second CDC sponsored Treatment Investigational Device Exemption (IDE) that we have been invited to take part in, in addition to our participation in the CDC's LIFE Initiative. These programs, together with our own clinical trials, provide us with an ever-growing body of data now totaling more than 10,000 OraQuick tests. This collective data continues to reinforce the outstanding performance of the tests."

The MIRIAD Project will take place at public hospitals in five U.S. metropolitan areas with relatively high (0.8% to 4%) HIV seroprevalence among pregnant women: Atlanta, Georgia; Chicago, Illinois; Miami, Florida; New Orleans, Louisiana; and New York City, New York.

The MIRIAD Project is expected to offer voluntary rapid HIV testing annually to between 6,000 and 8,000 pregnant women with unknown HIV status late in pregnancy, and offer antiretroviral therapy to the woman, if indicated, to prevent perinatal transmission of HIV to the fetus.

The question of how best to provide rapid HIV testing, perform urgent confirmatory testing in this setting, and present women with risk/benefit information and treatment options will be investigated.

Under federal regulations, the U.S. Food and Drug Administration (FDA) can authorize the use of an investigational test in the treatment of patients with serious or life-threatening conditions when no comparable or satisfactory alternative exists. The CDC has received permission from the FDA to use the OraQuick HIV device for specific purposes where rapid tests are uniquely required.

The CDC stated in their IDE application that critical decisions about treatment in a number of clinical settings depend on the availability of immediate HIV test results. Implementation of prenatal counseling and voluntary HIV testing, and the use of zidovudine regimens to prevent HIV transmission, resulted in a steep decline in new cases of AIDS in infants during the 1990s in the United States.

However, an estimated 10% to 20% of pregnant women do not know their HIV status at the time of delivery. Expedited testing with rapid HIV tests will permit therapy to be initiated for these mothers during labor, and after birth in their infants. This is expected to substantially reduce the chance that these infants will become infected with HIV.

The value of rapid tests in public health is well established. The CDC estimates that nearly one third of the estimated 800,000 to 900,000 HIV-infected persons in the United States have not been tested for HIV and thus cannot benefit from early intervention with effective antiviral therapy.

In March 2001, OraSure Technologies announced that the CDC had selected the OraQuick HIV rapid test to be used in a CDC sponsored IDE. Key areas of focus for the use of OraQuick in this IDE were five U.S. metropolitan public hospitals, AIDS service organizations, community based organizations, as well as outreach programs.

About OraSure

OraSure Technologies, Inc. develops, manufactures and markets medical devices and diagnostic products for use by public- and private-sector clients, clinical laboratories, physicians' offices and workplace testing.

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. In addition, the Company supplies oral fluid testing solutions for drugs-of-abuse testing. For more information on the Company, please visit www.orasure.com.

This press release contains certain forward-looking statements, including with respect to product development, performance, benefits and markets. Actual results could be significantly different.

Factors that could affect results include ability to market products; impact of competitors, competing products and technology changes; failure to comply with regulations of the FDA or other regulatory agencies; loss or impairment of sources of capital; ability to develop product distribution channels; ability to develop new products; market acceptance of oral fluid testing products; changes in international, federal or state laws or regulations; exposure to product liability or other types of litigation; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; equipment failures and ability to obtain needed raw materials and other components; and general business and economic conditions.

These factors are discussed more fully in the Securities and Exchange Commission filings of OraSure Technologies, including the Company's Annual Report on Form 10-K for 2000 and Quarterly Report on Form 10-Q for the first quarter of 2001.

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 those statements.

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