OraSure Technologies Files for Pre-Market Approval of OraQuick Rapid HIV Test

July 11, 2001

BETHLEHEM, Pa.--(BW HealthWire)--July 11, 2001--OraSure Technologies, Inc. (NASDAQ:OSUR) today announced that it filed with the U.S. Food and Drug Administration (FDA) for Pre-Market Approval of its OraQuick(R) HIV test.

OraQuick is a rapid test device that can detect antibodies to the HIV disease within 20 minutes, and is the only rapid device in the world designed to use oral fluid, whole blood, serum or plasma samples.

The submittal, which is for serum and whole blood applications only, was made on June 29, 2001. The Company intends to file for use with oral fluid specimens as soon as its oral fluid clinical trials are completed, which is anticipated to be in the fourth quarter of 2001.

OraSure Technologies' Chief Executive Officer, Robert D. Thompson, said, "There is a clear and immediate public-health need for a rapid HIV test in the United States. Critical decisions about treatment depend on the availability of accurate, immediate HIV test results and we expect OraQuick to fill that need."

OraQuick is currently available in several developing countries and has been through extensive trials in the United States, Africa, and Thailand. In March, the product was selected by the Centers for Disease Control and Prevention (CDC) to be used in a CDC-sponsored Treatment Investigational Device Exemption.

Under federal regulations, the FDA can authorize the use of an investigational test in the treatment of patients with serious life-threatening conditions when no comparable or satisfactory alternative exists.

The CDC has determined that the absence of approved rapid HIV tests in the United States meets that definition and has received permission from the FDA to use the OraQuick HIV device for specific purposes where rapid tests are uniquely required.

In hospital delivery rooms, an estimated 10 percent to 20 percent of pregnant women do not know their HIV status at the time of delivery. Expedited testing will permit therapy to be initiated for these mothers during labor, and after birth for their infants, substantially reducing the risk of these infants contracting HIV.

Likewise, rapid HIV results are needed for deciding whether to initiate treatment for health care workers after accidental exposures to patient body fluids. In public health outreach testing programs, up to 40 percent of those tested do not return to learn their test results and continue to be uninformed of their HIV status.

Rapid HIV testing all but eliminates this problem by providing on-the-spot results and permitting immediate counseling.

Mr. Thompson added, "This submittal represents the culmination of an extraordinary amount of effort on the part of our employee team. We are proud to have reached this milestone and look forward to working with the FDA during the review process."

About OraSure Technologies

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 go to www.orasure.com.

Forward-Looking Statements

This press release contains certain forward-looking statements including with respect to product regulatory submissions, benefits, availability 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.

www.orasure.com

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