



OraQuick® HIV Self-Test Now Approved for Use in Adolescents

January 7, 2025

BETHLEHEM, Pa., Jan. 07, 2025 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. ("OTI") (NASDAQ: OSUR), a leader in point-of-need and home diagnostic tests and sample management solutions, today announced that The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) has approved a labeling change to the OraQuick® HIV Self-Test that will increase access to HIV testing for adolescents. The change expands the approved age range to include individuals 14 years of age and older for the OraQuick® HIV Self-Test. Previously the test was approved for use in those 17 and older.

According to the most recent data available from the Centers for Disease Control & Prevention, it is estimated that 19 percent of new HIV diagnoses in the United States were among young people aged 13 to 24, and only 6 percent of high school students have ever been tested for HIV. Almost half of young people with HIV do not know that they have it.

"Increasing access to different testing options is critical to ending the HIV epidemic for all people, and early connection to care is essential for adolescents who test positive for HIV," said Carrie Eglinton Manner, President and CEO of OraSure Technologies. "We are pleased that our OraQuick® HIV Self-Test can now be used within this younger population who needs it, and we are proud of the work we have done to promote HIV testing, help people know their HIV status, and stop the stigma of infection. This approval will allow us to expand access to help those who need it."

The OraQuick® HIV Self-Test has been available direct to consumers in the U.S. since 2012. Since its launch, OraSure has been committed to providing consumers with access to critical information and connection to care. The packaging contains robust educational material and linkage to care information, giving individuals information that they can use to make informed decisions, regardless of the test result.

About OraSure Technologies, Inc.

OraSure Technologies, Inc. ("OraSure") transforms health through actionable insight and powers the shift that connects people to healthcare wherever they are. OraSure improves access, quality, and value of healthcare with innovation in effortless tests and sample management solutions. OraSure, together with its wholly-owned subsidiaries, DNA Genotek Inc. and Sherlock Biosciences, Inc., is a leader in the development, manufacture, and distribution of rapid diagnostic tests and sample collection and stabilization devices designed to discover and detect critical medical conditions. OraSure's portfolio of products is sold globally to clinical laboratories, hospitals, physician's offices, clinics, public health and community-based organizations, research institutions, government agencies, pharmaceutical companies, and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com.

Forward-Looking Statement

This press release contains certain forward-looking statements addressing expectations, prospects, estimates and other matters that are dependent upon future events or developments. These statements may be identified by words such as "expect," "anticipate," "intend," "plan," "believe," "will," "should," "could," "would," "project," "continue," "likely," and similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: our ability to satisfy customer demand; ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture or have manufactured products in accordance with applicable specifications, performance standards and quality requirements; ability to comply with applicable regulatory requirements; ability to meet increased demand for OraSure's products; competition from new or better technology or lower cost products; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention or other agencies; ability to obtain and maintain new or existing product distribution channels; impact of negative economic conditions; ability to maintain sustained profitability; changes in international, federal or state laws and regulations; equipment failures and ability to obtain needed raw materials and components. These and other factors that could affect our results are discussed more fully in our SEC filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2023, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. 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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