OraSure Submits CT/NG Molecular Self-Test and Colli-Pee™ Urine Collection Device for FDA Review

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BETHLEHEM, Pa., Jan. 05, 2026 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR) ("OraSure" and "OTI"), a leader in point-of-need and home diagnostic tests and sample management solutions, today announced that it submitted two separate applications at the end of 2025 to the U.S. Food and Drug Administration (FDA) for clearance of its rapid molecular self-test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (CT/NG) as well as its Colli-Pee™ at-home urine collection device for sexually transmitted infections (STIs).

"These submission milestones reflect meaningful progress on our innovation roadmap and bring us closer to realizing our vision of decentralizing diagnostics and connecting people to care that is more accessible, convenient, private, and personalized," said Carrie Eglinton Manner, President and CEO of OTI. "As we look ahead to 2026, we are continuing to execute on our strategy with purpose and momentum to create value for all our stakeholders."

OTI's rapid self-test for CT/NG is built on the Sherlock molecular diagnostics platform and is designed to provide results in approximately 30 minutes in a disposable, over-the-counter format. The test uses a self-collected swab, and results can be read directly on the hand-held testing device without the need for an electrical connection, enhancing flexibility and convenience. OTI estimates that testing for CT/NG represents a total addressable market of more than $1.5 billion. Today, the vast majority of CT/NG tests in the U.S. are processed in centralized laboratories, creating an opportunity for meaningful market expansion through the introduction of an affordable rapid self-test.

OTI also submitted the Colli-Pee™ device, which is designed for at-home urine collection and is aligned with patient preferences for private and convenient diagnostic testing. The submission covers multiple STI indications and is being pursued in collaboration with a leading diagnostics platform provider. Receipt of clearance for the Colli-Pee™ device for these indications would be in addition to the existing Research-use Only (RUO) product and is expected to expand access to testing and further strengthen OTI's leadership position in novel collection devices and chemistries.

About OraSure Technologies, Inc.
OraSure Technologies, Inc. ("OraSure" and "OTI") transforms health through actionable insight and decentralizes diagnostics to connect people to healthcare wherever they are. OTI improves access, quality, and value of healthcare with innovation in effortless tests and sample management solutions. Together with its wholly-owned subsidiaries, DNA Genotek Inc., Sherlock Biosciences, Inc., and BioMedomics, Inc., OTI 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. OTI's portfolio of products is sold globally to clinical laboratories, hospitals, physicians' offices, clinics, public health and community-based organizations, research institutions, government agencies, pharmaceutical companies, and direct to consumers. For more information, please visit www.orasure.com.

Forward Looking Statements
This press release contains certain "forward-looking statements," including with respect to products, product candidate development, regulatory submissions and authorizations and other matters. Forward-looking statements are based on current expectations of future events and are not guarantees of future performance or results. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from expectations and projections. 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: uncertainty of commercial success; ability to manufacture or have manufactured products in accordance with applicable specifications, performance standards and quality requirements; uncertainty and timing of regulatory clearances or approvals; ability to comply with applicable regulatory requirements; uncertainty relating to patent protection and potential patent infringement claims; impact of competitors, competing products and technology changes and patents obtained by competitors; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; impact of negative economic conditions; changes in behavior and spending patterns of purchasers; and changes to applicable laws and regulations. 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, 2024, 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 undertakes no duty to update these statements.

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