OraSure to Receive up to $13.6 Million from Biomedical Advanced Research Development Authority to Support InteliSwab™ COVID-19 Rapid Test 510(k) Clearance and CLIA Waiver

September 23, 2021

BETHLEHEM, Pa., Sept. 23, 2021 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a global leader in point-of-care and home diagnostic testing and sample collection technologies, announced today that the Biomedical Advanced Research Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS), will provide up to $13.6 million in funding for the Company to obtain 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) waiver for OraSure's InteliSwab™ COVID-19 rapid test from the Food and Drug Administration (FDA).

InteliSwab™ is a simple "swab, swirl, and see" test that uses an integrated swab to self-collect a sample from the lower nostrils. The result appears right on the test stick within 30 minutes, with no instruments, batteries, smartphone or laboratory analysis needed. It has three Emergency Use Authorizations from the Food and Drug Administration for professional point-of-care use, prescription (Rx) home use, and over-the-counter (OTC) use.

"Rapid COVID-19 antigen tests can help to facilitate containment and minimize outbreaks by detecting those individuals infected with COVID-19. Testing with InteliSwab™ is expected to be an important component of governments', private industries' and communities' response to the COVID-19 pandemic, along with vaccination and protection," said OraSure President and CEO, Stephen Tang, Ph.D. "Once received, this full regulatory clearance will help ensure continued availability of the InteliSwab™ COVID-19 Rapid Test long-term."

The InteliSwab™ COVID-19 Rapid Test is authorized for emergency use for the duration of the public health declaration. With FDA 510(k) clearance, InteliSwab™ can continue to be marketed without a public health emergency declaration from the Secretary of the Department of Health and Human Services (HHS). To date, there are no COVID-19 rapid antigen tests with 510(k) clearance and the requirements for 510(k) clearance are expected to be more stringent than the requirements for EUA.

Following 510(k) clearance, the Company will pursue Clinical Laboratory Improvement Amendments (CLIA) waiver for InteliSwab™, ensuring the test can continue to be performed by an untrained user outside of the laboratory setting.

This project has been funded in whole or in part with federal funds from BARDA, part of the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response under contract number 75A50120C00061.

About InteliSwab ™

OraSure has received Emergency Use Authorizations (EUA) from the U.S. Food and Drug Administration (FDA) for its InteliSwab™ COVID-19 rapid tests. The FDA has authorized the InteliSwab™ COVID-19 Rapid Test for Over-the-Counter (OTC) use without a prescription. FDA has also authorized the InteliSwab™ COVID-19 Rapid Test Pro for professional use in point of care (POC) CLIA-waived settings, and InteliSwab™ COVID-19 Rapid Test Rx for Prescription Home Use. These remarkably simple COVID-19 lateral flow tests use samples self-collected from the lower nostrils. InteliSwab™'s unique design incorporates a built-in swab fully integrated into the test stick. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution, and the result appears right on the test stick within 30 minutes, with no instruments, batteries, smartphone or laboratory analysis needed to see the result. With less than one minute of "hands-on time," it is as simple as Swab, Swirl, and See.

This product has not been FDA cleared or approved; but authorized by the FDA under an EUA; This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for the detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

OraSure's Response to COVID-19

OraSure is leveraging its expertise in infectious disease testing and molecular sample collection with EUAs for rapid antigen self testing and molecular sample collection for PCR-based tests. The Company's portfolio of COVID-19 tests and collection kits all feature easy, convenient, pain-free self-collection, and help increase access to testing, while alleviating the burden on the healthcare system and minimizing exposure risks.

About OraSure Technologies

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information. OraSure, together with its wholly-owned subsidiaries, DNA Genotek, Diversigen, and Novosanis, provides its customers with end-to-end solutions that encompass tools, services, and diagnostics. The OraSure family of companies is a leader in the development, manufacture, and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular services solutions 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, pharma, commercial entities and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues, products, product development activities, regulatory submissions and authorizations and other matters. 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: ability to successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of

acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; impact of increased or different risks arising from the acquisition of companies located in foreign countries; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration ("FDA") or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collector products, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; 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 ("CDC") or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. 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, 2020, 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.

Investor Contact:
Scott Gleason
SVP Investor Relations & Corporate Communications
484-425-0588
sgleason@orasure.com

Media Contact:
Amy Koch
Sr. Mgr. Corporate Communications
484-523-1815
media@orasure.com