OraSure Awarded $109 Million Contract from U.S. Department of Defense to Ramp Manufacturing of InteliSwab™ COVID-19 Rapid Test

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Agreement Ensures OraSure Will Have Sufficient Capacity to Meet Market Need for Rapid Antigen Tests and Ensure Future Preparedness

BETHLEHEM, Pa., Oct. 04, 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 it has been awarded a $109 million contract from the U.S. Department of Defense (DOD), in coordination with the Department of Health and Human Services (HHS), to build additional manufacturing capacity in the United States for InteliSwab™ COVID-19 rapid tests as part of the nation's pandemic preparedness plan.

InteliSwab is a remarkably simple test that rapidly detects active COVID-19 infection. It was granted three Emergency Use Authorizations (EUAs) by the Food and Drug Administration (FDA) in June for professional point-of-care use, prescription (Rx) home use, and over-the-counter (OTC) use.

"The U.S. government's selection of OraSure's InteliSwab™ rapid test for this national pandemic preparedness effort is a great honor and ensures we can make the necessary investments to scale manufacturing in order to support our nation's pandemic response," said OraSure President and CEO Stephen Tang, Ph.D. "This test will play a key role in ensuring our nation is prepared to continue the fight against this, and possible future pandemics and potential resurgences in disease activity."

The federal funding will expand OraSure's production capacity by 100 million tests annually, by March 2024. An existing OraSure location in Bethlehem, Pennsylvania, will be retrofitted to accommodate increased manufacturing and an additional new facility will be added in another U.S. location to be determined. In addition to this contract, OraSure also has internally funded expansion plans to achieve 120 million tests annually by the second quarter of 2022.

A recent study by the National Institutes of Health shows rapid antigen tests perform on par with lab PCR tests when testing at least twice per week with the antigen test.[1]

"Home testing options prevent the risk of further spread of the virus, and minimize the burden on the individual, making them an ideal cornerstone of any national pandemic preparedness strategy," Tang said. "As a company we stand ready to aid in the government's efforts to allow individuals to return to work and school safely. Beyond that, this funding will allow OraSure to respond to future public health crises."

Multiple government agencies, including the DOD and HHS are working to address COVID-19 testing needs. Development of the InteliSwab™ COVID-19 Rapid Test has been funded in whole or in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research, Innovation and Ventures under contract number 75A50120C00061, utilizing Health Care Enhancement Act (HCEA) funding. The DoD's Defense Assisted Acquisition (DA2) Cell led the manufacturing expansion effort for the InteliSwab™ COVID-19 rapid test in coordination with the Department of the Air Force's Acquisition COVID-19 Task Force (DAF ACT). This effort was funded through the American Rescue Plan Act (ARPA) to enable and support domestic industrial base expansion for critical medical resources.

[1] Longitudinal assessment of diagnostic test performance over the course of acute SARS-CoV-2 infection, The Journal of Infectious Diseases, 2021; jiab337, https://doi.org/10.1093/infdis/jiab337

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 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.

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