OraSure Technologies Receives Three Emergency Use Authorizations for its COVID-19 Rapid Antigen Tests for Non-Prescription (OTC), Professional and Prescription Use

June 7, 2021

Branded as InteliSwab™, the easy-to-use diagnostic tests rapidly detect active COVID-19 infection

BETHLEHEM, Pa., June 07, 2021 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR) announced today that it has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its COVID-19 rapid antigen tests, which the Company is branding as InteliSwab™. These tests detect active COVID-19 infection. 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 the *InteliSwab ™ COVID-19 Rapid Test Rx* for Prescription Home Use.

OraSure will market three versions of InteliSwab™:

- *InteliSwab ™ COVID-19 Rapid Test* The OTC home test for use without a prescription in individuals 15 years or older (with or without symptoms) when tested twice over two or three days with at least 24 and no more than 36 hours between tests.
- *InteliSwab™ COVID-19 Rapid Test Pro:* The Professional Test, which is packaged in bulk configurations, is authorized for use at the point of care in healthcare settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, for individuals 15 years or older who are suspected of COVID-19 by their healthcare provider within 7 days of symptom onset or for individuals without symptoms when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests.
- *InteliSwab ™ COVID-19 Rapid Test Rx:* The prescription home test is authorized for prescription home use with self-collection (unobserved) of anterior nasal samples from individuals 18 years or older or adult collected samples from individuals age 15 years or older who are suspected of COVID-19 infection by their healthcare provider within the first seven (7) days of symptom onset.

The unique design of InteliSwab™ incorporates a built-in swab that is fully integrated into the test stick, simplifying the entire testing process. Use of this integrated swab also helps ensure supply continuity, as InteliSwab™ does not require sourcing scarce nasal swabs. Testing with InteliSwab™ is simple: users swab their lower nostrils with the test stick, swirl it in a pre-measured solution, and see their result on the test stick in 30 minutes – with no instruments, batteries, smartphone or laboratory analysis needed to see the result. Using InteliSwab™ to test for COVID-19 requires less than one minute of “hands-on” time.

In a clinical study at five independent US sites, InteliSwab™ had strong performance, with positive results agreeing with highly sensitive FDA-authorized PCR tests 84% of the time, and negative results agreeing 98% of the time. In addition, 98% of consumers in the clinical trial found InteliSwab™ easy-to-use.

“OraSure is on a mission to make COVID-19 testing dramatically simpler. We believe that this easy and intuitive ‘swab, swirl and see’ test will be one of the simplest COVID-19 tests on the market. We expect that InteliSwab’s™ simplicity and accuracy will give users peace of mind that they performed the test correctly and can rely on the results,” said OraSure President and CEO Stephen Tang, Ph.D. “Simple and accessible at-home tests, like InteliSwab™, make it easier for individuals to know if they are infectious and to quickly self-isolate if they test positive. With InteliSwab™, we believe OraSure will play an even larger role in safely reopening – and keeping open – workplaces, schools and other places where people congregate.”

The Company’s installed manufacturing capacity for InteliSwab™ is currently 55 million units annually; the Company will be ramping up to a production capacity of 70 million units annually in the third quarter of 2021[1].

OraSure will be completing the required post market studies as specified in the FDA authorization letter which can be found at InteliSwab.com or on the FDA website at fda.gov.

Visit InteliSwab.com for more details.

The Company has built product inventory at risk, but because the EUAs require updates to labelling the Company is expecting only nominal, if any, InteliSwab™ revenue in the second quarter of 2021. The Company plans to provide an update on its expectations for InteliSwab™ revenue at or before its second quarter earnings call in August.

The pan-SARS-coronavirus antigen rapid in-home self-test project 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, under Contract No. 75A50120C00061.

OraSure’s Response to COVID-19

OraSure is leveraging its expertise in infectious disease testing and molecular sample collection to advance COVID-19 testing and sample collection solutions across three modalities: Antigen, Molecular/PCR, and Antibody. 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.

[1] Manufacturing capacity numbers include existing tests for HIV, HCV and Ebola.

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/b0875e37-ad0b-4761-bc61-4141d6a221a3

A video accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/92f1e416-146d-4cf4-a166-17f635cf9f91

Source: OraSure

The InteliSwab™ COVID-19 Rapid Test

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Technologies, Inc.