

OraSure's OMNIgene® ORAL Saliva Collection Kit Selected by Chronomics for Use in UK Government "Test to Release for International Travel" COVID-19 Testing Program

January 26, 2021

BETHLEHEM, Pa., Jan. 26, 2021 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests, specimen collection devices, and microbiome laboratory and analytical services, today announced that Chronomics Limited has selected the OMNIgene®·ORAL (OME-505) saliva collection device as a component of its SARS CoV-2 PCR test. Chronomics Limited will supply its test for the United Kingdom's "Test to Release for International Travel" program. The OMNIgene®·ORAL device is a product of OraSure's DNA Genotek subsidiary.

The "Test to Release for International Travel" program enables travelers to England to purchase a COVID-19 test privately from providers including Chronomics. Travelers who receive a negative test result can reduce their self-isolation period. The project is part of the UK's plan to use Covid-19 testing to reduce the spread of the virus.

"Our selection as a supplier of oral fluid sample collection devices by Chronomics demonstrates the broad applicability of DNA Genotek's technology and capabilities in testing for, and helping to reduce the spread of, COVID-19 and confirms DNA Genotek's position as the leading provider of saliva-based collection kits for detection of SARS CoV-2," said Kathleen Weber, Executive Vice President, Business Unit Leader, Molecular Solutions at DNA Genotek. "If we want people to widely adopt COVID-19 testing, a requirement to manage the current pandemic and slowly get back to normal life, we need to make the process painless, cost-effective, scalable and simple."

"Our COVID-19 PCR laboratory test, using DNA Genotek's OMNIgene® ORAL as the saliva collection device, is non-invasive, easy to self-administer and the gold standard in COVID-19 tests. We all have a responsibility to minimize the spread of Covid-19 and our saliva test makes it far simpler to provide customers with an easy and accurate way to test for the virus," said Dr. Tom Stubbs, CEO of Chronomics.

DNA Genotek's saliva collection devices are widely used in molecular testing to detect active COVID-19 infection. The OMNIgene®-ORAL (OME-505) collection device has Emergency Use Authorization (EUA) from the United States Food and Drug Administration (FDA) and is CE marked for use in the European Union. DNA Genotek's sample collection devices have been included in seven customer EUAs from a range of laboratories facilitating non-invasive collection of saliva samples for COVID-19 tests.

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 about OraSure, visit www.orasure.com

About DNA Genotek

DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., focuses on providing high-quality biological sample collection products and end-to-end services for human genomics and microbiome applications. The Company's Oragene®·Dx and ORAcollect®·Dx product lines are the first and only FDA 510(k) cleared saliva-based DNA collection devices for in vitro diagnostic use. DNA Genotek also offers Research Use Only products to collect and preserve large amounts of DNA or RNA from multiple sample types. DNA Genotek markets its products worldwide and has a global customer base with thousands of customers in over 100 countries. For more information about DNA Genotek, visit www.dnagenotek.com

About Chronomics

Founded in 2017, Chronomics, Ltd. is a UK-based biotechnology company founded on the use of epigenetics to give people the knowledge of how their environment and lifestyle is imprinting itself on their DNA and affecting their health. In response to the COVID-19 pandemic, Chronomics developed a CE-marked, UK Government-approved saliva testing kit trusted by thousands of people per day across Europe to detect the presence of RNA from SARS-CoV-2 (COVID-19 virus). visit www.chronomics.com or contact at partnerships@chronomics.com.

Proof of UK Government Approval of Chronomics: <u>https://www.gov.uk/government/publications/list-of-private-providers-of-coronavirus-testing/list-of-providers-of-coronavirus-testing/list-of-providers-of-coronavirus-testing/list-of-pro</u>

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. 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 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, 2019, Quarterly Report on Form 10-Q for the guarter ended September 30, 2020, 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: Sam Martin Argot Partners 212-600-1902 orasure@argotpartners.com

Media Contact: Jeanne Mell OraSure Technologies 484-353-1575 media@orasure.com



Source: OraSure Technologies, Inc.