OraSure's DNA Genotek Subsidiary Receives FDA Emergency Use Authorization for its ORAcollect®·RNA Saliva Collection Device for SARS CoV-2

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Second FDA EUA for the Subsidiary's Saliva Collection Devices

BETHLEHEM, Pa., Nov. 03, 2020 (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 its DNA Genotek subsidiary has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the use of the ORAcollect®·RNA (OR/ORE-100) saliva collection device for the collection, stabilization and transport of saliva specimens suspected of containing SARS-CoV-2 RNA. This is the second FDA EUA that DNA Genotek has received for its saliva collection devices.

Like the EUA DNA Genotek recently obtained for OMNIgene®·ORAL (OM/OME-505), this EUA allows for the unsupervised use of the device at-home or in a healthcare setting when used as a component of an authorized or cleared self-collection kit. This means it can be part of a kit that is authorized under its own EUA for use by an individual to collect saliva specimens at home.

"Accessible and accurate testing programs that include a non-invasive, saliva-based collection option will be essential throughout the duration of the COVID-19 pandemic," said Kathleen Weber, Executive Vice President, Business Unit Leader, Molecular Solutions at DNA Genotek. "This second EUA gives our customers additional non-invasive options for SARS CoV-2 sample collection. Saliva sample collection is quick, painless, non-invasive and requires less human contact both minimizing the need for PPE and reducing exposure to potentially infected patients."

The ORAcollect·RNA collection device is an important component of molecular/PCR tests as laboratories are able to use it as the saliva sample collection method for their COVID-19 tests.

In addition to molecular sample collection devices for lab-based molecular/PCR COVID-19 testing from its DNA Genotek subsidiary, OraSure is also developing a lab-based oral fluid SARS-CoV-2 antibody test, and a rapid antigen self-test for COVID-19.

The ORAcollect·RNA and OMNIgene·ORAL sample collection devices have not been FDA cleared or approved; the devices have been authorized by FDA under an EUA. The ORAcollect·RNA and OMNIgene·ORAL sample collection devices have been authorized only to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA), not for any other viruses or pathogens; and the ORAcollect·RNA and OMNIgene·ORAL sample collection devices are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in medical devices during the COVID-19 outbreak under Section564(b)(1) of the Federal Food, Drug, and Cosmetic Act,21U.S.C. §360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

About OraSure Technologies
OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information. Together with its wholly-owned subsidiaries, DNA Genotek, Diversigen, CoreBiome (now operating under the Diversigen brand), UrSure and Novosanis, OraSure 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.

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.

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 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:	Media Contact:
Sam Martin	Jeanne Mell
Argot Partners	VP Corporate Communications
212-600-1902	484-353-1575
orasure@argotpartners.com	media@orasure.com



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