OraSure Technologies Receives General Clearance for its ORAcollect®•Dx Device for Over-the Counter (OTC) Use from the U.S. Food and Drug Administration (FDA)

November 3, 2022

FDA Clearance Received Through Partnership with Grifols to Support Screening for Risk of Alpha$_1$- Antripsyn Deficiency (Alpha-1) in U.S. Adult Population

BETHLEHEM, Pa., Nov. 03, 2022 (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 Company received U.S. FDA clearance for its ORAcollect®•Dx saliva collection device for OTC (i.e. direct-to-consumer) use. The device had been previously cleared for prescription use by the FDA. ORAcollect®•Dx joins the Oragene®•Dx product line which previously received FDA general clearance for prescription and OTC use. This new designation now allows ORAcollect®•Dx devices to be used by OraSure's commercial partners and legally marketed with their therapeutics or devices in conjunction with their product's intended use. Both the ORAcollect®•Dx, and Oragene®•Dx devices are designed to be used by an adult at home, without direction from a healthcare professional.

OraSure received this designation through its partnership with Grifols to support screening for alpha1-antitrypsin deficiency (alpha-1) in individuals who may be at risk for alpha-1. Alpha-1 raises patients' risks for lung disorders and it is estimated that about 3% of COPD patients have alpha-1. Beginning in Q2 2023, Grifols will offer free AlphaID™ At Home Genetic Health Risk Service, supporting alpha-1 screening, that utilize the ORAcollect®•Dx device to help identify individuals at risk. According to the Centers for Disease Control, COPD affects over 15 million people in the United States.

"This clearance represents a major milestone for OraSure as we work in conjunction with our commercial partners to increase access to healthcare," said Kathleen Weber, President of Molecular Solutions for OraSure Technologies. "With the movement toward precision medicine, we increasingly see the need for genetic testing supporting FDA approved therapeutics as drugs become more specialized for targeted patient populations. This expanded designation now allows us to better support our customers and expands the potential for future indications with the ORAcollect®•Dx device."

"We look forward to working with an experienced partner such as OraSure to expand access to alpha-1 testing and awareness," said Antonio Martínez, President, Grifols Diagnostic.

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 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 the Company's 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: risk that the Company's exploration of strategic alternatives may not result in any definitive transaction or enhance stockholder value and may create a distraction or uncertainty that may adversely affect operating results, business or investor perceptions; the diversion of management's attention from the Company's ongoing business and regular business responsibilities due to the Company's exploration of strategic alternatives; ability to resolve the Company's ongoing manufacturing challenges and satisfy customer demand; 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 the Company's business and 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; 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, 2021, 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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