OraSure Technologies Provides Update on Its Emergency Use Authorization Application for Its Lab-based Oral Fluid SARS-CoV-2 Antibody Test

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BETHLEHEM, Pa., Dec. 21, 2020 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today disclosed that the U.S. Food and Drug Administration (FDA) has requested additional information as part of its review of the Company's application for Emergency Use Authorization (EUA) for its laboratory-based oral fluid SARS-CoV-2 antibody test. The OraSure SARS-CoV-2 Antibody ELISA is intended for qualitative detection of total antibodies to SARS-CoV-2 in human oral fluid specimens collected with the OraSure Oral Antibody Collection Device.

At the FDA's request, the Company intends to resubmit two separate EUAs for the ELISA and the oral specimen collection device. In addition, the FDA has requested that additional analytical studies be conducted on sample collection and stability.

"To date, there are no oral fluid antibody tests for COVID-19 authorized for sale in the U.S. As such, FDA's guidance on EUA submissions for COVID-19 antibody tests focuses on blood samples for tests; the Agency did not outline specific requirements for an oral fluid test. Consequently, we were unable to completely anticipate all of the data that would be required for a first-of-its-kind oral fluid antibody test," said OraSure President and CEO Stephen S. Tang, Ph.D. "This request is within the normal course of an FDA review and we are confident that we'll be able to provide the requested data, and resubmit our EUA application for this pioneering product promptly."

Antibody tests are well suited for community surveillance and seroprevalence studies to identify people who have antibodies against COVID-19. Oral sample collection is quick, painless, non-invasive and requires less human contact than a blood draw, minimizing the need for personal protective equipment and reducing exposure to potentially infected patients.

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.

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 quarter 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.

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