

OraSure Receives Federal Funding for Development of Marburg Virus Rapid Antigen Test

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BETHLEHEM, Pa., Dec. 02, 2024 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care and home diagnostic tests and sample management solutions, today announced that it received an award through the Rapid Response Partnership Vehicle (RRPV) for the development of a Marburg Virus Disease (MVD) rapid antigen test. The RRPV is a Consortium funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS).

The initial contract award, valued at approximately \$7.5 million over multiple years in the base period with potential value up to \$11 million, funds the development to achieve U.S. Food and Drug Administration (FDA) 510(k) clearance of a single-use lateral flow immunoassay intended for the qualitative detection of antigens from viruses within the Marburg virus genus. We expect that the proposed test will be intended for use with specimens from individuals with epidemiological risk factors who have signs or symptoms of MVD or from recently deceased individuals with epidemiological risk factors who are suspected to have died of MVD.

"A test with this utility has the potential to be an important tool in the containment of future Marburg virus outbreaks, and we are proud to partner with BARDA to develop it, helping to prevent the spread of this deadly virus, which has the capacity to cause outbreaks with a fatality rate similar to Ebola," said Carrie Eglinton Manner, President and Chief Executive Officer of OraSure. "At OTI, we remain committed to partnering with government agencies to develop such tests that help address global public health challenges."

OraSure has previously collaborated with BARDA in the development of the InteliSwab[®] COVID-19 Rapid Test and maintains an ongoing partnership focused on enhancements to its 510(k) cleared point-of-care OraQuick[®] Ebola Rapid Antigen Test.

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Number: 75A50123D00005.

About OraSure Technologies

OraSure Technologies, Inc. ("OraSure") transforms health through actionable insight and powers the shift that connects people to healthcare wherever they are. OraSure improves access, quality, and value of healthcare with innovation in effortless tests and sample management solutions. OraSure, together with its wholly owned subsidiary, DNA Genotek Inc., is a leader in the development, manufacture, and distribution of rapid diagnostic tests and sample collection and stabilization devices 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, pharmaceutical companies, commercial entities, and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com.

Forward-Looking Statement

This press release contains certain forward-looking statements. 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: our ability to satisfy customer demand; ability to reduce our spending rate, capitalize on manufacturing efficiencies and drive profitable growth; ability to achieve the anticipated cost savings as a result of our business restructuring, including from insourcing third party manufacturing and exiting microbiome services; 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 or have manufactured 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 FDA or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on OraSure's business, supply chain, labor force, 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, and demand for our COVID-19 testing products; 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 OraSure's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of OraSure to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales and the ability to continue to reduce costs; 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 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 OraSure'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; cybersecurity breaches or other attacks involving our systems or those of our third-party contractors and IT service providers; the impact of terrorist attacks, civil unrest, hostilities and war; and general political, business and economic conditions, including inflationary pressures and banking stability. 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, 2023, 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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