Study Concludes Self-Sampling Using Colli-Pee® Device for HPV Screening Is Both Cost Effective and Could Improve Patient Access

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BETHLEHEM, Pa., June 13, 2023 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a global leader in point-of-care and at-home diagnostic testing, as well as non-invasive self-sampling technologies and microbiome-focused biocomputational solutions, announced today that a major health economics study featuring its Colli-Pee® device has been published in the biomedical journal “BMJ Open.” This study, conducted by experts from Aquarius Population Health Limited in London and the University of Manchester, presents valuable insights into the cost-effectiveness of self-sampling for routine human papillomavirus (HPV) primary cervical cancer screening using the Colli-Pee® UCM® self-collection device.

The study's noteworthy findings suggest that self-sampling with the Colli-Pee® device could offer a more affordable alternative to clinician-collected sampling and other self-sampling methods. This has the potential to significantly expand access to cervical cancer screening for underserved and rural populations on a larger scale.

The health-economic research employed an innovative cost-benefit analysis model, utilizing real-world evidence from England’s primary HPV NHS Cervical Screening Programme (NHSCSP). The study compared three sampling approaches using a deterministic decision-tree model. The biocomputational analysis simulated a cohort of 10,000 individuals representative of the 400,000 people with a cervix aged 25 to 64 in England’s NHSCSP during 2020 and 2021. The three sampling strategies evaluated were routine clinician-collected cervical sample (identified as the most expensive option), self-collected first-void urine via the Colli-Pee® device (the least expensive option), and self-collected vaginal swab (the second-most expensive). The Colli-Pee® first-void urine collection device evaluated in the study is manufactured by OraSure's Belgium-based subsidiary, Novosanis.

“OraSure is committed to delivering user-friendly tests and collection devices that can be conveniently used in decentralized settings. The Colli-Pee ® collection device has the potential to reduce cost to the healthcare system, expand access to screening, and eliminate an invasive, sometimes painful, procedure for women,” said Carrie Eglinton Manner, President and Chief Executive Officer of OraSure. “We are excited about the potential of the Colli-Pee® UCM® device in improving access to cost-effective HPV screening and enhancing the patient experience worldwide and are actively engaged in multiple clinical research and commercial collaborations to establish first-void urine as a validated sample type for HPV screening, women's health therapeutics, and the detection of innovative oncology-related biomarkers,” she said.

According to the World Health Organization, HPV is responsible for over 99 percent of cervical cancer cases. The National Cancer Institute reports that half of new HPV cases occur among unscreened women. The UK-based study found that, if self-screening led to a 15 percent increase in women accessing the HPV cervical cancer screening program in England, along with an additional 50 percent transition to self-screening by women currently undergoing screening in physician practices, the NHSCSP could potentially save £19.2 million per year through minimally invasive first-void urine self-screening or £16.5 million per year through more invasive vaginal swab-based self-screening. These figures highlight the significant economic benefits associated with implementing self-sampling methods.

Overall, this pioneering study underscores the potential of self-sampling with the Colli-Pee® device as a cost-effective solution for HPV cervical cancer screening. With its substantial impact on improving access to screening and reducing healthcare costs, it holds great promise in advancing women's health globally.

Full study results can be viewed at https://bmjopen.bmj.com/content/13/6/e068940.

About OraSure Technologies
OraSure Technologies, Inc., 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.

About Novosanis
Novosanis NV, a subsidiary of OraSure, is an innovator of first-void urine (FVU) urine sample collection with the Colli-Pee® sample collection device family to improve the quality of diagnostic tests for infectious diseases and oncology. The Colli-Pee® devices provide non-invasive, self-collected, and volumetric sampling to standardize FVU collection, with a unique design to enable the immediate mixing of urine and preservative for FVU sample stability. Offering various sizes to capture a range of urine volumes for different application purposes, Novosanis is pioneering FVU sample collection as an alternative to invasive sampling demonstrated by strong clinical research outcomes, patient preference and affordability.

Important Information
This press release contains certain forward-looking statements, including with respect to products, product development activities, regulatory submissions and authorizations, revenue growth, cost savings, cash flow, increasing margins 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: 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; 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 FDA or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on the Company'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 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 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 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, 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, 2022, 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:
Jason Plagman
VP, Investor Relations
investorinfo@orasure.com

Media Contact:
Amy Koch
Director, Corporate Communications
media@orasure.com