



## OraSure Technologies Receives FDA Clearance for UPLink Test System

April 8, 2002

- First FDA-Cleared Oral Fluid Point-of-Care Test -
- Conference Call and Webcast Scheduled for April 11, 2002 -

BETHLEHEM, Pa.--(BW HealthWire)--April 8, 2002-- OraSure Technologies, Inc. (Nasdaq NM:OSUR), today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for its UPLink(TM) test system to detect opiates in oral fluid.

This clearance is based on data submitted by the Company demonstrating that the UPLink(TM) point-of-care oral fluid test system for opiates provides safety and efficacy equivalent to that provided by the Company's FDA-cleared, laboratory-based Intercept(R) oral fluid drug test. The UPLink(TM) test system for opiates is the only point-of-care, oral fluid drug test that has received FDA clearance.

UPLink(TM) is OraSure Technologies' first product platform based on Up-Converting Phosphor Technology (UPT(TM)). UPLink(TM) is a point-of-care system comprised of an oral fluid sample collector, test cassette, and analyzer developed for detecting drugs of abuse. UPLink(TM) delivers instrument-read results in approximately ten minutes, and is expected to dramatically improve turnaround time and reduce costs associated with traditional lab-based urine drug testing.

Dr. Sam Niedbala, Executive Vice President and Chief Science Officer, explained, "We have achieved a significant milestone, and have established a framework for the Company to obtain FDA clearance for the full five-drug panel of assays in an oral fluid specimen. FDA clearance of the UPLink(TM) analyzer, related software, collector and test cassette system should streamline future approvals, not only for our remaining drug tests, but also for the infectious disease applications currently in development for use on the UPLink(TM) platform."

The Company is continuing to optimize performance of the five-panel multiplex test and gather additional clinical data required by the FDA for the remaining UPLink(TM) oral fluid drug tests - cocaine, methamphetamine/amphetamine, PCP and marijuana, and expects to submit a 510(k) application for the full National Institute of Drug Association ("NIDA") five-drug panel of tests ("NIDA-5") in mid-summer 2002. In the interim, within the next several months the Company expects to commence beta-site testing and initial commercial sales of a four-panel UPLink(TM) drugs of abuse detection system in the non-regulated criminal justice market in the United States. After receipt of FDA clearance for the full panel of drug tests, the product is expected to be marketed and sold in the workplace, occupational health, and drug rehabilitation settings. Additionally, the Company has been working closely on the international launch of the product through its development partner, Drager Safety AG & Co. KGaA, which is also expected later this year.

The Company is also in the final stages of obtaining certification by Underwriters Laboratories Inc. ("UL") that the UPLink(TM) analyzer meets certain industry safety and performance standards applicable to electrical equipment and lasers, which will allow the Company to market the UPLink(TM) test system in the United States and around the world. UL is an internationally-recognized, independent product safety testing and certification organization. The UL certification will also aid the Company in obtaining a CE mark on the product. A CE mark evidences compliance with certain international quality and safety requirements established by the Council for the European Economic Community, and must be obtained in order to sell the UPLink(TM) test system in Europe after December 31, 2003.

OraSure Technologies currently manufactures and markets Intercept(R), the only FDA-cleared laboratory-based oral fluid drug test, and believes that its Intercept(R) and UPLink(TM) products will provide the only total oral fluid drug testing solution for its customers. The size of the domestic market for laboratory-based, drugs of abuse testing is estimated at approximately \$1.5 billion, involving more than 42 million specimens per year.

Mike Gausling, President and Chief Executive Officer, stated, "We are pleased to have achieved this significant milestone, which helps validate our mission to become the world's best oral fluid diagnostics company."

### Internet Audio Broadcast

OraSure Technologies will host a conference call with financial analysts on Thursday, April 11, 2002, at 11:00 a.m. Eastern Time (8:00 a.m. Pacific Time), to discuss the 510(k) clearance described above and the Company's progress towards achieving certain other 2002 milestones. On the call will be Mike Gausling, President and Chief Executive Officer, R. Sam Niedbala, Ph.D., Executive Vice President and Chief Science Officer, Ron Spair, Executive Vice President and Chief Financial Officer, and P. Michael Formica, Senior Vice President, Operations.

The call will include brief remarks by management and a question and answer session. In order to listen to the conference call, please either dial 888/742-2024 (Domestic) or 706/643-0033 (International), or go to OraSure Technologies' web site, [www.orasure.com](http://www.orasure.com), at least ten minutes prior to the start of the call to register, and download and install any necessary audio software. A replay will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until April 16, 2002, by dialing 800/642-1687 (Domestic) or 706/645-9291 (International) and entering the Conference ID #3782294.

### About Up-Converting Phosphor Technology (UPT(TM))

UPT(TM) is a proprietary label detection technology developed by OraSure Technologies and research partners, SRI International, Menlo Park, California, and Leiden University, The Netherlands. UPT(TM) uses phosphor particles that convert light from low energy infrared light to high-energy visible light. This rare optical process, not found in nature, is expected to make UPT(TM) useful as a reporter label to detect a wide variety of targets, including drugs of abuse, infectious diseases, cancer markers, food pathogens, cardiac risk markers, and DNA probes. UPT(TM) particles produce zero background interference, which dramatically increases the potential sensitivity of any test system. In addition, the many colors of particles can allow simultaneous detection of multiple biological markers (i.e. multiplexing).

## About OraSure Technologies

OraSure Technologies, Inc. is the market leader in oral fluid diagnostics. The Company develops, manufactures and markets medical devices and diagnostic products for use by insurance companies, public health agencies, clinical laboratories, physicians' offices, and workplace sites. For more information on the Company and its products, please visit [www.orasure.com](http://www.orasure.com).

## Important Information

This press release contains certain forward-looking statements, including with respect to products, regulatory filings and clearances, markets and product sales. Actual results could be significantly different. Factors that could affect results include the ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to obtain and timing of obtaining necessary regulatory approvals; ability to develop product distribution channels; uncertainty relating to patent protection and potential patent infringement claims; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer inventory practices and consolidations; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general business, political and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission filings of OraSure Technologies, including its registration statements and its Annual Report on Form 10-K for the year ended December 31, 2001. Although forward-looking statements help to provide complete information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

[www.orasure.com](http://www.orasure.com)

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