



## **OraSure Technologies Issues Statement Regarding Proceedings of the Blood Products Advisory Committee Meeting of the FDA; Company Applauds FDA's Recommendations for Proposed Studies To Support Approval of Home-Use HIV Test Kits**

March 13, 2006

BETHLEHEM, Pa.--(BUSINESS WIRE)--March 13, 2006--OraSure Technologies, Inc. (NASDAQ:OSUR), the market leader in oral fluid diagnostics and the manufacturer of the OraQuick(R) ADVANCE(TM) Rapid HIV-1/2 Antibody Test, today issued a statement following a meeting of the Blood Products Advisory Committee ("BPAC") of the Food and Drug Administration ("FDA"), held Friday, March 10, 2006, in Gaithersburg, MD.

The BPAC meeting included a discussion of proposed studies to support the approval of over-the-counter home-use HIV test kits. At the conclusion of the meeting, the Committee agreed to a proposal by FDA setting forth clinical study requirements for approval of a home use HIV test kit.

Following the meeting, Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies, made the following statements:

"We are extremely encouraged by the proposal put forward by FDA and the endorsement of that proposal by the Committee. This has provided significant clarification of the regulatory pathway for approval of an over-the-counter rapid HIV test. The discussion and feedback from the Committee and the public has been extremely valuable as we take the next steps in bringing our OraQuick(R) ADVANCE(TM) test over the counter and we are very pleased with the strong support received from the public health and hospital community for an over-the-counter rapid HIV test."

"As a follow up to the BPAC meeting, we intend to begin immediately to plan for the recommended proposed studies to support FDA approval of our OraQuick(R) ADVANCE(TM) test for home use. We intend to begin these required clinical studies as soon as possible."

"We look forward to the day, hopefully in the near future, when millions of individuals will be empowered to know their HIV status through greater access to rapid testing. We will continue to work in partnership with the FDA and other members of the healthcare community to make that a reality."

Materials from the March 10, 2006 BPAC meeting can be found at <http://www.fda.gov/ohrms/dockets/ac/cber06.html#BloodProducts>.

OraQuick(R) ADVANCE(TM) is the first and only FDA approved and CLIA (Clinical Laboratory Improvements Amendments Act of 1988) waived rapid point-of-care test that can detect antibodies to both HIV-1 and HIV-2 in 20 minutes, using oral fluid, finger-stick or venipuncture whole blood or plasma specimens. The Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA) have effectively deployed over 1 million OraQuick(R) tests in various public health, drug treatment and outreach settings throughout the country. OraQuick(R) is also used by hospitals, state departments of health, clinics, community-based organizations, and college/university health centers throughout the country.

### **About OraSure Technologies**

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other in vitro diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities.

OraSure Technologies is the leading supplier of oral fluid collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV. In addition, the Company supplies oral fluid testing solutions for drugs of abuse testing. For more information on the Company, please go to [www.orasure.com](http://www.orasure.com).

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