



## **OraSure Technologies Files Additional Data With FDA in Support of PMA Application for OraQuick Rapid HCV Test**

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BETHLEHEM, Pa., Jan 7, 2010 (GlobeNewswire via COMTEX) -- OraSure Technologies, Inc. (Nasdaq:OSUR) announced today the recent filing of a pre-market approval ("PMA") amendment with the U.S. Food and Drug Administration ("FDA") for the Company's OraQuick(R) Rapid HCV Antibody Test. The amendment contains additional clinical data requested by the FDA for use of the test in detecting antibodies to the Hepatitis C Virus ("HCV") in venous whole blood samples.

When approved for use with venous whole blood, the OraQuick(R) HCV test is expected to be the first rapid HCV test approved by the FDA for use in the United States. The Company is also currently completing an additional clinical study to obtain FDA approval of the OraQuick(R) HCV test for use with oral fluid and fingerstick whole blood.

Filing of the amendment with the FDA follows the Company's announcement this past December that it received approval to affix the CE mark to its OraQuick(R) HCV Test for use with oral fluid, fingerstick blood, venous whole blood, serum and plasma. The CE mark is required to sell this test in the 27 countries that currently make up the European Union. The OraQuick(R) Rapid HCV Antibody Test is the first and only rapid Hepatitis C test bearing a CE mark that can be used with oral fluid.

As previously announced, OraSure entered into agreements with Merck & Co., through its predecessor Schering Plough Corp., to collaborate on the development and promotion of the OraQuick(R) HCV test. Under these agreements, Merck will provide detailing and other promotional support for the test in the physicians' office markets in the United States and internationally.

### **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. For more information on the Company, please go to [www.orasure.com](http://www.orasure.com).

The OraSure Technologies, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=6440>

### **Important Information**

This press release contains certain forward-looking statements, including with respect to products, clinical programs and regulatory approvals. Actual results could be significantly different. Factors that could affect results include the ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; changes in relationships, including disputes or disagreements, with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and credit crisis; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance and extended shelf life; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; 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 product components; availability of related products produced by third parties or products required for use of our products; 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; history of losses and ability to achieve sustained profitability and ability to utilize net operating loss carryforwards 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 changes in international funding sources; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to patent infringement, 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; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission ("SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2008, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. 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.

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