

FOR IMMEDIATE RELEASE



## News

### Abbott to Collaborate with GSK on Molecular Diagnostic Test to Select Candidate Patients for Future Skin Cancer Immunotherapy

DES PLAINES, Ill., March 3, 2010 — Abbott announced today that it has entered into an agreement with GlaxoSmithKline (GSK) to develop a molecular diagnostic test intended for use as an aid in selecting patients who may benefit from a skin cancer treatment in development by GSK.

GSK's MAGE-A3 ASCI (Antigen-Specific Cancer Immunotherapeutic) candidate is currently being evaluated as an adjuvant treatment in melanoma biopsy specimens in the Phase III clinical study DERMA. To be eligible to receive GSK's MAGE-A3 ASCI, patients must have MAGE-A3 expressing melanoma tumors.

Under terms of the agreement, Abbott, in conjunction with GSK, will develop and commercialize a PCR (polymerase chain reaction) test for use on the Abbott *m2000*<sup>™</sup> automated molecular instrument system. The test will be designed to detect MAGE-A3, a tumor-specific antigen that is expressed in skin cancer and a wide variety of other cancers, but not in normal cells. In July 2009, both companies announced a similar collaboration and Phase III investigation for the MAGE-A3 marker in non-small-cell lung cancer.

Currently, there are no nucleic acid-based tests approved by the U.S. Food and Drug Administration for use in identifying patients who may derive treatment benefits from targeted skin cancer therapies. Abbott, in collaboration with GSK, will seek regulatory approval for the test in several markets, including the United States and Europe.

"This is an exciting continuation of our important collaboration with GSK, a leading company in cancer immunotherapy research," said Stafford O'Kelly, head of Abbott's molecular diagnostics business. "The agreement is indicative of our commitment to personalized medicine and our focus on developing innovative companion diagnostic tests that can be used to identify patients most likely to benefit from specific cancer therapies."

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According to the Skin Cancer Foundation (<http://www.skincancer.org/Melanoma>), melanoma is the most serious form of skin cancer. However, if it is recognized and treated early, it is nearly 100 percent curable. While it is not the most common of skin cancers, it causes the most deaths. The American Cancer Society estimates that in 2008, there were 8,420 fatalities in the U.S. alone, 5,400 in men and 3,020 in women. The number of new cases is estimated at more than 62,000; of these, approximately 35,000 will be in men and approximately 27,000 in women.

### **ASCIs and MAGE-A3 ASCI**

GSK's ASCIs represent a novel class of medicines designed to train the immune system to recognize and eliminate cancer cells in a highly specific manner. These candidate cancer immunotherapeutics combine tumor antigens, delivered as purified recombinant proteins, and GSK's proprietary immunostimulants, which are specific combinations of immunostimulating compounds selected to increase the anti-tumor immune response. ASCIs are being investigated in the clinic to support their use to reduce the risk of tumor recurrence following surgery, or to impact tumor growth in an early metastatic setting.

The highly specific mode of action of GSK's ASCIs is linked to the development of diagnostic tools to aid in selecting patients eligible for the treatment, depending on the expression of the tumor antigens. MAGE-A3 is a tumor-specific antigen that is expressed in a large variety of cancers, including melanoma, non-small cell lung cancer, liver and bladder cancer, with no expression in normal cells. MAGE-A3 ASCI is an investigational compound and it is not approved for use in any indication in any country at this time.

Websites have been created to provide information on the ASCI approach and the DERMA clinical study. Please visit [www.immunotherapyforcancer.com](http://www.immunotherapyforcancer.com) and [www.gsk-asci.com](http://www.gsk-asci.com) for more information

### **Molecular Tests for Oncology**

Abbott is a leader in the development of molecular tests based on PCR and fluorescence *in situ* hybridization (FISH) technologies with the intent to aid clinicians in the selection of appropriate pharmacogenomic therapies. The Vysis FISH products are designed with the sensitivity to aid in early diagnosis and monitoring of cancer and help identify patients who may benefit from appropriate therapies.

Abbott Molecular's development efforts in areas such as MAGE-A3 will further build its leadership position in cancer diagnostics and personalized medicine.

**The *m2000* System**

The Abbott *m2000* system is an automated instrument for DNA and RNA testing in molecular laboratories. The *m2000* system is based on real-time PCR technology and consists of the *m2000sp* for automated sample preparation and the *m2000rt* for real-time PCR detection and analysis, offering an efficient workflow for the lab. The Abbott *m2000* instrument is available in most major markets throughout the world. Outside the United States, an extensive menu for infectious disease testing is available that includes HIV-1 viral load, hepatitis B (HBV) viral load, chlamydia, chlamydia/gonorrhea (CT/NG) combination, hepatitis C (HCV) viral load, HCV genotyping, cytomegalovirus (CMV), Epstein Barr virus (EBV) and human papillomavirus (HPV). In December 2009, Abbott Molecular introduced the first oncology assay on its *m2000* system — the Abbott RealTime *mS9* Colorectal Cancer — that detects the methylated form of Septin 9, a gene linked to colorectal cancer, in blood specimens. Except for the RealTime HIV-1 and the RealTime CT/NG, no other tests are currently available on the *m2000* in the United States.

**About Abbott Molecular**

Abbott's molecular diagnostics business, headquartered in Des Plaines, Ill., provides physicians with critical information based on the early detection of pathogens and subtle changes in patients' genes and chromosomes aiding in earlier diagnosis and selection of appropriate therapies and monitoring of disease progression. The business includes instruments and reagents used to conduct sophisticated analysis of patient DNA and RNA. Additional information is available on Abbott Molecular's Web site at [www.abbottmolecular.com](http://www.abbottmolecular.com).

**About Abbott**

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 83,000 people and markets its products in more than 130 countries.

Abbott's news releases and other information are available on the company's Web site at [www.abbott.com](http://www.abbott.com).

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