



## NEWS RELEASE

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## FOR IMMEDIATE RELEASE

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## Independent Proficiency Panels Demonstrate Critical Value of Cross-Laboratory Assay Harmonization for Immune Biomarker Development

### *Guiding and Improving Immune Response Measurements in Early Clinical Studies*

Mainz, Germany and New York, NY, USA, Nov. 9, 2011 – The Association for Cancer Immunotherapy (CIMT) Immunoguiding Program (CIP) and the Cancer Immunotherapy Consortium (CIC) of the Cancer Research Institute (CRI) today announced the publication of a joint paper discussing recent results of independent international, cross-laboratory immune assay harmonization studies. More than 120 academic, pharmaceutical, biotechnology, contract research, and government laboratories from the United States and Europe have participated in CIMT-CIP and CRI-CIC sponsored proficiency panels to test and compare immune response assays, including measurement variability and reproducibility. The collaboration between both organizations dedicated to cancer immunotherapy has enabled this successful program, which represents the largest in the field and delivers an important practical advance to the research community.

Unlike most anticancer treatments, immune-based therapies primarily target the immune system and not the tumor. Therefore, an essential component of immunotherapy trials is the study of the patient's immune response to such treatment, measuring clinical efficacy and ultimately deciding on the progress of early clinical studies. However, differing protocols between laboratories for measuring immune responses often result in high data variability and poor reproducibility. This precludes an objective comparison of data across studies and the identification of biomarkers.

“To save costs and prevent redundant trials one should be able to use the datasets from many different phase I/II clinical trials as building blocks for strategies. This, however, requires a reduction in data variability and the implementation of cross-laboratory harmonization guidelines,” says Sjoerd van der Burg, Ph.D., chairman of the CIMT Immunoguiding Program and professor of Experimental Cancer Immunology and Therapy at Leiden Medical Center, Netherlands. “A higher probability to identify biomarkers through harmonization of immunological assays will in the end guide timely and rational decisions about candidate agents that move through the clinical trial process.”

According to van der Burg, any size laboratory, regardless of experience level, can benefit from participating in proficiency panels as an effective mechanism for quality control in assay development and application.

“The proposed methodological improvements to clinical cancer immunology that have resulted from our international collaborations, such as our assay harmonization guidelines, when implemented, have been shown to reduce data variability and enhance the clinical development process,” says Sylvia Janetzki, Ph.D., leader of the proficiency panel program of the CRI Cancer Immunotherapy Consortium. “With many new promising immune-based therapeutic agents now in development, it’s important that members of the broader cancer immunotherapy community consider these simple harmonization guidelines as a possible means to increasing efficiencies across laboratories and shortening the time it takes to develop biomarkers and bring effective new treatments to cancer patients.”

Since 2005, the Cancer Immunotherapy Consortium (CIC) of the Cancer Research Institute in the United States and the Association for Cancer Immunotherapy Immunoguiding Program (CIP) in Europe have conducted large proficiency panel experiments to address assay harmonization. Enrollment instructions for new laboratories and clinical trial sites interested in participating in the harmonization process initiated by CIP and CIC are available on their websites, [www.cimt.eu](http://www.cimt.eu) and [www.cancerresearch.org/consortium](http://www.cancerresearch.org/consortium), respectively.

#### **References:**

Sjoerd H. van der Burg, Michael Kalos, Cecile Gouttefangeas, Sylvia Janetzki, Christian Ottensmeier, Marij J.P. Welters, Pedro Romero, Cedrik M. Britten, Axel Hoos. Harmonization of immune biomarker assays for clinical studies. Science Translational Medicine 3, 108ps44 (2011).

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#### **About the Association for Cancer Immunotherapy (CIMT)**

The Association for Cancer Immunotherapy (CIMT) is an international networking and education platform aiming to facilitate the development of new immunotherapies against cancer for the benefit of patients. CIMT was founded in 2002, and has its home office in Mainz, Germany. The association hosts the largest European expert meetings on cancer immunotherapy, publishes therapeutic guidelines and has established two topic-specific working groups: the CIMT Regulatory Research Party, focusing on the regulatory aspects of drug development, which is pioneering the regulatory framework of actively personalized vaccines for single patient use only; and the CIMT Immunoguiding Program (CIP), which focuses on the quality control and harmonization of immunomonitoring assays. To reach its goals, CIMT closely cooperates with various partners, among them the Cancer Research Institute’s Cancer Immunotherapy Consortium (CRI-CIC). Visit [www.cimt.eu](http://www.cimt.eu) for more information.

### **About the Cancer Immunotherapy Consortium of the Cancer Research Institute**

The Cancer Immunotherapy Consortium (CIC), a program of the nonprofit Cancer Research Institute, is an international association of more than 100 pharmaceutical and biotechnology companies and academic institutions that share a common interest in immunotherapy research and development. CIC's mission is to improve patient care by making cancer immunotherapies part of the standard-of-care in oncology. CIC provides a platform that allows its stakeholders to advance the field by working together to achieve solutions to scientific and developmental challenges creating a single and powerful voice within the biomedical research community. From these collaborative, community-wide efforts, CIC has developed and published a number of landmark recommendations for practical solutions to key challenges in the field, including the development of new immune related response criteria and clinical trial endpoints for evaluation of cancer immunotherapy impact on patient health.

Founded in 2002 as the Cancer Vaccine Consortium (CVC), CIC amended its name in early 2010 to represent more accurately the broader diversity of the many promising clinical developments in immune-based treatment of cancer beside vaccines, including monoclonal antibodies and other modulators of immunity.

### **About the Cancer Research Institute**

The Cancer Research Institute (CRI), established in 1953, is the world's only nonprofit organization dedicated exclusively to transforming cancer patient care by advancing scientific efforts to develop new and effective immune system-based strategies to prevent, treat, and cure cancer. Guided by a world-renowned Scientific Advisory Council that includes three Nobel laureates and thirty members of the National Academy of Sciences, CRI has invested more than \$200 million in support of research conducted by immunologists and tumor immunologists at the world's leading medical centers and universities, and has contributed to many of the key scientific advances that demonstrate the potential for immunotherapy to change the face of cancer treatment.

To accelerate the pace of progress in the field, CRI convenes and coordinates global collaborations among academics, industry scientists and decision makers, regulatory representatives, and health research associations focused on discovery, development, and refinement of new cancer immunotherapies. A founding visionary and scientific leader in tumor immunology, CRI is helping to shape the emerging field of immuno-oncology, and is ushering in a new era of medical progress to bring more treatment options to cancer patients sooner.

The Cancer Research Institute has one of the lowest overhead expense ratios among nonprofit organizations, with more than 86 percent of its resources going directly to the support of its science, medical, and research programs. CRI meets or exceeds all 20 standards of the Better Business Bureau Wise Giving Alliance, the most comprehensive U.S. charity evaluation service, and has earned the GuideStar Exchange Seal, indicating our commitment to the transparency of our organizational information to donors, funders, those we serve, the public, and regulators. CRI has also received an 'A' grade for fiscal disclosure and efficiency from the American Institute of Philanthropy, as well as top accolades from other charity watchdog organizations. For more information, visit <http://www.cancerresearch.org>.

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