

Improving cancer patient outcomes by advancing the development and application of immunotherapy and biological therapy

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NIH Awards Major Funding to Support "Cancer Immunotherapy Trials Network"

(WASHINGTON, D.C) - In an effort to accelerate clinical trials of promising cancer immunotherapies, the National Institutes of Health (NIH) has announced Martin "Mac" Cheever, MD (Fred Hutchinson Cancer Research Center, University of Washington) as the recipient of the U01 grant that will fund the Cancer Immunotherapy Trials Network (CITN), with approximately \$14 million budgeted for total costs over a 5-year period.

The International Society for Biological Therapy of Cancer (iSBTc) congratulates iSBTc member Dr. Cheever for his selection to direct this national, cooperative research program. As the leading professional association to promote education and collaboration in the field of cancer immunotherapy, the iSBTc and its broad base of member scientists and clinicians are eager to support and participate in the CITN. At a special session of the 25th iSBTc Annual Meeting in Washington, D.C., October 3, 2010, William Merritt, PhD (NCI), Scientific and Research contact for CITN and Dr. Cheever, (University of Washington), CITN PI, first publicly announced the award of the CITN grant and discussed the application process for the clinical immunotherapy Member Sites. For details on the Member Site applications process, please see www.ctep.info.nih.gov.

"This is an exciting new program representing an important step toward speeding up the delivery of novel treatment options for patients with cancer," stated Bernard A. Fox, PhD, iSBTc President. In recognition of the importance of the future work of the CITN and the effective collaboration and high-level scientific exchange that occurs at its Annual Meetings, the iSBTc has promised \$50,000 in travel grants to support CITN investigators' participation at upcoming iSBTc meetings.

The CITN will support a multi-investigator team that will be assembled to bring new immunotherapy agents to the clinic. The emphasis will be on clinical trials of 'high priority' agents that were identified at the 2007 National Cancer Institute (NCI) immunotherapy agent workshop and on clinical trials using combinations of immunotherapy modalities and other agents. Trials will incorporate high quality, centralized immuno-monitoring services, along with biomarker assessment and correlative studies using patient samples. Up to 25 institutions will conduct the clinical trials as

CITN Member Sites. The NCI will provide data coordinating services for the CITN using other funds.

"The National Cancer Institute awarded funding this September to the Fred Hutchinson Cancer Research Center (Dr. Martin A. 'Mac' Cheever, PI) for a new Cancer Immunotherapy Trials Network, through a Cooperative Agreement mechanism," stated Dr. William Merritt. "In response to an RFA released in late 2009, the U01 grant was awarded to fund the network's Central Operations and Statistical Office (COSC). Drs. Mary L. 'Nora' Disis and Kim Margolin [iSBTc members] are the co-investigators. The FHCRC COSC will function as a central office to provide overall leadership and the organizational and biostatistical coordination for the network. The CITN will be managed in concert with the NIH/NIAID-funded HIV Vaccine Trials Network (HVTN). The CITN will include: 1) up to 25 Member institutions that will conduct the clinical trials (supported though subcontracts within the COSC award); 2) several tumor immunology laboratories to perform standardized immunomonitoring, biomarker and correlative studies related to the clinical trials; and 3) a data coordinating service to be operated by the Cancer Trials Support Unit, a contractor to the Cancer Therapy Evaluation Program at NCI."

Dr. Merritt continued, "The goal of the CITN will be to design, develop and conduct trials not otherwise possible, but with broad input and appeal for the immunotherapy community. Trials will focus on developing 'off the shelf' regimens that can be used by multiple investigators in multiple circumstances and thus can serve as the backbone for further immunotherapy agent development. A great deal of progress in the last 10 years in tumor immunology has led to a deeper understanding of the complex immune response against tumors and potential therapeutic avenues to utilize the body's own immune response to fight tumors; however, single institution studies and immune enhancing drugs used as single agents have not been able to take best advantage of these exciting findings in the pre-clinical and early clinical arena to date. Thus, the CITN will conduct multi-institutional Phase I and Phase II trials in the area of cancer immunotherapy through a consortium of leading investigators in the immunotherapy field who are capable of designing and conducting optimal trials with prioritized immunotherapy agents in rational combinations and utilizing a variety of immunotherapeutic mechanisms."

The International Society of Biological Therapy of Cancer (iSBTc) is a 501 (c) 3 non-profit organization of clinicians, researchers, students, post-doctoral fellows and allied health professionals dedicated to improving cancer treatment outcomes by advancing the development and application of biological therapy/immunotherapy through interaction, innovation, translation and leadership. For more information about the society, please visit www.isbtc.org.