

Society for Immunotherapy of Cancer

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SITC leaders publish landmark studies of new cancer immunotherapeutics

MILWAUKEE, WI (June 2, 2012) – Clinical activity of two cancer immunotherapeutic agents, anti-PD-1 and anti-PD-L1 were reported today. The data on anti-PD-1 were published today in the New England Journal of Medicine1 and featured in four oral presentations at the 48th Annual Meeting of the American Society of Clinical Oncology (Abstract # 2509, 4505, 7509 and 8507). Additionally, abstracts from the NSCLC cohort (Abstract# 7509) and the melanoma cohort (Abstract #8507) of study 003 have been chosen for the Best of ASCO® educational program. Objective response rates (ORs) across dose cohorts, as measured by standard RECIST criteria, ranged from 6% to 32% in NSCLC, 19% to 41% in metastatic melanoma and 24% to 31% in RCC. Most responses were durable.

"This Phase 1 study of anti-PD-1 showed clinical activity across RCC, metastatic melanoma and NSCLC. This is a paradigm shift in terms of generalizing mechanisms of immune regulation which can be manipulated for treatment and are common to numerous cancers," said Dr. F. Stephen Hodi, from the Dana Farber Cancer Institute, which was involved in the clinical trials and is a member of the SITC Board of Directors.

Data on a second investigational immunotherapy from Bristol-Myers Squibb, anti-PD-L1 (BMS-936559), were also published today in the New England Journal of Medicine2 and featured in an oral presentation at ASCO (Abstract # 2510). BMS-936559 is fully-human antibody that targets one of the immunosuppressive ligands for PD-1, PD-L1, which is often expressed on tumor, stromal and immune cells.

"This is strong evidence that continued bi-directional translational research has identified a pathway that regulates antitumor immune responses that, when targeted with an appropriate agent, is leading to continued benefit," said Dr. Thomas Gajewski, from the University of Chicago and President of SITC. "This is a paradigm that needs to be continued and one that SITC supports." Anti-PD-L1 induced durable tumor regression and objective responses rates of 6 to 17% and prolonged stabilization of disease in patients with melanoma, NSCLC and renal cell cancer.

"These initial observations suggest that antibodies blocking PD-1 or PD-L1 are likely to provide a new benchmark for antitumor activity in immunotherapy," reported Dr. Antoni Ribas, from UCLA and a SITC board member, in an accompanying editorial.

Founded in 1984, the Society for Immunotherapy of Cancer (formerly the International Society for Biological Therapy of Cancer; iSBTc) is a non-profit organization of clinicians, researchers, students, post-doctoral fellows, and allied health professionals dedicated to improving cancer patient outcomes by advancing the development and application of cancer immunotherapy through interaction, innovation and leadership. For more information about SITC, please visit the Society website at <u>www.sitcancer.org</u>.

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