Society for Immunotherapy of Cancer

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FDA Review in Journal for ImmunoTherapy of Cancer Offers New Insights into Cancer Immunotherapy Product Development & Clinical Evaluation

Milwaukee, WI – A picture of what the FDA is looking for in cancer immunotherapy product development appears in an extensive new review article published in the inaugural issue of the Journal for ImmunoTherapy of Cancer. Providing a US regulatory perspective on pre-clinical to first in man studies, the review is described by Nora Disis, Professor of Medicine at the University of Washington/Fred Hutchinson Cancer Center, as a "must-read for anyone interested in immunooncology." The review was written by members of the FDA's Office of Cellular, Tissue and Gene Therapies (OCTGT), Center for Biologics Evaluation and Research (CBER), and Center for Drug Evaluation and Research (CDER).

As mechanisms of tumor immune escape have become better defined, approaches that combine two or more modalities to overcome immune resistance are increasingly being proposed and the FDA provides a plan for such approaches. The FDA recommends that researchers characterize each product individually and provide a strong scientific rationale for the combination. Further, even if the combination regimen uses a standard cytoreductive agent with immunologic effects, dose and timing of administration need to be presented.

"Importantly, the flexible parameters for development and evaluation presented in the document reflect the broader experience now in place and deeper understanding of how immune therapies might be applied in the new generation of trials in development," said Lisa Butterfield, Associate Professor of Medicine, Surgery and Immunology at the University of Pittsburgh Cancer Institute.

The complexity of cancer immunotherapy products has made issues such as the definition of product potency, purity, and toxicology evaluation difficult. This review and series of recommendations from the FDA, in addition to the cited FDA guidances, provides considerations for product development that will be valuable for cell based and vaccine therapies, along with state of the art data needed for manufacturing, pre-clinical studies, and clinical trial designs of cancer immunotherapies. The review is particularly timely, given the rapid series of important recent advances and refinements of therapeutic approaches, and the significantly positive clinical outcomes achieved.

The document also addresses the issues of only testing immunotherapeutic interventions in advanced and metastatic disease patients, as well as of early tumor progression while in a study. It is now understood that both early and late stage patients can be included in immunotherapy trials, and considerations for both settings are addressed. The potential importance of keeping

patients who show signs of early tumor progression on a study from which they may subsequently benefit later is also discussed. These are both important steps forward, based on the lessons learned in the field. In short, the recommendations provided by the FDA should streamline the development of complex biologics in immunooncology today.

To read the full review visi, http://www.immunotherapyofcancer.org/content/1/1/5/abstract.

To read the rest of the inaugural issue visit http://www.immunotherapyofcancer.org/.

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 www.sitcancer.org

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