SNMMI and NCI Theranostics Consensus Conference 2018

SNMMI and the National Cancer Institute (NCI) held the Theranostics Consensus Conference 2018 on November 8 and 9 on the National Institutes of Health campus in Bethesda, MD. The conference was sponsored by Progenics Pharmaceuticals, Inc. (New York, NY). Participants included representatives from the U.S. Food and Drug Administration (FDA) and NCI, as well as academicians, clinical physicians, and pharmaceutical company executives. The conference was organized to share perspectives and identify consensus views on: (1) a pathway for regulatory approval of targeted radiotherapies and their companion diagnostics; and (2) data needed by government and private payers to support reimbursement for imaging and therapeutic agents. Daniel Pryma, MD (president of the SNMMI Therapy Center of Excellence), Dan Lee, MD (vice president of the SNMMI Therapy Center of Excellence), and John Sunderland, PhD, MBA (SNMMI Clinical Trials Network cochair), organized the conference in collaboration with NCI representatives.

Education sessions and Q&A panels over the 2-day meeting focused on key aspects of rapidly evolving theranostic research and clinical applications. Sessions on November 8 reviewed the current state of related technology as well as the drug development approval process, strategies to study 2 investigational agents in a single trial, balancing costs with outcomes and science in personalized dosimetry, specific data needed for reimbursement, and an introduction to NCI's Experimental Therapeutics (NExT) Program. Each session was followed by a Q&A panel that targeted definition of areas of consensus and challenges highlighted in the presentations.

A particularly robust discussion followed the presentation by Robert Hobbs, PhD (Johns Hopkins University), Frank Lin, MD, PhD (NCI), Stanley Stern, PhD (FDA), Maurizio Mariani, MD, PhD (Advanced Accelerator Applications), and Jacek Capala, PhD (NCI). Consensus areas included agreement that the right drug/right dose/right patient approach is an excellent model for personalized precision medicine and that the technology to perform quantitative personalized dosimetry with reasonable accuracy either is here or will be available quite soon. The group also identified several long- and short-term challenges, including agreement that the effort to perform personalized dosimetric measurements and calculations is considerable, that a better understanding of radiation toxicity to normal tissue and of therapeutic levels of radiation dose to tumors is needed, that the costs of personalized dosimetry must be weighed against perceptions that it is too costly and/or logistically difficult, that the tension between commercial business profit maximization and longer-term assessments of patient outcome optimization must be resolved, and that next steps should be clearly defined in achieving broader consensus and approvals needed for routine personalized dosimetry in theranostics.

Sessions on November 9 focused on the advantages of conducting theranostic trials earlier in the disease process (using prostate-specific membrane antigen studies as an example), study endpoints beyond overall and progression-free survival, Drug Master Files for radioisotopes to facilitate development of therapeutic radiopharmaceuticals, strategies to expand label indications to earlier-line therapy, the need for specialized physician training in radiotherapeutics, and dose planning qualifications for physicists working with theranostic agents.

Sessions from the conference were recorded and will be made available online, and a summary paper is in preparation for publication. Slides from presenters will be available soon on the SNMMI website. These discussions will continue during a categorical course at the SNMMI 2019 Annual Meeting in Anaheim, CA (June 22–25).

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