Joint NCI/SNMMI Workshop on Targeted Radionuclide Therapy

The National Cancer Institute and SNMMI hosted a joint Workshop on Targeted Radionuclide Therapy on March 18 and 19 on the National Institutes of Health (NIH) campus in Bethesda, MD. Plans for the workshop were initiated in 2012 by Frederic H. Fahey, DSc, now SNMMI president, and Jacek Capala, PhD, program director in the Clinical Radiation Oncology Branch at the National Cancer Institute (NCI). "At the SNMMI 2012 meeting in Miami Beach, we met with Jacek and other representatives from NCI and discussed the tremendous potential for targeted radionuclide therapy for a broad range of applications and the challenges of moving the field forward," said Fahey. "We decided to host a workshop that would assemble experts in the field as well as stakeholders to discuss the state of the field and its most promising areas of research." At NCI, Capala welcomed the opportunity to cohost the event on the NIH campus. Along with Fahey, Katherine Zukotynski, MD, a radiologist at Sunnybrook Health Sciences Center (Toronto, Canada) and assistant professor at the University of Toronto, cochaired the 2-day event. "We wanted to get a small but diverse group of stakeholders together to see how their viewpoints agree and diverge and to look at how best to collaborate on bringing some of the most promising therapies into routine clinical use," she said.

Experts representing the range of stakeholders presented state-of-the-art reviews in their respective areas on the first morning of the workshop. George Sgouros, PhD, from Johns Hopkins University School of Medicine (Baltimore, MD), reviewed the current physics of radionuclide therapy. Michael R. Zalutsky, PhD, from Duke University Medical Center (Durham, NC), summarized the radiochemistry of radionuclide therapy. Richard Wahl, MD, from the Johns Hopkins University School of Medicine, described existing clinical radionuclide therapy and potential new therapies. Eric Jacobsen, MD, from the Dana–Farber Cancer Institute (Boston, MA), offered a look at the challenges of radionuclide therapy in lymphoma. David I. Quinn, MD, PhD, from the University of Southern California Norris Comprehensive Cancer Center (Los Angeles), reviewed current therapy in bone disease. Jorge Carrasquillo, MD, from the Memorial Sloan–Kettering Cancer Center (New York, NY), provided an overview of radionuclide therapy in neuroendocrine tumors. The complementary role of targeted radionuclide therapy in radiation oncology was reviewed by Bhadrasain Vikram, MD, and Capala from NCI's Radiation Research Program.

Morning overviews were followed by breakout sessions in the afternoon. Attendees in each of the 4 breakout sessions represented a cross-section of stakeholders and included groups that focused on lymphoma, bone therapy, solid tumors, and neuroendocrine and other targets. On the following morning, these lively discussions were summarized by breakout participants. "We were impressed by the similarities in the conclusions these groups reached, despite the fact that their participants came from different work environments and areas of expertise," said Zukotynski. "This

More than 40 physicians, physicists, basic scientists, and others gathered at NIH on March 18 and 19 for a workshop on targeted radionuclide therapy.

suggests—as did many of the informal interactions at the workshop—that physicians and scientists involved in targeted radionuclide therapy share common hopes and interests in its development and future applications."

Janis O'Malley, MD, from the University of Alabama at Birmingham, summarized the results of the breakout group focusing on targeted radionuclide therapy in lymphoma. The group identified, among other long- and short-term targets, the need for more evidence-based clinical trials to generate new data on therapy effectiveness; creation of centers of excellence to coordinate and translate advances from basic science to clinical use; and increased interaction among the various disciplines and professional organizations with investments in targeted therapy.

Quinn presented the results of the group focusing on bone therapy, which detailed elements affecting current and future standards of care, as well as key questions for future clinical trials. The group also noted that radionuclide research today exists outside current cooperative group mechanisms and that consideration of integration into these groups or initiation of a new cooperative group might be a positive step in advancing radionuclide therapy.

Wolfgang Weber, MD, from Memorial Sloan–Kettering Cancer Center, described discussions in the breakout group on solid tumors. After a review of the current status of radionuclides and solid tumors, the group looked in detail at the immediate challenges, the most promising technologic and radiopharmaceutic advances, and most likely near-term disease targets.

Ananth Srinivasan, PhD, from Stanford University (CA), reported on the breakout group on neuroendocrine and other targeted therapies. The group looked at both the strengths and weaknesses of current radionuclide therapy in neuroendocrine tumors, including the discrepancy between the wide availability of such treatment in Europe and its lack of coverage in the United States. As in the other breakout sessions, participants called for more basic scientific work to enhance understanding of the biology of radionuclide therapy.

Hossein Jadvar, MD, PhD, MPH, MBA, from the University of Southern California (Los Angeles) provided a summary overview and highlights of the workshop, emphasizing group consensus in areas including the regulatory and economic environment, basic biology, and radiochemistry. He summarized the workshop findings with a list of major current and future issues for consideration. He noted that new partnerships are needed among federal agencies, academia, pharmaceutical companies, patients and their advocates, providers, payers, professional societies, and philanthropic and venture capital supporters.

In concluding remarks Fahey pointed to the significance of the workshop as the first of its kind to bring together diverse stakeholders in targeted radionuclide therapy and expressed the hope that similar and expanded gatherings can be scheduled in the future. "We want to identify specific next steps that can build on the important goals participants have discussed at this meeting," he said. "This is clearly a community with diverse but complementary interests in advancing this unique therapeutic approach and realizing its promise in a broad range of disease." A white paper on the workshop consensus findings, including a full bibliography of sources and evidence cited, will be published later this year.

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posttreatment management only in those groups of patients for whom some type of benefit is most likely to occur."

Siegel also cited the problematic nature of leaving the decision to local carriers on coverage of most oncologic scans after the single covered posttreatment scan. "The risk for nonuniformity is very real," he said. "Local carriers have always had the discretion to set frequency limits, but a 1-scan limit is not consistent with current oncology practice. Different hospitals in different areas may now have widely varying coverage in posttreatment oncologic PET, and this will doubtless be confusing for oncologists and their patients."

At Newsline press time, NOPR was compiling its formal comments on the proposed decision memorandum, including urging CMS to consider extension of ^{18}F-FDG PET coverage in the posttreatment period. Siegel said, "The NOPR working group is pleased that data collection over almost 7 years has helped to shape Medicare policy in respect to PET coverage. We look forward to providing additional information to CMS over the coming months to help the agency craft a final decision memo that reflects the optimal use of PET in the right patients."

The complete proposed Decision Memorandum is available at www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=263. The comment period was slated to close on April 13. A final decision memo will be issued later this year.