establish safety and optimal scanning parameters and a dose expansion phase focusing on two API doses (0.5 mg (n=4) or 1.5 mg (n=5) API). All patients were monitored for drug-related adverse events with blood chemistry, hematology, cyto-kine assay and anti-drug antibodies (ADA). Biodistribution, radiodosimetry and SUV PET uptake was performed in all patients.

Results 15 subjects (31–82 years, M/F = 9/6) with metastatic melanoma (n=8), NSCLC (n=6), and HCC (n=1) were enrolled. Treatment histories included naïve (n=2), discontinued prior IOT (n=3), active IOT (n=10). No drug-related AEs nor abnormal laboratory tests were noted except for a transient increase in ADA in 1 subject. The CD8-tracer accumulated in tumors and CD8 rich tissues (e.g. spleen, marrow, nodes) with maximum uptake at 24–48 hours post injection along with low background activity in non-T cell rich tissues (e.g. muscle, heart). More favorable dosimetry was seen at 1.5 mg versus 0.5 mg API (effective dose=0.64 mSv/MBq versus 0.67 mSv/MBq, respectively). Comparison of 1.5 mg and 0.5 mg API in expansion cohorts demonstrated similar uptake in nodes but with reduced uptake in marrow and spleen at the higher API. Tracer-uptake in tumors was noted in 10/15 (67%) subjects, favoring slightly higher tumor uptake in the 1.5 mg cohort. One patient with advanced melanoma on IOT had increased CD8-tracer uptake in several metastases on an early post treatment scan, which correlated with response (figure 1).

Conclusions 89Zr-IAB22M2C targets CD8+ rich tissues and visualizes whole-body biodistribution of CD8+ cells in tumors and reference tissues and may predict early response to IOT. A 1.5 mg protein dose provides similar distribution to 0.5 mg IOT, with more favorable dosimetry and is used in the ongoing Phase 2 study.

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Trial Registration ClinicalTrials.gov Identifier: NCT03107663

Ethics Approval The study was approved by Institutional Review Boards of MSKCC (IRB #16-1109), Honor Health (West IRB #1179278) and University of Pennsylvania (IRB #828992).

Consent Written informed consent was obtained from the patient for publication of this abstract and any accompanying images. A copy of the written consent is available for review by the Editor of this journal.

REFERENCE


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