Preliminary efficacy and safety results from the TATCIST trial: A PSMA-directed targeted alpha therapy with FPI-2265 (225Ac-PSMA-I&T) for the treatment of metastatic castration-resistant prostate cancer

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Methods

- The study was an open-label, single-arm, single-phase study of FPI-2265 (225Ac-PSMA-I&T) for the treatment of metastatic castration-resistant prostate cancer (mCRPC).

- Participants were treated with 177Lu-PSMA-617 (PSMA-RLT) for up to 4 cycles.

- The primary endpoint was a ≥50% decrease in prostate-specific antigen (PSA) count (PSA50) from baseline to week 12.

- Secondary endpoints included a ≥50% decrease in standard uptake value (SUV) mean from baseline to week 12 (SUVmean50).

- Participating centers included: Memorial Sloan Kettering Cancer Center, New York, NY; Massachusetts General Hospital, Boston, MA; and the University of Maryland Medical System, Baltimore, MD.

- Participants were evaluable if they had at least 12 weeks of follow-up.

- Participants were required to have a baseline PSMA PET SUVmean >6.

- All participants had evaluable 225Ac-PSMA-I&T PET/CT scans at baseline and week 12.

- Treatment-related adverse events (TRAEs) were assessed.

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Conclusions

- Data from this prospective study support prior clinical reports on the safety and efficacy of 225Ac-PSMA-I&T for the treatment of mCRPC.

- Safety and tolerability were consistent with published data on 225Ac-PSMA-I&T.

- The majority of TRAEs were grade 1 or 2.

- The study was stopped early due to lack of efficacy.

- Additional clinical trials with 225Ac-PSMA-I&T are warranted.