

Results of the first Phase 3 Trial of 68Ga-PSMA-11 in Biochemical Recurrence

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Background: 68Ga-PSMA-11 has been used extensively outside of the United States for the imaging and staging of prostate cancer patients. This prospective Phase III study performed between UCSF and UCLA was conducted in order to obtain approval of 68Ga-PSMA-11 in the United States.

Methods: 635 patients with biochemical recurrence (defined as two PSAs greater than 0.2 in the post-radical prostatectomy population, and as a PSA rise of greater than 2.0 over the post-radiation nadir) were included in this study. The imaging studies were distributed among 9 blinded readers so that each imaging study was interpreted by three blinded readers, and the studies were recorded for the presence of prostate cancer on a patient level and region level. Patients were then followed after imaging for up to twelve months, and imaging findings were determined as either true or false positive based on both histopathology as well as a composite imaging follow-up to estimate the positive predictive value of 68Ga-PSMA-11 PET.

Results: The average PSA in the imaged population was 2.1, and 136 patients had a PSA less than 0.5, while 173 had a PSA greater than 173. Overall, 75% of patients had a positive PSMA PET with the following distribution: PSA < 0.5 = 38%; 0.5-1.0 = 57%; 1.0-2.0 = 84%; 1.0-5.0 = 86% and >5.0 = 97%. Of the patients imaged, 273 had a lesion with follow-up (43% of patients overall), 37% of which was biopsies of lesions. The positive predictive value in the patients with histopathology correlation was 0.84 on a per patient and per region level, and in patients with the composite endpoint the PPV was 0.92 on a per patient and per region level. Overall there was substantial inter-reader agreement with a Cohen's Kappa ranging from 0.68-0.78 depending on the region imaged. No patients reported a related adverse event, and no patients reported a Grade 2 CTCAE adverse event that was unrelated.

Conclusions: 68Ga-PSMA-11 PET has a high positive predictive value in determining sites of biochemical recurrence in patients with prostate cancer. It is hoped that this data will help support an New Drug Application to the FDA in the coming year.

Conflicts of Interest: None

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