Performance of fluciclovine F 18 in men with recurrent prostate cancer

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Introduction: Fluciclovine F 18 Injection is a diagnostic agent for positron emission tomography (PET) imaging in men with suspected prostate cancer (PCa) recurrence, based on elevated blood PSA levels following prior treatment. The aim of this poster is to summarize key studies that served as the basis for the May 2016 FDA approval of fluciclovine F 18 (1). Such an agent is needed, as abdominal CT may not detect recurrent prostate tumors <1 cm in size and bone scans are often negative when PSA is <20 ng/mL, when cancer may be more effectively managed or treated with localized therapy (2, 3).

Methods: Safety and clinical results from four sites [Emory University, Atlanta, USA (n=137), Ospedale St'Orsola, Bologna, Italy (n=88), Oslo University Hospital (n=225) and Aleris Helse AS (n=146), Oslo, Norway] were analyzed. All patients from Emory were bone scan (BS) negative. Those from Bologna were both CT and BS negative. Two sets of data were analysed; BED-001 (877 subjects, of which 596 had BCR) and BED-002 (a blinded re-read of images from Emory and Bologna). For the BED-002 Emory data, 105 scans from subjects with histological confirmation of presence or absence of disease were re-read by three naïve readers who were unaware of on-site read results or of the clinical and biopsy results from subjects. For the BED-002 Bologna data, 96 fluciclovine F 18 images for subjects studied with both fluciclovine F 18 and 11C-choline were read by on-site readers. The fluciclovine F 18 scans for these patients were read by the same three blinded readers.

Results: Detection rate (DR) increased with increasing PSA. In Study 1, DR varied between 15/25 in the lowest PSA quartile ($\leq$1.78 ng/mL) to 71/74 across the remaining quartiles. For the 15 patients with PSA <1.78 ng/mL, 11 were histologically confirmed as positive. For the 74 patients with PSA levels greater than 1.78 ng/mL, there were 13 false positive scans and no false negative scans. The blinded reader agreement values between the fluciclovine F 18 and 11C-choline reads were 61%, 67% and 77%, respectively for readers 1-3. The results of the readers were generally consistent with one another and confirmed the results of the on-site reads. For n=877 subjects, mild adverse reactions were reported in ≤ 1% of patients (primarily injection site redness and pain, dysgeusia).

Conclusions: Fluciclovine F 18 can detect sites of PCa recurrence even at PSA values $\leq$2 ng/mL, where standard imaging methods may show poor performance. Standardized reader training helps ensure consistent results.

References: 1) Axumin™ (fluciclovine F 18) Injection US Prescribing Information, May 2016. 2) Choueiri TK et al. J Urol. 2008 179(3):906. 3) Bruce JY et al. Clin Adv Hematol Oncol 2012 (10):716.

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