

## **Impact of <sup>18</sup>F-fluciclovine PET/CT on clinical management of patients with recurrent prostate cancer: results from the Phase III FALCON trial**

E. J. Teoh<sup>1</sup>, D. Bottomley<sup>2</sup>, A. Scarsbrook<sup>2</sup>, H. Payne<sup>3</sup>, A. Afaq<sup>3</sup>, J. Bomanji<sup>3</sup>, N. van As<sup>4</sup>, S. Chua<sup>4</sup>, P. Hoskin<sup>5</sup>, A. Chambers<sup>5</sup>, G. J. Cook<sup>6</sup>, V. S. Warbey<sup>6</sup>, A. Chau<sup>7</sup>, P. Ward<sup>7</sup>, M. P. Miller<sup>7</sup>, D.J. Stevens<sup>7</sup>, L. Wilson<sup>7</sup>, and F. V. Gleeson<sup>1</sup>. Presented by [K. Linder](#).

<sup>1</sup>Departments of Radiology and Nuclear Medicine, Oxford University Hospitals NHS Foundation Trust, Oxford, UK, <sup>2</sup>The Leeds Teaching Hospitals NHS Trust, Leeds, UK, <sup>3</sup>University College London, London, UK, <sup>4</sup>The Royal Marsden NHS Foundation Trust, London, UK, <sup>5</sup>Mount Vernon Cancer Centre, Northwood, UK, <sup>6</sup>King's College London, London, UK, <sup>7</sup>Blue Earth Diagnostics Ltd., Oxford, UK.

**Background:** When biochemical recurrence (BCR) of prostate cancer is suspected, early and accurate localisation of metastases facilitates treatment when tumours are small and most amenable to localised therapy, and may guide clinicians in making management plans regarding salvage therapy. Here, we present results of a pre-planned analysis of the FALCON trial (NCT02578940), which assessed the impact of PET/CT imaging with <sup>18</sup>F-fluciclovine on clinical management choices for men with BCR of prostate cancer.

**Methods:** Men with a first BCR episode following radical curative therapy who were being considered for curative-intent salvage therapy were recruited at six UK sites. Intended management plans were recorded prior to and following <sup>18</sup>F-fluciclovine PET/CT imaging. The primary outcome measure was the impact of a <sup>18</sup>F-fluciclovine PET/CT scan on clinical management. Post-scan changes to treatment modality (e.g. salvage radiotherapy [RT] to hormone deprivation) were classed as 'major', while changes within a modality (e.g. alteration to salvage RT fields) were classed as 'other'. Diagnostic accuracy using clinical follow-up, histological correlation and concordance with multimodal imaging as a truth standard was studied as a secondary outcome.

Based upon an expected ~40% change in management, a pre-planned analysis of the first 85 evaluable patients was performed with intent to terminate recruitment for overwhelming efficacy if the number of treatment changes was greater than 45 (52.9%; 97.5% CI: 40.3–62.3%), or for futility, if fewer than 8 (9.4%, 97.5% CI: 3.6–18.9%).

**Results:** Between Dec 2015 and Feb 2017, 85 evaluable patients (median age at screening, 67.0 y; median post-BCR PSA, 0.63 ng/mL) were imaged. Fifty-six (65.9%) had previously had a radical prostatectomy. <sup>18</sup>F-fluciclovine detected lesions in the prostate/bed or extraprostatic region in 40.0% and 22.4% of scans, respectively.

Therapeutic management was revised post-scan in 52/85 (61.2%) patients. For 41/52 (78.8%) patients, the decision was made due to a positive finding on the <sup>18</sup>F-fluciclovine scan. Major revisions were made for 32/52 (61.5%) of those subjects with updated plans. Salvage treatment was revised to watchful waiting for 13/85 patients (15.3%) and to systemic therapy for 18/85 (21.2%), while 20/85 (23.5%) patients had their planned RT field modified post-scan to include a boost to a positive lesion or to widen the field to include the whole pelvis. As a result of these findings, recruitment was stopped as the pre-set condition defining overwhelming efficacy was met.

**Conclusions:** This prospective study shows that <sup>18</sup>F-fluciclovine PET/CT has substantial impact on the clinical management of men with a first BCR of prostate cancer after curative-intent therapy. Future studies to assess the long-term impact of these management changes on disease outcomes are warranted.

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