

Title: Phase I/II study to evaluate the safety, biodistribution, radiation dosimetry and tumor imaging potential of ⁶⁸GaNOTA-Anti-MMR-VHH2, a new radiopharmaceutical for in vivo imaging of Tumour-Associated Macrophages by means of Positron Emission Tomography (PET)

EudraCT number: 2017-001471-23

Protocol name: UZBRU-VHH2_1

Trial prematurely ended. Not all planned patients were included in the trial.

The data from the phase I study has been reported by dr. Odrade Gondry: *Gondry O et al. Phase I Study of [⁶⁸Ga]Ga-Anti-CD206-sdAb for PET/CT Assessment of Protumorigenic Macrophage Presence in Solid Tumors (MMR Phase I). J Nucl Med. 2023 Sep;64(9):1378-1384.*

This single centre, open-label, non-randomized, phase II study evaluated the clinical potential of ⁶⁸GaNOTA-Anti-MMR-VHH2 for in vivo imaging of MMR-expressing Macrophages by means of Positron Emission Tomography (PET) in patients with melanoma, Head & Neck cancer and breast cancer. 13 patients were included. One adverse event was reported, but it was unrelated to the study drug.

On behalf of UZ Brussels.

Department of nuclear medicine.