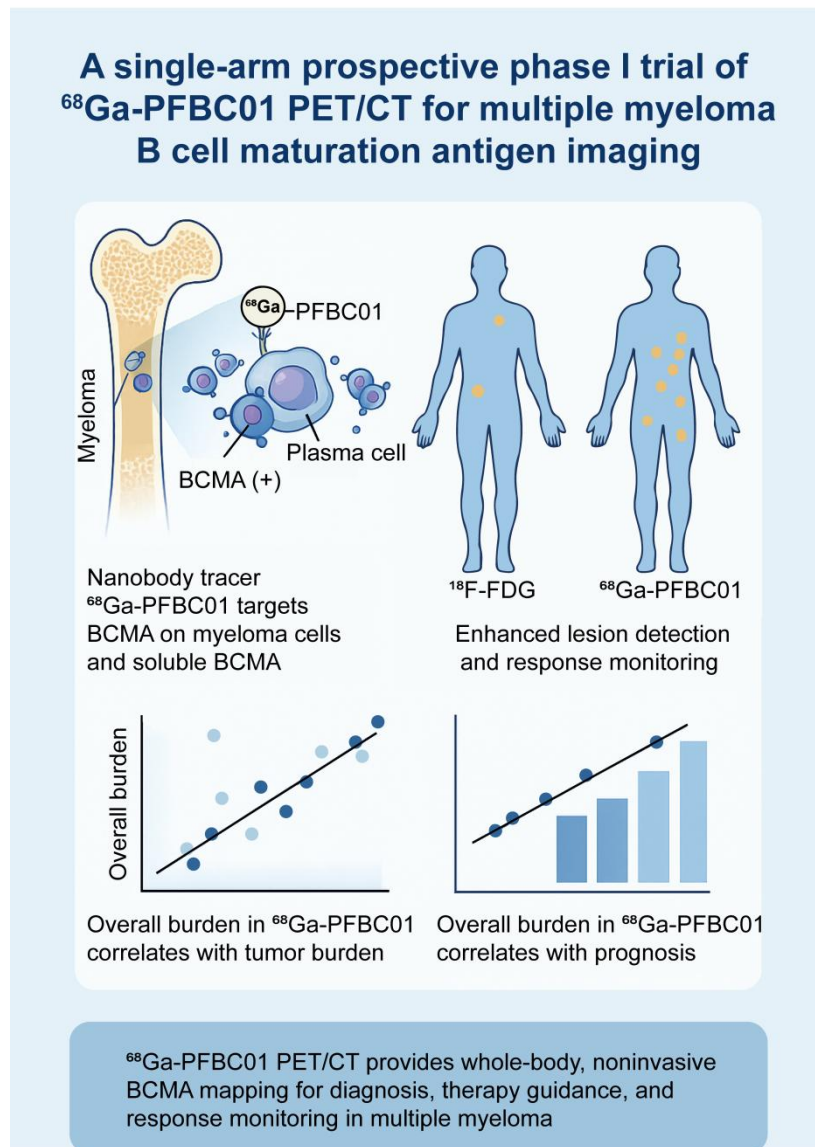


A single-arm prospective phase I trial of ^{68}Ga -PFBC01 PET/CT for multiple myeloma B cell maturation antigen imaging

Supplemental data



Graphical abstract

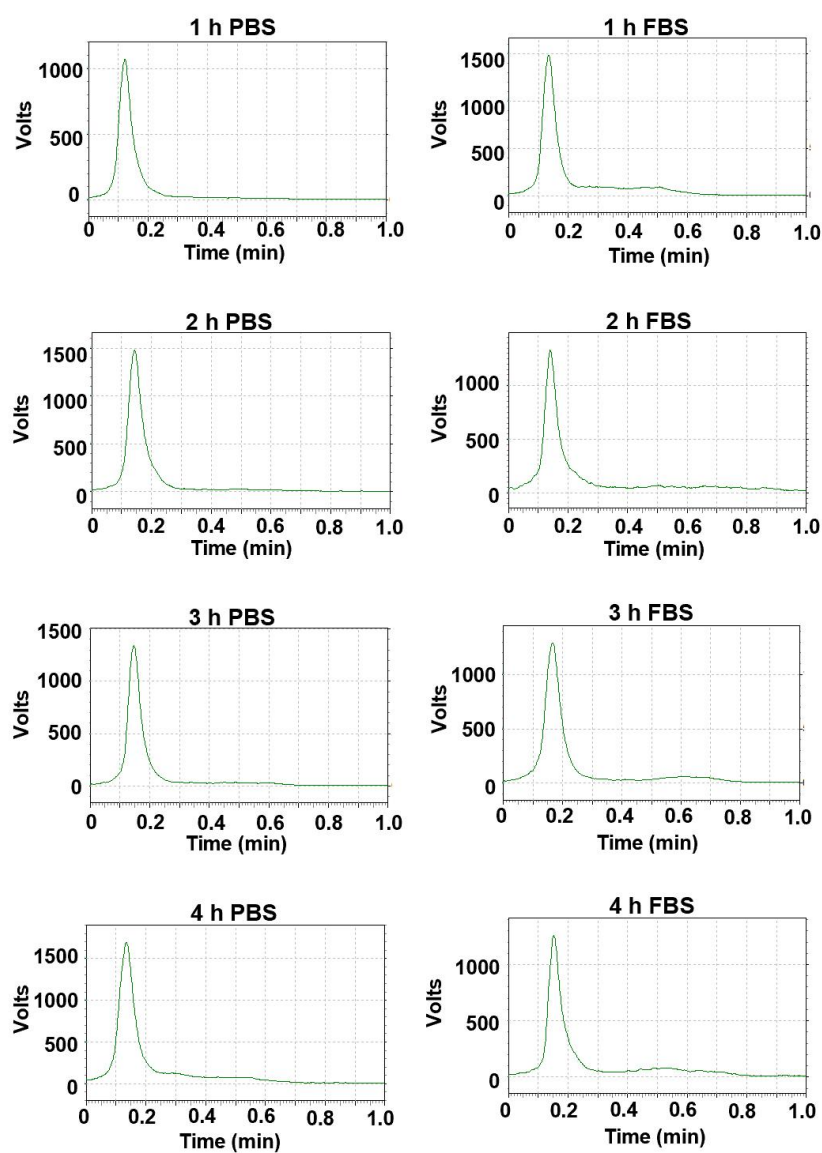


Figure S1 In-vitro stability of ^{68}Ga -PFBC01 in (A) PBS and (B) FBS from 15 minutes to 4 hours, as assessed by radio-TLC.

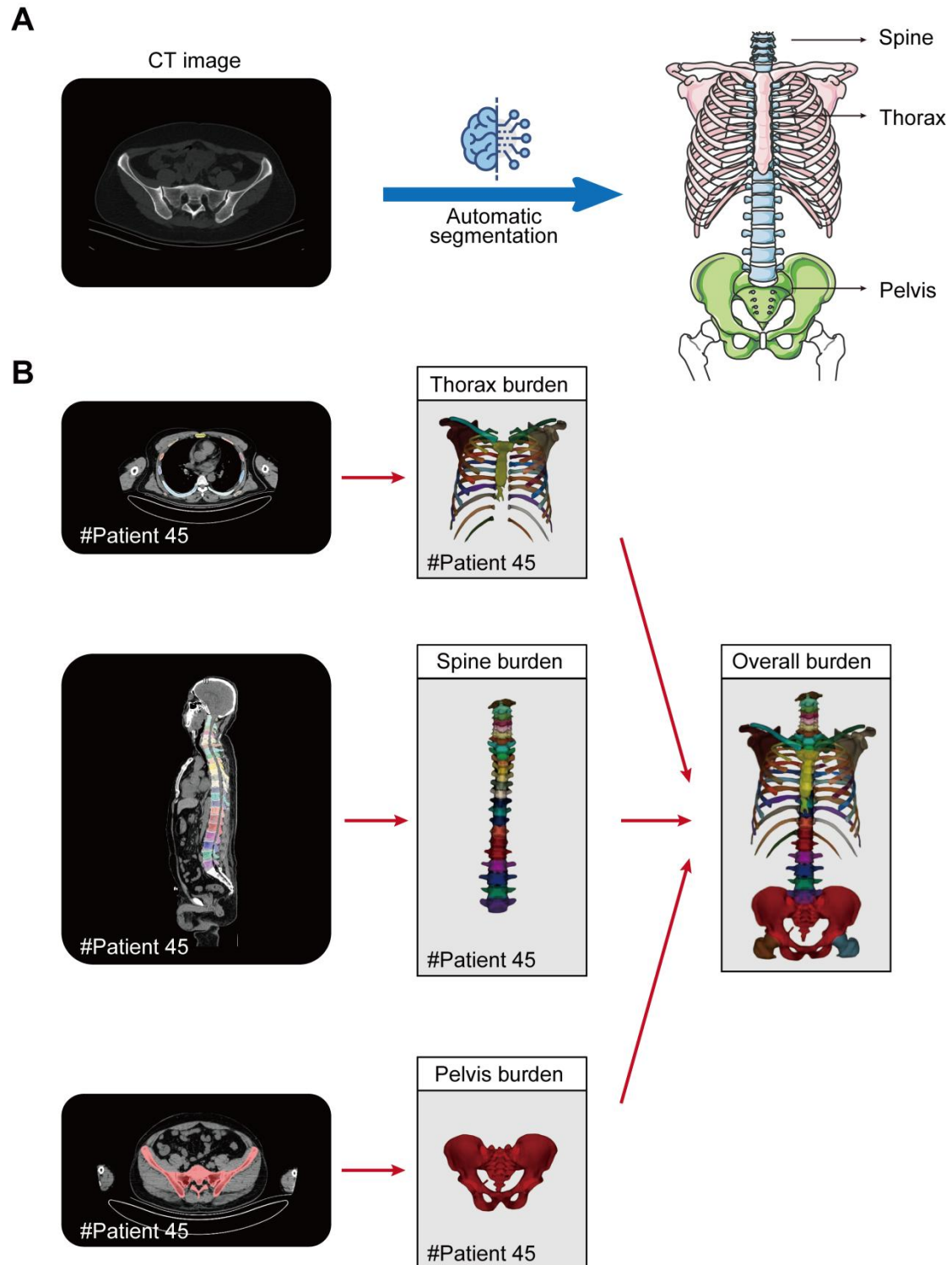


Figure S2 Schematic illustration of overall burden calculation on PET/CT

- A. Artificial intelligence–based segmentation of skeletal structures on CT images for automated quantification of metabolic activity. The algorithm identifies the entire bony framework and calculates the mean standardized uptake value (SUV_{mean}) for each region, enabling objective, reproducible PET-based assessment of skeletal involvement.
- B. Example of automated skeletal segmentation and burden quantification in Patient No.45. The algorithm independently identifies the thoracic bones, spine, and pelvis to calculate

corresponding SUVmean values, defined as thorax burden, spine burden, and pelvis burden, respectively. The overall burden is then computed as the sum of thorax, spine, and pelvis burden values.

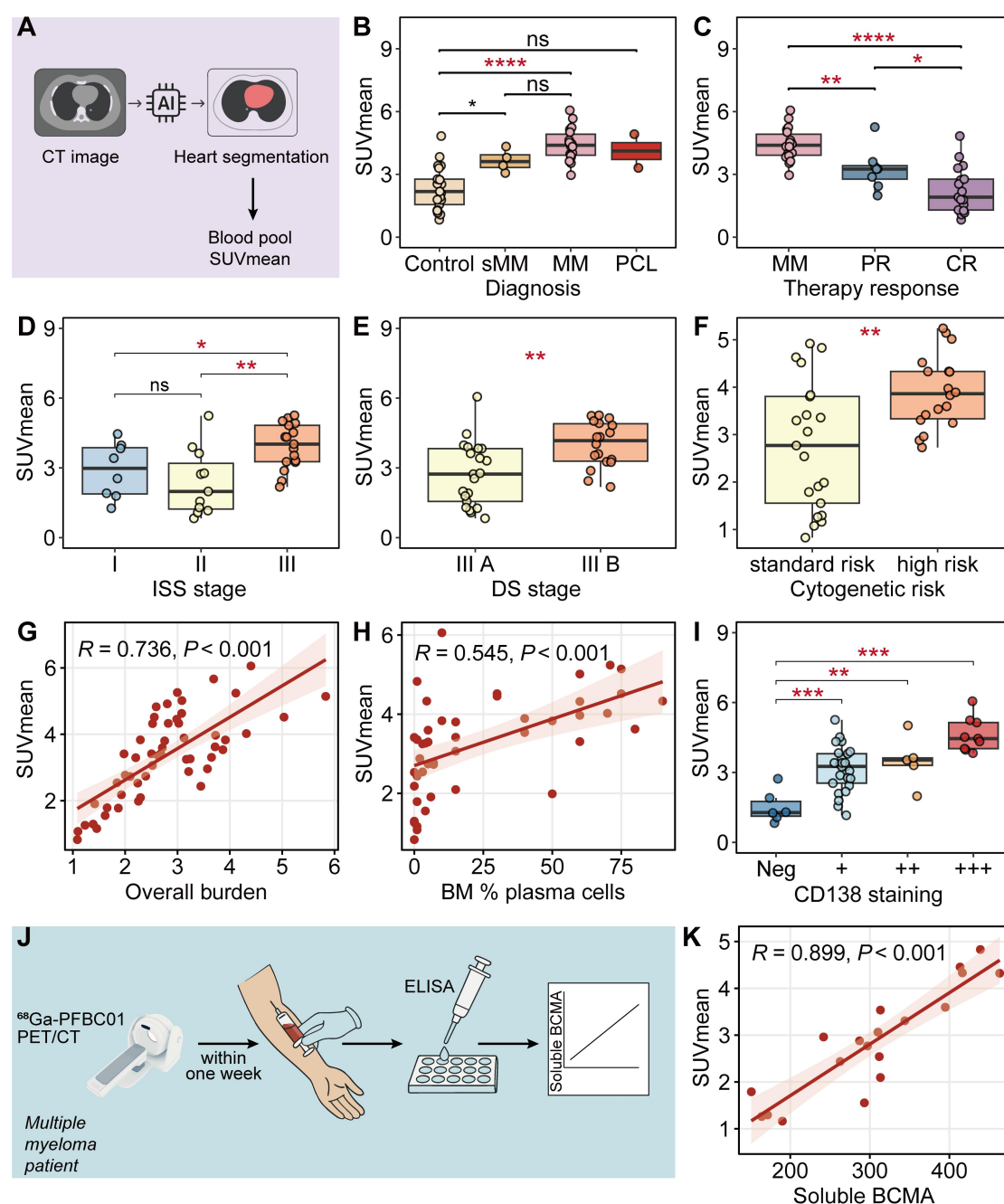


Figure S3 Elevated blood-pool uptake on ^{68}Ga -PFBC01 PET/CT and its clinicopathologic correlations

- Schematic illustration of artificial intelligence–assisted segmentation on CT images for automated quantification of cardiac blood-pool uptake
- Comparison of blood-pool uptake among plasma cell disorders: control patients, smoldering multiple myeloma (sMM), MM, and plasma cell leukemia (PCL).
- Blood-pool uptake across treatment response categories: multiple myeloma (MM, untreated), partial response (PR), and complete response (CR).
- Prognostic evaluation of blood-pool uptake according to International Staging System (ISS) stage.
- Prognostic evaluation of blood-pool uptake across Durie–Salmon (DS) stages.

- F. Prognostic evaluation of blood-pool uptake based on cytogenetic risk.
- G. Correlation between blood-pool uptake and overall burden on ^{68}Ga -PFBC01 PET/CT.
- H. Correlation between blood-pool uptake and bone-marrow plasma-cell percentage.
- I. Blood-pool uptake on ^{68}Ga -PFBC01 PET/CT in patients with pathologically confirmed multiple myeloma (MM) across different CD138 immunohistochemistry (IHC) scores.
- J. Within one week of ^{68}Ga -PFBC01 PET/CT, soluble BCMA levels in patient plasma using enzyme-linked immunosorbent assay (ELISA) were measured.
- K. Correlation between blood-pool uptake and serum soluble BCMA concentration.

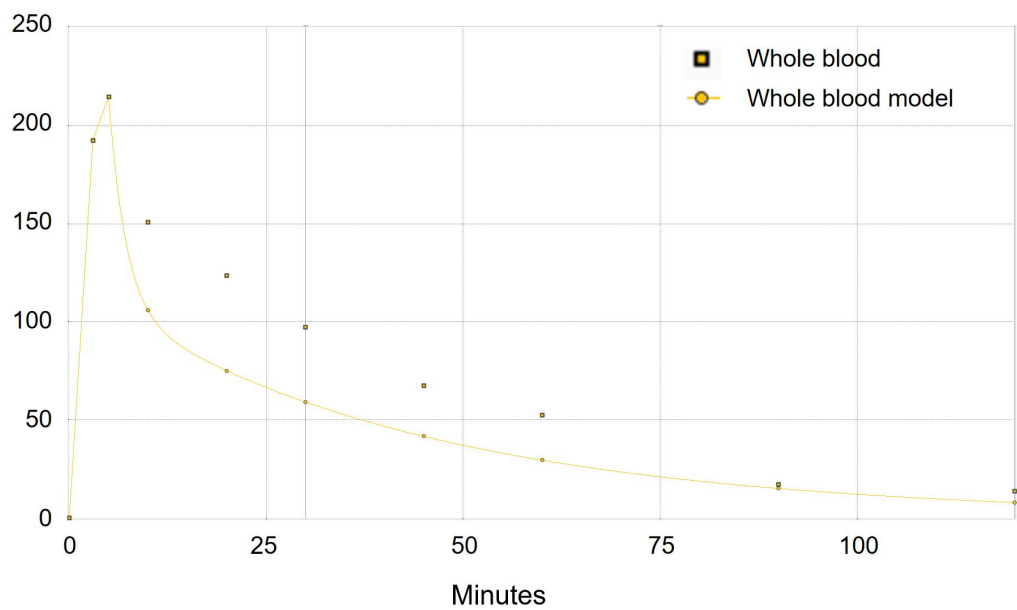


Figure S4 Whole-blood pharmacokinetic modeling of ^{68}Ga -PFBC01 in healthy non-human primates.

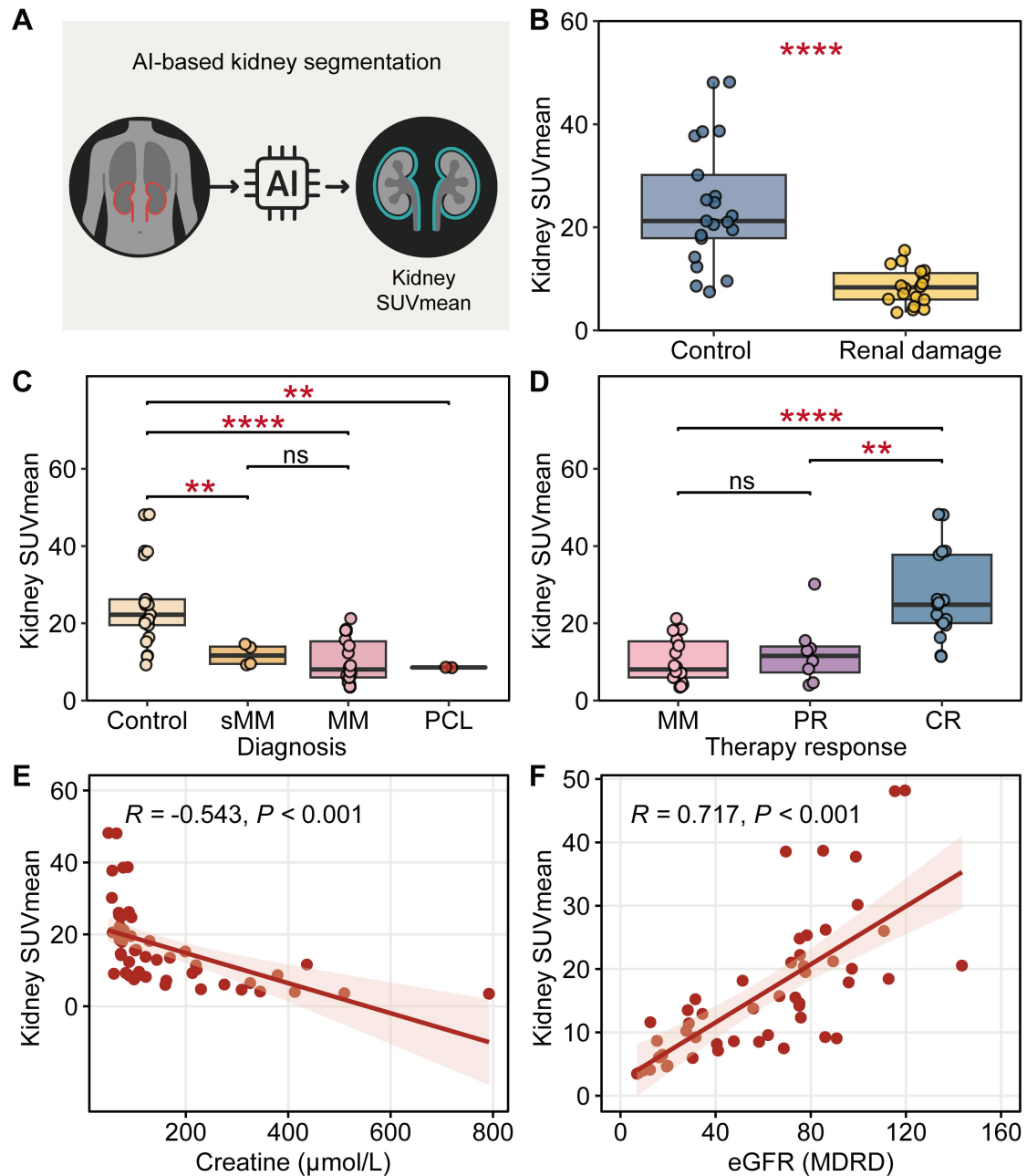


Figure S5 Association between renal function and kidney uptake of ^{68}Ga -PFBC01 PET/CT

- Schematic illustration of the artificial intelligence-based kidney segmentation workflow for automated quantification of kidney SUVmean.
- Comparison of kidney SUVmean between participants with normal renal function (control) and renal impairment.
- Kidney SUVmean across different plasma cell disorder subgroups, including smoldering multiple myeloma (sMM), multiple myeloma (MM), and plasma cell leukemia (PCL).
- Kidney SUVmean according to treatment response categories, including active MM, partial

response (PR), and complete response (CR).

- E. Correlation between kidney SUVmean and serum creatinine levels.
- F. Correlation between kidney SUVmean and estimated glomerular filtration rate (eGFR, MDRD equation).

Table S1 Preliminary Dosimetry Estimates of ^{68}Ga -PFBC01 in Non-human Primates

Organ	Sample 1	Sample 2	Sample 3
Adrenals	4.41E-04	3.68E-03	9.24E-04
Brain	5.81E-06	6.42E-06	4.58E-06
Breasts	1.11E-04	9.18E-05	8.12E-05
Esophagus	4.71E-04	3.85E-04	3.48E-04
Eyes	7.30E-06	7.00E-06	5.58E-06
Gallbladder Contents	1.95E-04	7.75E-04	2.40E-04
Left colon	2.58E-04	3.85E-04	2.39E-04
Small Intestine	6.12E-05	2.71E-04	8.79E-05
Stomach Wall	1.90E-04	5.51E-04	2.08E-04
Right colon	7.45E-05	2.75E-04	8.82E-05
Rectum	9.32E-06	4.79E-05	1.53E-05
Heart Wall	8.67E-03	3.01E-03	6.20E-03
Kidneys	2.92E-03	3.52E-02	1.07E-02
Liver	2.20E-03	3.74E-03	1.02E-03
Lungs	3.39E-04	1.06E-03	4.08E-04
Ovaries	1.58E-05	8.12E-05	2.57E-05
Pancreas	2.26E-04	6.42E-04	2.14E-04
Salivary Glands	1.63E-05	1.60E-05	1.26E-05
Red Marrow	8.79E-05	1.81E-04	8.59E-05
Osteogenic Cells	4.93E-05	1.05E-04	4.85E-05
Spleen	6.17E-04	1.68E-02	2.99E-03
Thymus	4.09E-04	2.49E-04	3.05E-04
Thyroid	8.15E-05	7.61E-05	6.37E-05
Urinary Bladder Wall	7.83E-06	3.38E-05	1.11E-05
Uterus	1.35E-05	6.59E-05	2.12E-05
Total Body	2.16E-04	4.57E-04	2.06E-04

Table S2 Inter-scan Time Differences Between ^{68}Ga -PFBC01 and ^{18}F -FDG PET Studies

Time Difference (days)	Number of Subjects
1	15
2	5
3	7
4	6
5	4
7	1
9	1
12	1

Table S3 Basic characteristics of patients.

	⁶⁸ Ga-PFBC01 PET (n = 50)
Age, median (IQR)	62 (55-66)
Sex	
Female	23 (46%)
Male	27 (54%)
Race and ethnicity	
Asian	52 (100%)
Diagnosis	
Smoldering multiple myeloma (sMM)	4 (8%)
Multiple myeloma (MM)	18 (36%)
Non multiple myeloma (control)	4 (8%)
Plasma cell leukemia (PCL)	2 (4%)
Complete response (CR)	16 (32%)
Partial response (PR)	6 (12%)
Durie–Salmon (DS) stage	
III A	21 (42%)
III B	15 (30%)
NA	14 (28%)
International Staging System (ISS) stage	
I	8 (16%)
II	11 (22%)
III	14 (28%)
NA	17 (34%)

Table S4 Possibly related adverse events

	Grades 1–2	Grades 3	Grades 4	Grades 5
Any	2 (4%)	0	0	0
Nausea	1 (2%)	0	0	0
Dizziness	1 (2%)	0	0	0

Possibly related adverse events documented within 7 days after ^{68}Ga -PFBC01 PET/CT in two (4%) of 50 participants. Graded according to Common Terminology Criteria for Adverse Events (version 5.0) and classified as possibly attributable to ^{68}Ga -PFBC01 PET/CT.