Supplementary Material

Supplementary Table S1. Baseline demographics and disease characteristics in patients with mCRPC from the phase III sipuleucel-T trials included in the eosinophil analysis and the overall pooled population

	Eosinophil analysis population (*n* = 377)	**Pooled phase III population (*n* = 737)**
Median age (range), years	71 (49–91)	71 (40–91)
Median weight (range), lbs	193 (131–384)	192 (116–384)
Race, *n* (%)		
Caucasian	334 (88.6)	666 (90.4)
Black or African American	25 (6.6)	43 (5.8)
Asian	2 (0.5)	4 (0.5)
Hispanic	12 (3.2)	19 (2.6)
Other	4 (1.1)	4 (0.5)
ECOG PS = 0, *n* (%)	309 (82.0)	592 (80.3)
Gleason sum, *n* (%)		
≤6	54 (14.3)	105 (14.2)
7	228 (60.5)	417 (56.6)
≥8	94 (24.9)	213 (28.9)
Unknown	1 (0.3)	2 (0.3)
Localization of disease, *n* (%)		
Bone only	192 (50.9)	332 (45.0)
Soft tissue only	30 (8.0)	60 (8.1)
Both bone and soft tissue	155 (41.1)	340 (46.1)
Bisphosphonate use, *n* (%)	159 (42.2)	263 (35.7)
No. of bone metastases, *n* (%)		
0–5	160 (42.4)	318 (43.1)
6–10	55 (14.6)	106 (14.4)
>10	160 (42.4)	308 (41.8)
Unknown	2 (0.5)	5 (0.7)
Time from diagnosis to randomization, median (range), years	6.9 (0.8–24.5)	6.8 (0.8–24.5)
Prior hormone therapy, *n* (%)	377 (100)	734 (99.6)
Orchiectomy	44 (11.7)	94 (12.8)
Prior chemotherapy, *n* (%)		
Any	62 (16.4)	110 (14.9)
Docetaxel	47 (12.5)	77 (10.4)
Radical prostatectomy	132 (35.0)	262 (35.5)
Previous radiotherapy	198 (52.5)	394 (53.5)
Median serum laboratory value		
PSA (range), ng/mL	50.8 (5.2–8005.6)	49.9 (3.5–8005.6)
LDH (range), U/L	192.0 (84.0–1730.0)	190.0 (84.–1730.0)
Hemoglobin (range), g/dL	12.9 (8.4–17.9)	12.9 (8.4–17.9)
Alkphos (range), U/L	100.0 (18.0–3900.0)	103.0 (18.0–3900.0)
Median Halabi score (range), months	20.3 (4.8–32.0)	20.1 (4.8–32.0)

Abbreviations: Alkphos, alkaline phosphatase; ECOG PS, Eastern Cooperative Oncology Group performance status; LDH, lactate dehydrogenase.

Supplementary Figure Legends

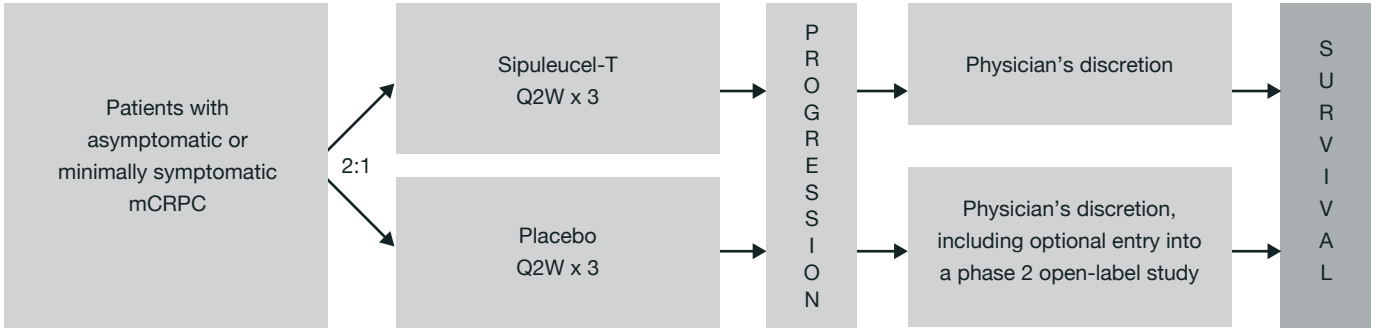
Supplementary Figure S1. Overview of the study designs of three phase III clinical trials from which data were pooled for this retrospective analysis.

The IMPACT (NCT00065442, n = 512), D9901 (NCT00005947, n = 127), and D9902A (NCT01133704, n = 98) studies were randomized, double-blind, multicenter studies of sipuleucel-T versus control in men with mCRPC that were similar in design and patient population. Q2W, every 2 weeks.

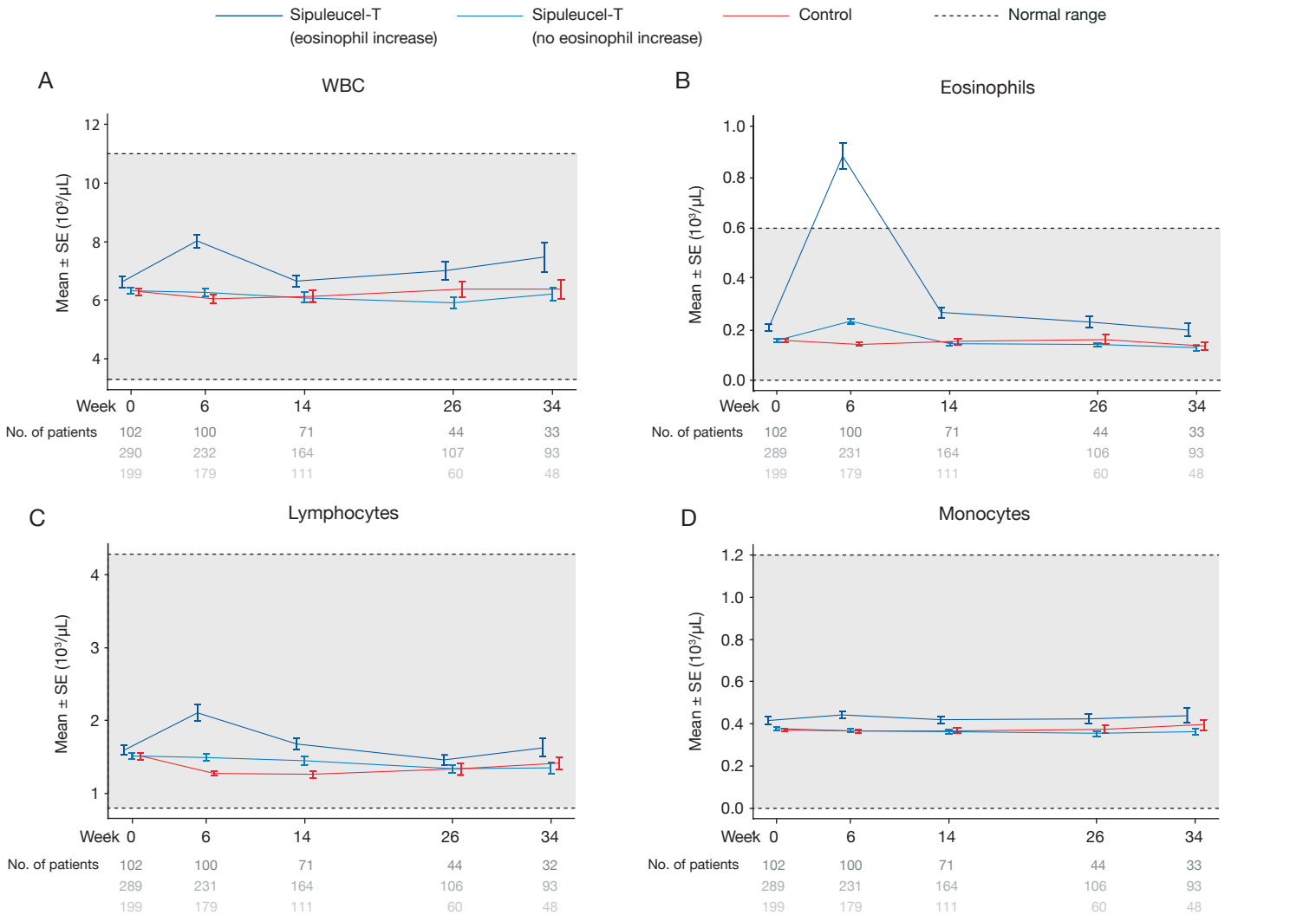
Supplementary Figure S2. Changes in eosinophil counts for sipuleucel-T-treated patients with or without an elevated eosinophil count in randomized phase III trials, versus the control group.

Shown are the mean and standard error of (A) WBC, (B) eosinophils, (C) lymphocytes, and (D) monocytes for patients treated with sipuleucel-T who did (dark blue) or did not (light blue) have an elevated eosinophil count, compared with the control group (red). The number of patients included is indicated for each data point.

Supplementary Figure S3. Association of immune response with change in eosinophil counts for sipuleucel-T-treated patients in randomized phase III trials. Patients treated in the randomized phase III trials were previously assessed for immune response. Patients who had evidence, or not, of an immune response to PA2024 by at any available time point after treatment by IFNγ ELISPOT (panel A) or T-cell proliferation (panel B), or by antibody titer at week 6 (panel C) were evaluated with respect to eosinophil change from baseline.


Patients with asymptomatic or minimally symptomatic mCRPC
2:1
Sipuleucel-T Q2W x 3
Placebo Q2W x 3
PROGRESSION
Physician's discretion
Physician's discretion, including optional entry into a phase 2 open-label study
SURVIVAL

Supplementary Figure 2



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