

Administration of Anzutresgene Autoleucel (Anzu-cel, Formerly IMA203)

ICD-10 Coordination and Maintenance
Committee Update - Fall 2026

Immatics



Anzutresgene autoleucel (anzu-cel, formerly IMA203) is an investigational therapy that has not been approved by any regulatory authority. The safety and effectiveness of anzu-cel has not yet been established.

Anzu-cel Treatment Regimen, Documentation, and Code Request

Code Request

- Current ICD-10-PCS codes do not adequately describe and identify the administration of anzu-cel, which is necessary to track utilization, outcomes, and resources associated with this product.

Anzu-cel Administration Summary

- Anzu-cel is a T cell receptor (TCR) T-cell therapy manufactured from a patient's own T cells obtained via leukapheresis. Anzu-cel is administered as a single intravenous infusion through the central or peripheral vein following lymphodepleting chemotherapy.

Expected Documentation

- Anzu-cel administration is likely to be described in medical records, physician orders, pharmacy notes, and treatment summaries.

Immatics is an innovative, pre-commercial, global leader in cancer research through its PRAME-directed immunotherapies



Since its founding, Immatics has focused on building its scientific approach from the ground up to develop and deliver novel PRAME-directed immunotherapies for patients with cancer



~700 Team Members



3 Global Sites
in Tübingen and Munich,
Germany and Houston, Texas



2

Therapeutic
Modalities

TCR-T and TCR bispecifics
in clinical development



4

Clinical
Programs



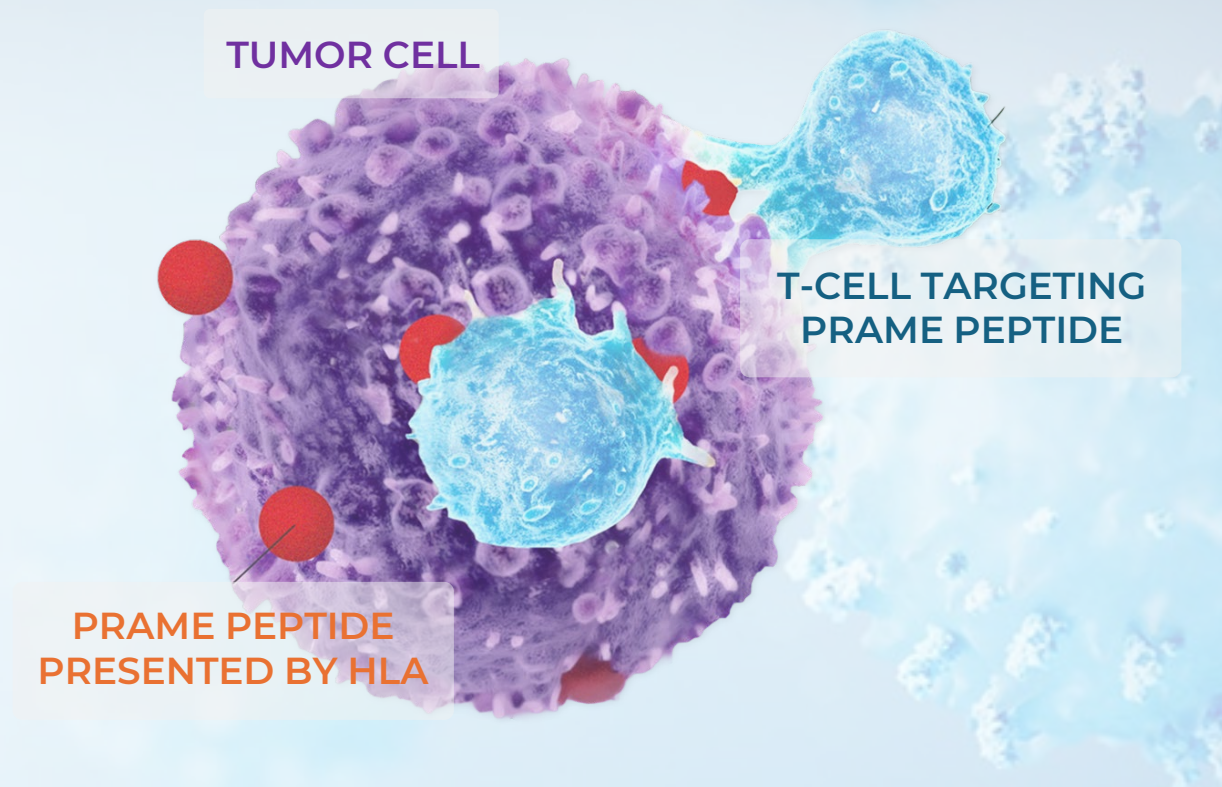
200+

Targets
across major
solid tumors

PRAME, PReferentially expressed Antigen in MELanoma; TCR, T-cell receptor.

PRAME-directed TCR-T therapies have the potential to reach a broad patient population

- **PRAME** is a tumor-associated antigen that has been found to overexpress in multiple cancers
- **PRAME is a protein found inside tumor cells** but not in most healthy cells
 - Peptides, small fragments of this protein, are presented at high levels on the surface of tumor cells by HLA molecules
- **PRAME exerts multiple functions in tumor biology**, including enhancing tumor cell survival, enhancing tumor growth (proliferation), and increasing resistance to tumor cell self-destruction (apoptosis)
- **PRAME is associated with poor prognosis and shorter survival** in a range of cancer types
- **It is considered a promising target** for T-cell receptor-based immunotherapies

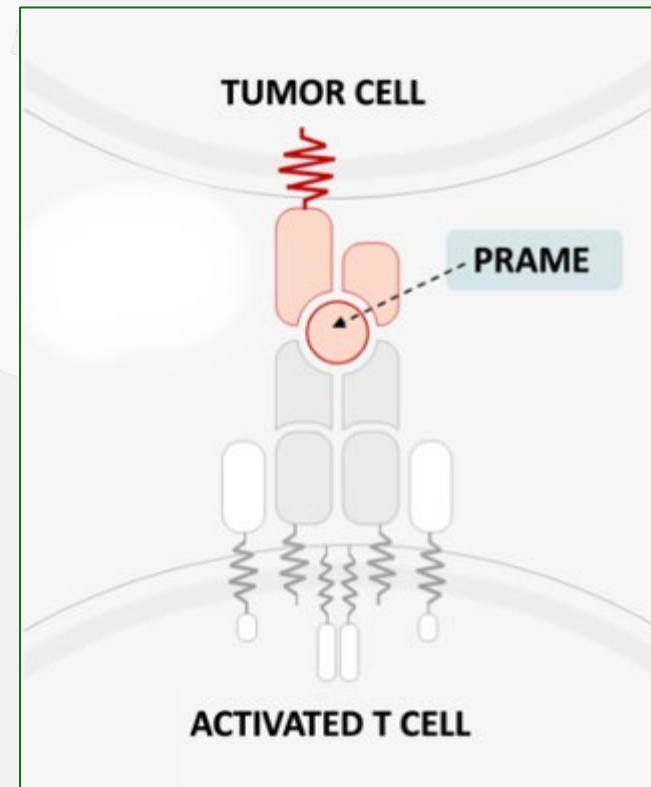
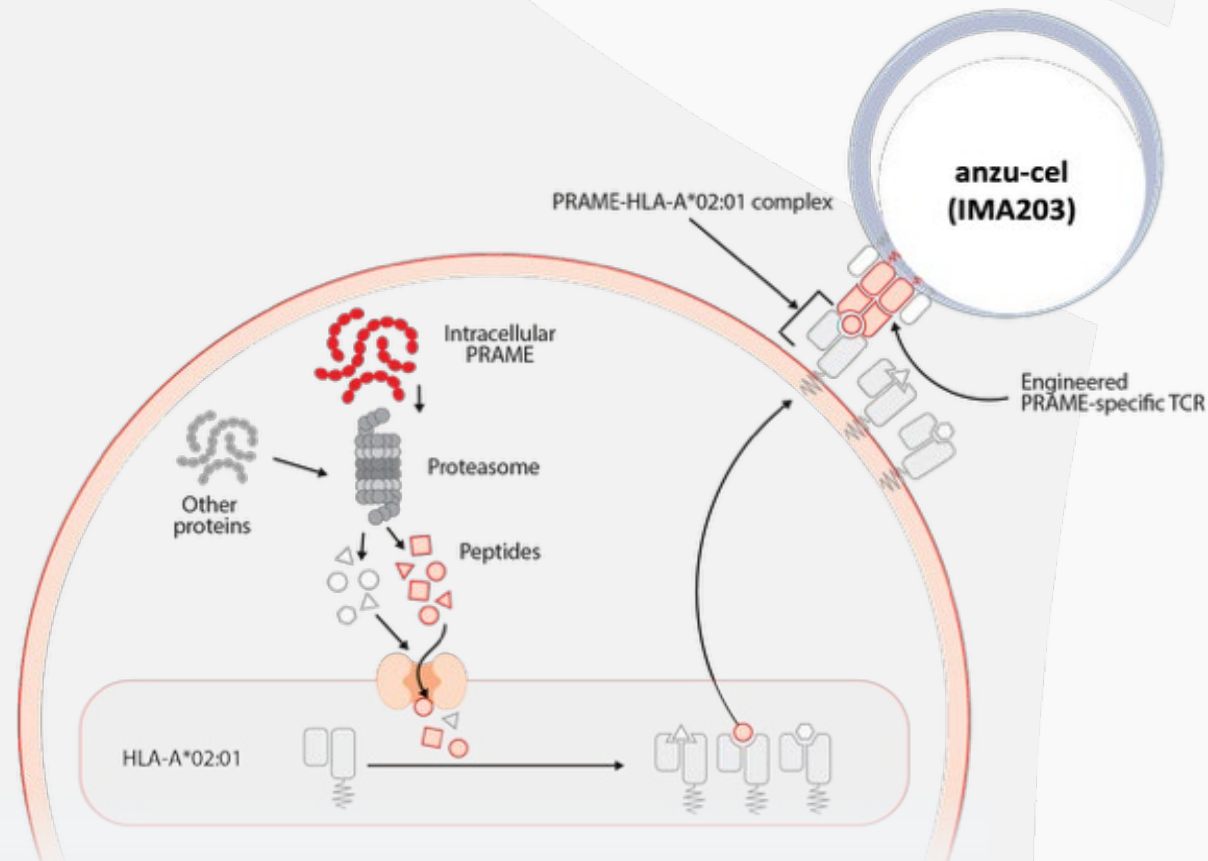


HLA, human leukocyte antigen; PRAME, PReferentially expressed Antigen in MElanoma; TCR, T-cell receptor.

Anzutresgene autoleucel (IMA203) is Immatics' candidate to treat metastatic melanoma

Currently under investigation in a phase 3 clinical trial

Anzutresgene autoleucel is designed to target PRAME



Anzutresgene autoleucel (IMA203) is an investigational therapy and its use has not been proven to be safe or effective. It has not been approved by the US Food and Drug Administration (FDA) or any other regulatory agency outside of the US.

PRAME, PReferentially expressed Antigen in MELanoma; TCR, T-cell receptor; US, United States.

Phase 1 study design

Anzutresgene autoleucel in advanced solid tumors expressing PRAME

Key Objectives

Primary:

- Tolerability
- Determination of RP2D (Phase 1a)

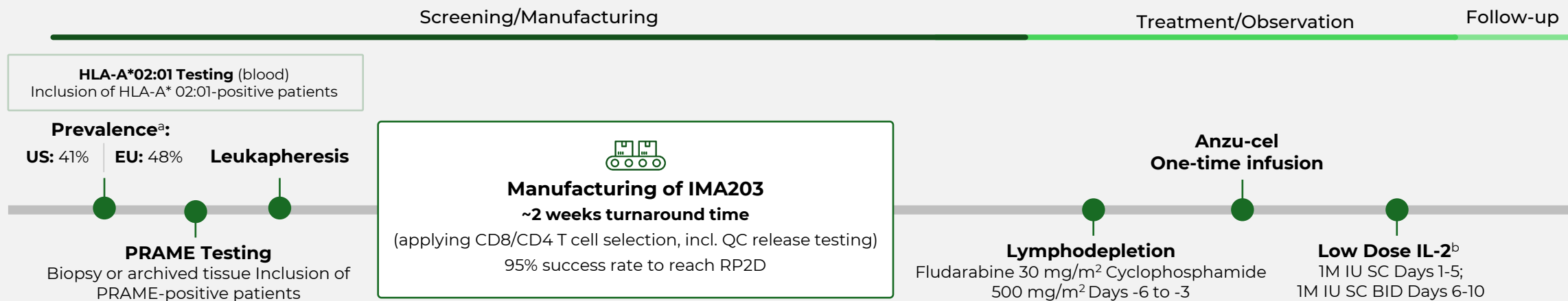
Secondary:

- IMA203 T cell engraftment, persistence
- Efficacy

Key Eligibility Criteria

- Confirmed advanced and/or metastatic solid tumor
- Patients ≥ 18 years of age
- ECOG PS 0-1
- HLA-A*02:01 and PRAME positive
- Patients having received, or not been eligible for all available indicated SOC treatment
- Adequate organ function
- No active brain metastasis

Patient Journey



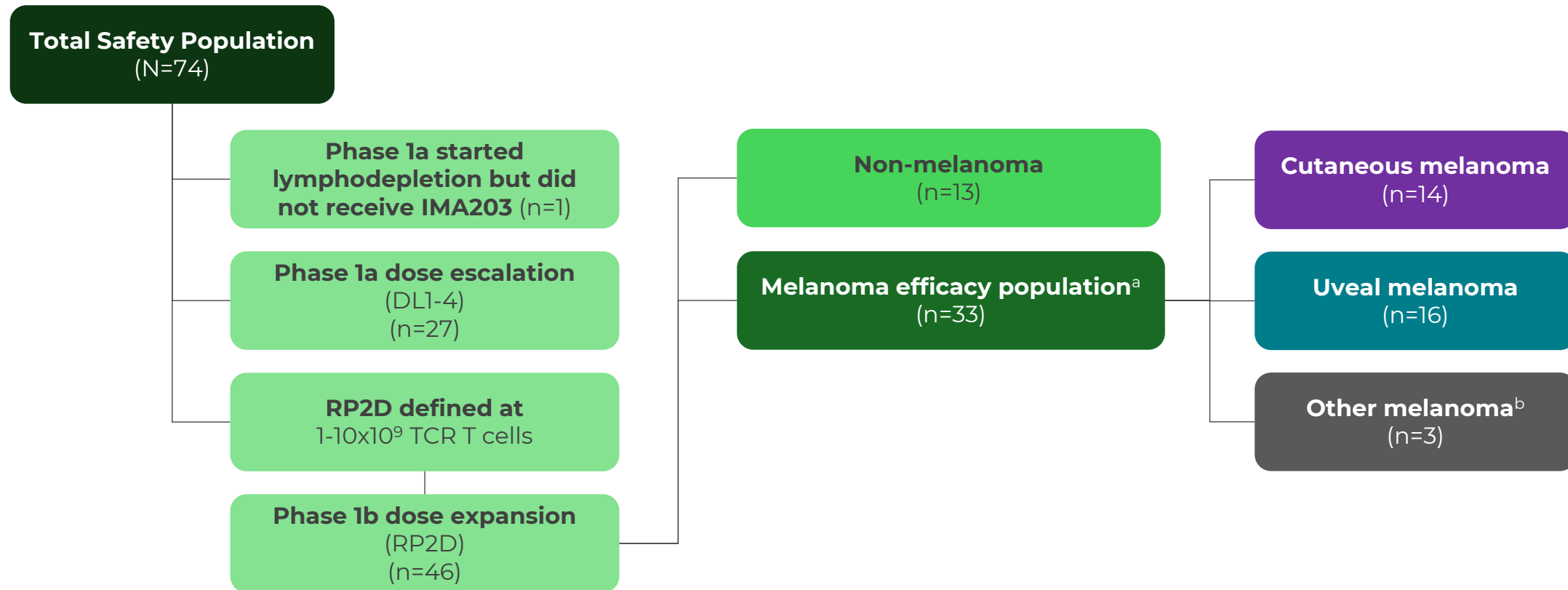
Data cutoff: April 7, 2025. ^aPrevalence data from Gragert et al (2013) and census numbers. ^bOutpatient administration at investigator's discretion.

1M, one million; BID, twice daily; CD, cluster of differentiation; ECOG PS, Eastern Cooperative Oncology Group performance status; EU, European Union; IL, interleukin; QC, quality control; RP2D, recommended phase 2 dose at $1-10 \times 10^9$ TCR T cells; SC, subcutaneous; SOC, standard of care; US, United States.

Reference: Wermke M, et al. Phase 1 clinical update of IMA203, an autologous TCR T Targeting PRAME in patients with PD1 refractory metastatic melanoma. Presented at: American Society of Clinical Oncology Annual Meeting 2025; May 30-June 3, 2025; Chicago, IL.

Phase 1 patient disposition (all populations)

Anzutresgene autoleucel in advanced solid tumors expressing PRAME



Data cutoff: April 7, 2025. ^aMelanoma efficacy population excludes 1 patient with uveal melanoma with ongoing unconfirmed PR from cORR; ^bMucosal melanoma n=2, melanoma of unknown primary n=1; RP2D: 1-10x10⁹ TCR T cells; DL4: 0.2-1.2x10⁹ TCR T cells/m² BSA.

BSA, body surface area; cORR, confirmed overall response rate; DL, dose level; PRAME, PReferentially expressed Antigen in MELanoma; PR, partial response; RP2D, recommended phase 2 dose; TCR, T-cell receptor.

Reference: Wermke M, et al. Phase 1 clinical update of IMA203, an autologous TCR T Targeting PRAME in patients with PD1 refractory metastatic melanoma. Presented at: American Society of Clinical Oncology Annual Meeting 2025; May 30-June 3, 2025; Chicago, IL.

Previously treated patients with a range of characteristics were studied

Phase 1 Patient Characteristics–All Populations

Baseline Characteristics	Total Safety Population N=74	Cutaneous Melanoma n=14	Uveal Melanoma n=16	All Melanoma n=33
Age, median (range)	54 (18, 79)	54.5 (31, 79)	62 (32, 74)	57 (31, 79)
Female, %	52.7	21.4	62.5	48.5
Baseline ECOG PS 1, %	51.4	35.7	43.8	39.4
Prior lines of systemic treatment, median (range)	3 (0, 10)	2.5 (1, 5)	2 (0, 6)	2 (0, 6)
Prior ICI treatment, median (range)	---	2 (1, 3)	1 (0, 4)	1 (0, 4)
≥1 line of ICI treatment, % (n/N)	---	100 (14/14)	62.5 (10/16)	81.8 (27/33)
Prior tebentafusp, % (n/N)	---	---	62.5 (10/16)	---
Elevated LDH at baseline, %	63.5	64.3	56.3	57.6
Median target lesion sum of diameter, mm (range)	116.1 (15.0, 309.8)	120.5 (15.0, 309.8)	101.6 (30.8, 210.0)	104.0 (15.0, 309.8)
Patients with liver metastasis, %	62.2	64.3	93.8	78.8
Patients with brain metastasis, %	12.2	0.0	0.0	3.0
Metastatic staging, % (CM, MM, UkM only)				
IIIb/IIIc/IVM1a	---	0.0	---	0.0
IVM1b/c/d	---	100.0	---	100.0
Metastatic staging, % (UM only)				
IVM1a	---	---	18.8	---
IVM1b/c/d	---	---	81.3	---

Treatment Experience

Infused TCR T cell dose (x10 ⁹), median (range)	2.34 (0.078, 10.20)	4.58 (1.30, 10.20)	3.94 (1.62, 8.43)	4.04 (1.30, 10.20)
---	---------------------	--------------------	-------------------	--------------------

Data cutoff: April 7, 2025.

CM, cutaneous melanoma; ECOG PS, Eastern Cooperative Oncology Group performance status; ICI, immune checkpoint inhibitor; LDH, lactate dehydrogenase; MM, mucosal melanoma; TCR, T-cell receptor; UkM, melanoma of unknown primary; UM, uveal melanoma.

Reference: Wermke M, et al. Phase 1 clinical update of IMA203, an autologous TCR T Targeting PRAME in patients with PD1 refractory metastatic melanoma. Presented at: American Society of Clinical Oncology Annual Meeting 2025; May 30-June 3, 2025; Chicago, IL.

Adverse events occurring in ≥20% of patients

Anzutresgene autoleucel phase 1 safety

Total Safety Population

TEAEs in ≥20% of patients

Preferred terms, n (%)	N=74	
	Any grade	Grade ≥3
Blood and lymphatic system disorders	73 (98.6)	73 (98.6)
Neutropenia ^a	68 (91.9)	67 (90.5)
Anemia	57 (77.0)	38 (51.4)
Thrombocytopenia ^a	50 (67.6)	27 (36.5)
Leukopenia	39 (52.7)	38 (51.4)
Lymphopenia	39 (52.7)	39 (52.7)
Gastrointestinal disorders	65 (87.8)	2 (2.7)
Nausea	45 (60.8)	0 (0.0)
Diarrhea ^a	28 (37.8)	1 (1.4)
Vomiting	25 (33.8)	1 (1.4)
Constipation	23 (31.1)	0 (0.0)
General disorders and administration site conditions	49 (66.2)	2 (2.7)
Fatigue	29 (39.2)	1 (1.4)
Pyrexia	22 (29.7)	1 (1.4)
Edema peripheral	17 (23.0)	0 (0.0)
Investigations	35 (47.3)	10 (13.5)
Aspartate aminotransferase increased	29 (39.2)	5 (6.8)
Alanine aminotransferase increased	28 (37.8)	7 (9.5)
Blood creatinine increased	15 (20.3)	2 (2.7)
Skin and subcutaneous tissue disorders	35 (47.3)	6 (8.1)
Rash	18 (24.3)	0 (0.0)
Rash maculo-papular	18 (24.3)	6 (8.1)
Metabolism and nutrition disorders	33 (44.6)	6 (8.1)
Hyponatremia	22 (29.7)	3 (4.1)
Hypokalemia	21 (28.4)	3 (4.1)

Adverse events of special interest

N=74	
CRS, any grade, n (%)	70 (94.6)
Grade 1	27 (36.5)
Grade 2	35 (47.3)
Grade 3 ^a	8 (10.8)
Grade 4	0 (0.0)
Grade 5	0 (0.0)
ICANS, any grade, n (%)	10 (13.5)
Grade 1	4 (5.4)
Grade 2	3 (4.1)
Grade 3	3 (4.1)
Grade 4	0 (0.0)
Grade 5	0 (0.0)
HLH, any grade, n (%)	2 (2.7)
Grade 1	0 (0.0)
Grade 2	1 (1.4)
Grade 3	1 (1.4)
Grade 4	0 (0.0)
Grade 5	0 (0.0)

- Tolerability consistent with previous reporting
- Most frequent TEAEs were anticipated cytopenias associated with lymphodepletion
- Expected and manageable CRS, mostly Grade 1/2, consistent with mechanism of action
- Infrequent, manageable, and mostly mild ICANS
- No IMA203-related Grade 5 events
- Tolerability in the melanoma subset generally consistent with the full IMA203 tolerability profile

Data cutoff: April 7, 2025. Patients are counted only once per adverse event and severity classification.

^aTwo patients with disease progression after first IMA203 infusion received exploratory second IMA203 infusion. They had these Grade ≥3 TEAEs (included in the table) only after second infusion: First patient: CRS, diarrhea; Second patient: neutropenia, thrombocytopenia.

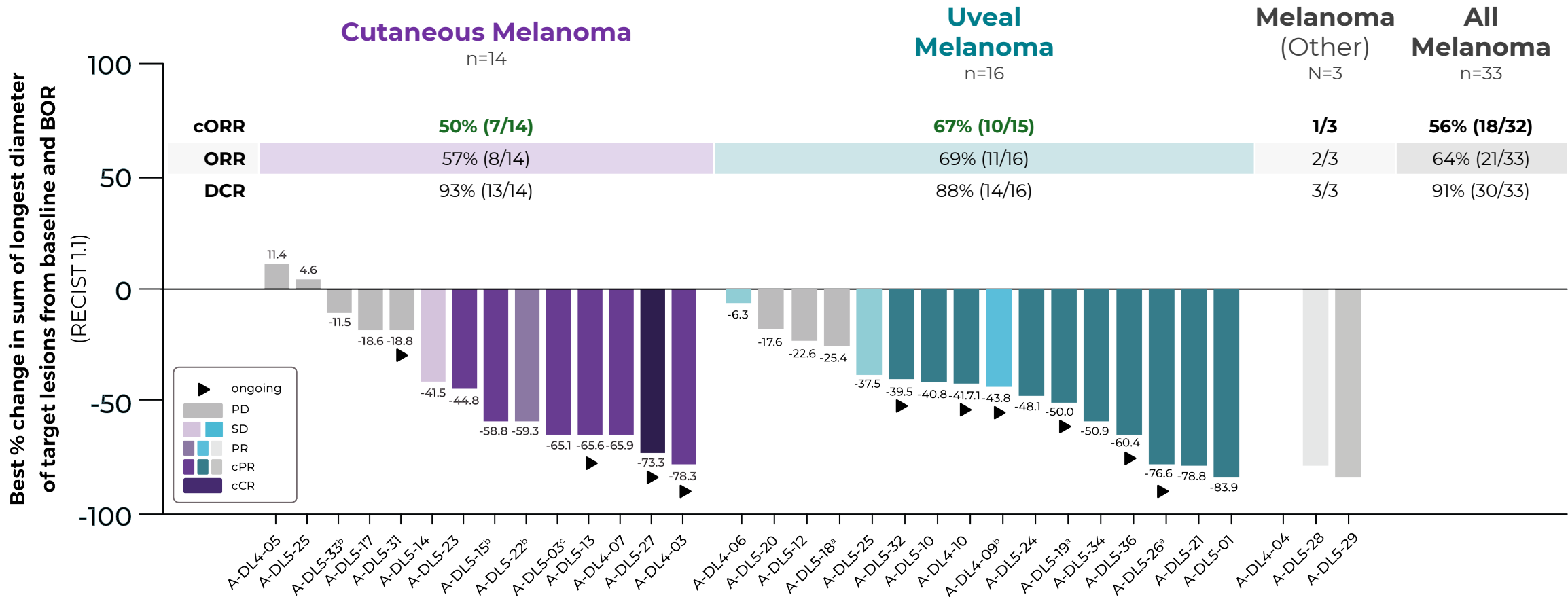
CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; HLH, hemophagocytic lymphohistiocytosis; TEAE, treatment-emergent adverse event.

Reference: Wermke M, et al. Phase 1 clinical update of IMA203, an autologous TCR T Targeting PRAME in patients with PD1 refractory metastatic melanoma. Presented at: American Society of Clinical Oncology Annual Meeting 2025; May 30-June 3, 2025; Chicago, IL.

Anzutresgene autoleucel best overall response in melanoma



Phase 1 results in advanced solid tumors expressing PRAME



Data cutoff: April 7, 2025.

^aIncludes melanoma (other) n=3: mucosal melanoma n=2, melanoma of unknown primary n=1; Melanoma efficacy population excludes 1 uveal melanoma patient with ongoing unconfirmed PR from cORR.

^bMaximum change of target lesions and RECIST1.1 response at different timepoints. ^cPatient out of study due to PD (external assessment); ^dPatient out of study at data-cut (withdrew consent).

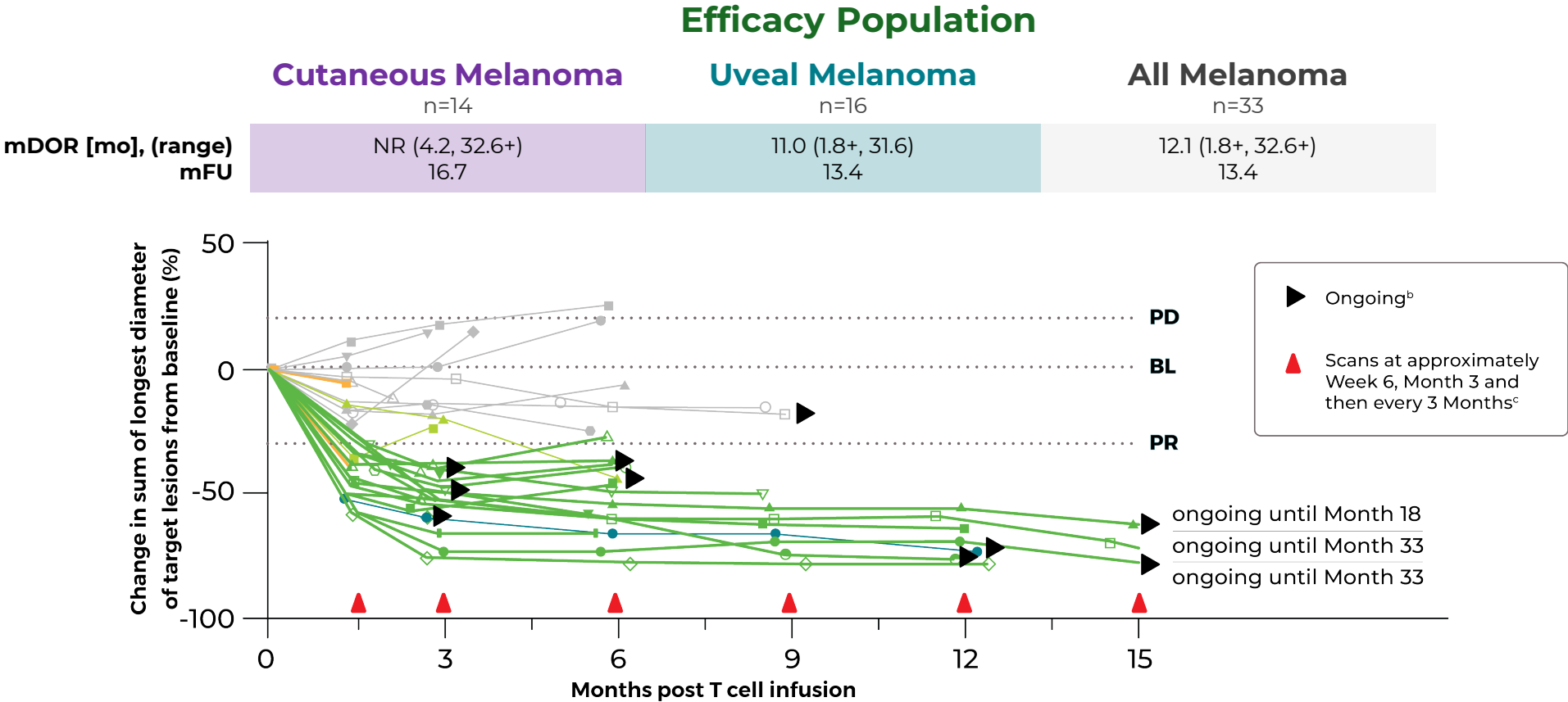
BL, baseline; BOR, best overall response; (c)CR, (confirmed) complete response; (c)ORR, (confirmed) objective response rate; (c)PR, (confirmed) partial response; DCR, disease control rate at Week 6; PD, progressive disease; PRAME, PReferentially expressed Antigen in MELanoma; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

Reference: Wermke M, et al. Phase 1 clinical update of IMA203, an autologous TCR T Targeting PRAME in patients with PD1 refractory metastatic melanoma. Presented at: American Society of Clinical Oncology Annual Meeting 2025; May 30-June 3, 2025; Chicago, IL.

Anzutresgene autoleucel duration of response in melanoma



Phase 1 results in advanced solid tumors expressing PRAME



Data cutoff: April 7, 2025.

^aIncludes melanoma (other) n=3: mucosal melanoma n=2, melanoma of unknown origin n=1. ^bPatient out of study due to PD (external assessment). ^cPatient out of study at data-cut (withdrew consent).

BL, baseline; (c)CR, (confirmed) complete response; (c)PR, (confirmed) partial response; mDOR, median duration of response; mFU, median follow-up; NR, not reached; PD, progressive disease; PRAME, PReferentially expressed Antigen in MELanoma; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

Reference: Wermke M, et al. Phase 1 clinical update of IMA203, an autologous TCR T Targeting PRAME in patients with PD1 refractory metastatic melanoma. Presented at: American Society of Clinical Oncology Annual Meeting 2025; May 30-June 3, 2025; Chicago, IL.

Anzutresgene autoleucel survival outcomes in melanoma

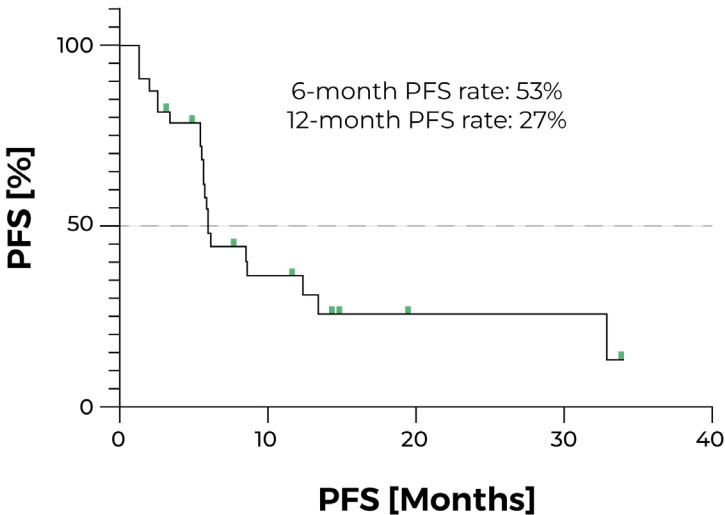


Phase 1 results in advanced solid tumors expressing PRAME

Efficacy Population

Median Progression-Free Survival

	Cutaneous Melanoma n=14	Uveal Melanoma n=16	All Melanoma n=33
mPFS [mo]	6.0 (1.4, 34.0+)	8.5 (1.4, 32.9)	6.1 (1.4, 34.0+)
(range) mFU [mo]	14.4	8.7	14.4



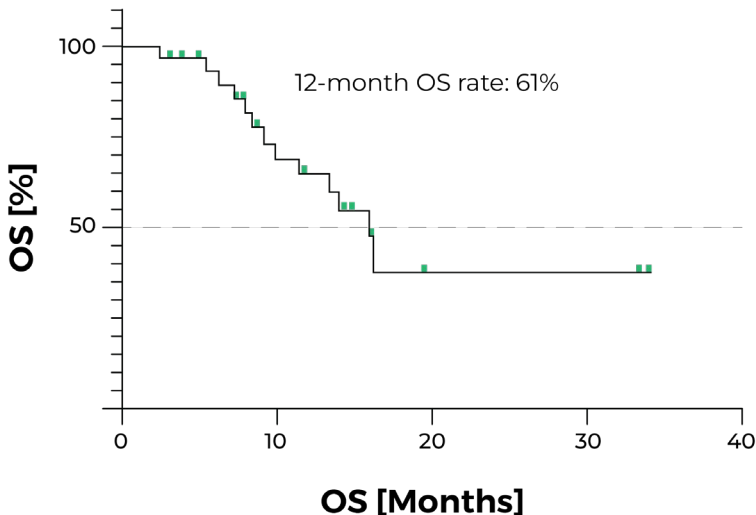
Data cutoff: April 7, 2025.

^aIncludes melanoma (other) n=3: mucosal melanoma n=2, melanoma of unknown origin n=1; PFS and OS censored at data-cut; PFS and OS rate shown as % of evaluable patients at indicated timepoint. mFU, median follow-up; (m)OS, (median) overall survival; (m)PFS, (median) progression-free survival; PRAME, PReferentially expressed Antigen in MELanoma.

Reference: Wermke M, et al. Phase 1 clinical update of IMA203, an autologous TCR T Targeting PRAME in patients with PD1 refractory metastatic melanoma. Presented at: American Society of Clinical Oncology Annual Meeting 2025; May 30-June 3, 2025; Chicago, IL.

Median Overall Survival

	Cutaneous Melanoma n=14	Uveal Melanoma n=16	All Melanoma n=33
mOS [mo]	13.9 (2.4, 34.0+)	16.2 (3.2+, 32.2+)	15.9 (2.4, 34.2+)
(range) mFU [mo]	14.4	14.5	14.4



Anzutresgene autoleucel vs investigator's choice in advanced cutaneous melanoma

Phase 3 Study Design

Endpoints

Primary:

- PFS

Key Secondary:

- OS

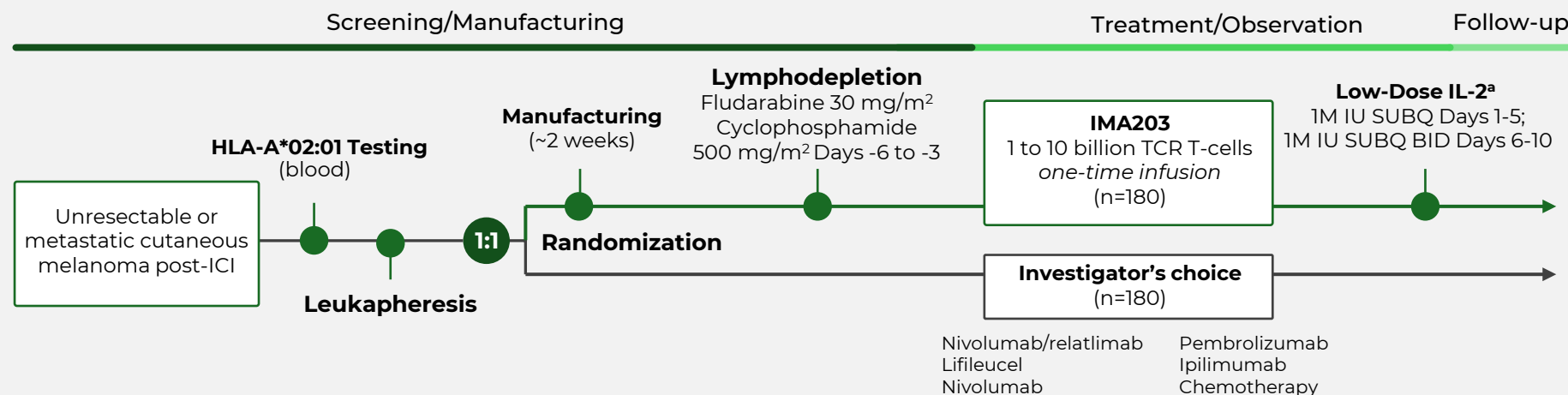
Secondary:

- Efficacy: ORR
- Safety: SAEs, AEs of special interest
- Quality of life

Key Eligibility Criteria

- Adults with advanced cutaneous melanoma (including acral and melanoma of unknown primary)
- ECOG PS 0-1
- HLA-A*02:01 positive
- Measurable disease (RECIST 1.1)
- Disease progression on or after ≥ 1 PD-1 inhibitor
- Adequate organ function
- No active brain metastases

Patient Journey



>65 planned study sites in North America and Europe

^aOutpatient administration at investigator's discretion.

AE, adverse event; BID, twice daily; ECOG PS, Eastern Cooperative Oncology Group performance status; ICI, immune checkpoint inhibitor; IL, interleukin; ORR, objective response rate; OS, overall survival; PD-1, programmed cell death protein 1; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; SAE, treatment-emergent serious adverse event; SUBQ, subcutaneous.

Reference: ClinicalTrials.gov: NCT06743126, Accessed Oct 28, 2025.

Making a Meaningful Impact on the Lives of Patients with Cancer

Thank you

www.immatics.com

