2026 ASCO® ANNUAL MEETING

First-in-Human Results With IMA401, a MAGEA4/8-targeted T-cell Receptor-based Bispecific T-cell Engager (TCER), in Recurrent or Refractory Solid Tumors

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Key Takeaways

- TCR-based therapies enable immune recognition of intracellular tumor antigens presented by cell-surface HLA, expanding the therapeutic landscape beyond targets accessible to conventional immunotherapies
- **IMA401** is a novel TCR-based bispecific T-cell engager targeting MAGEA4/8, expressed in multiple cancers incl. head & neck cancer and sqNSCLC
- **IMA401** demonstrates a manageable tolerability profile and encouraging efficacy as monotherapy or in combination with ICI
- **Next steps** include a combination with a PRAME-directed TCR-based T-cell engager (IMA402) for >90% prevalence in sqNSCLC

HLA, human leukocyte antigen; head and neck (H&N) cancer (squamous cell and adenocarcinoma); ICI, immune checkpoint inhibitor; MAGE, melanoma-assicated antigen; PRAME, preferentially expressed in melanoma; sqNSCLC, squamous cell non-small cell lung cancer; TCR: T-cell receptor;

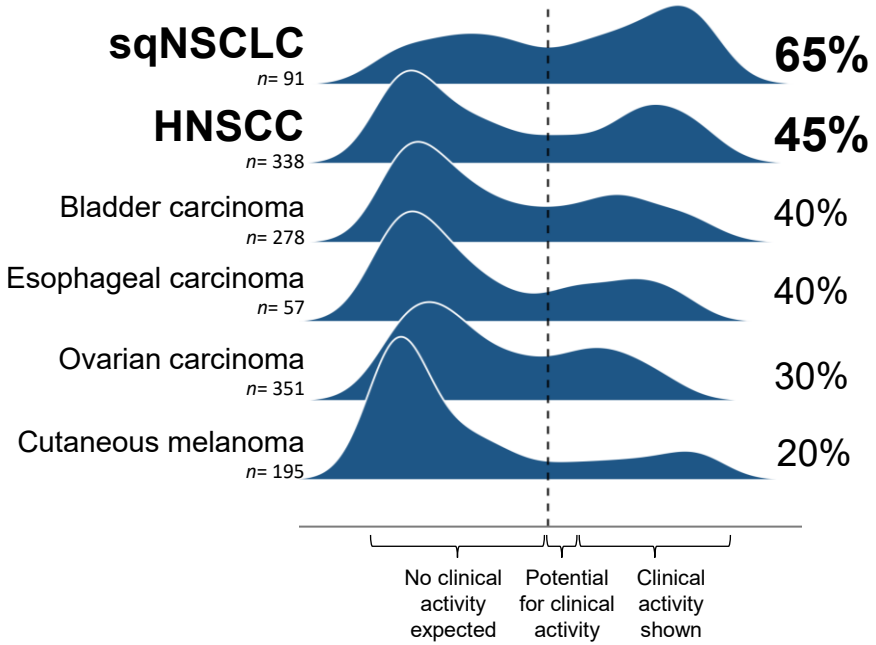
Dose escalation data presented by Wermke et al., ESMO 2024.

Target Biology of IMA401-Targeted MAGEA4/8 Peptide

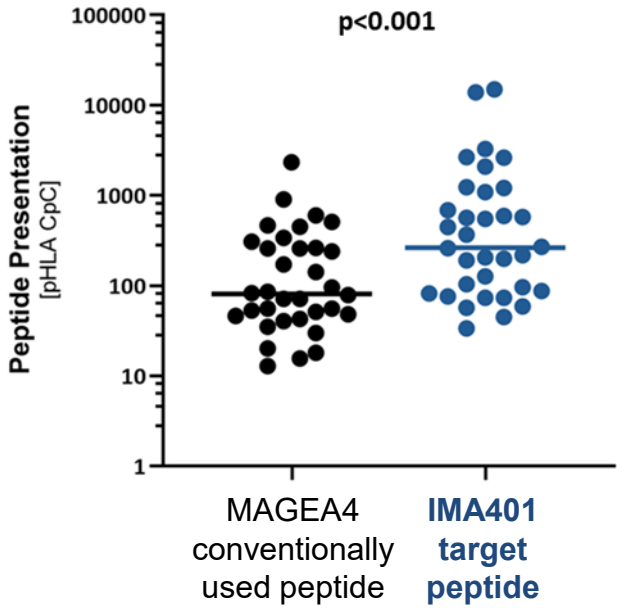
1 MAGEA4/8 is expressed in multiple cancers

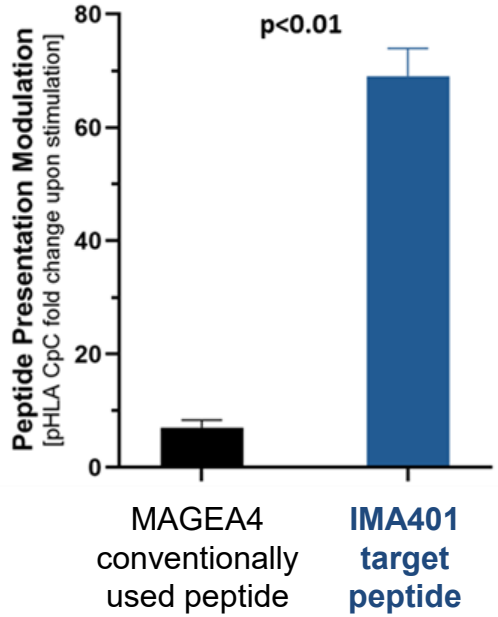
2 IMA401 target peptide shows high HLA-presentation levels

3 Further increase in target presentation by IFN-γ



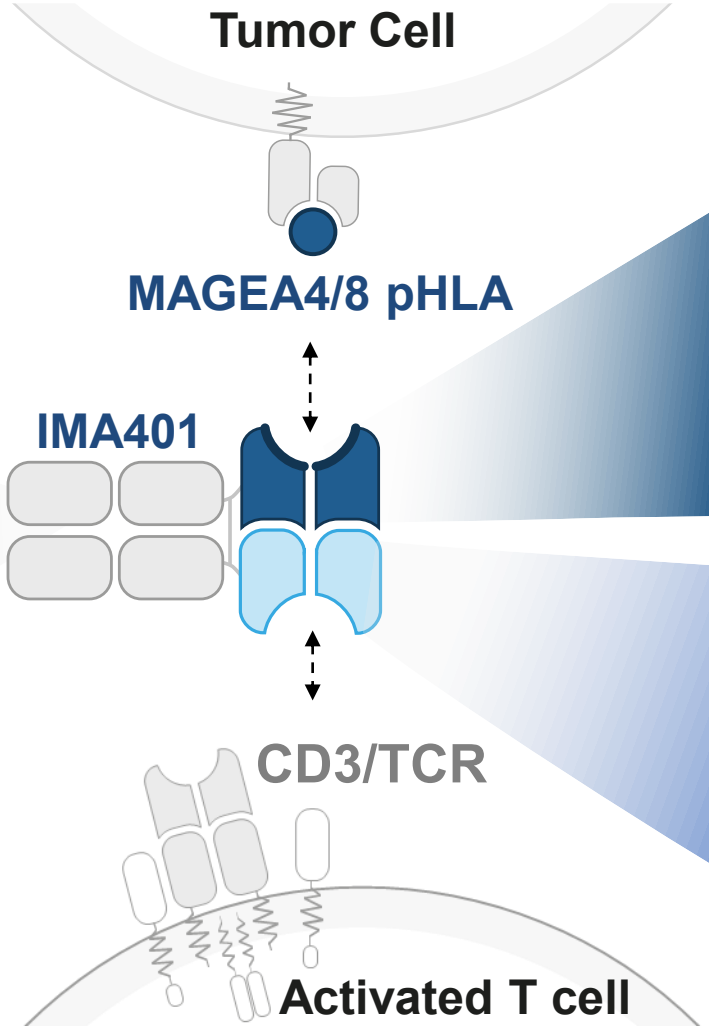
MAGEA4/8 mRNA expression (TPM, log-scaled)





Data on file: 1 MAGEA4/8 target prevalence by mRNA expression in late-stage solid tumors based on an optimized proprietary target expression threshold applied to TCGA data (TCGA stage III/IV); 2 Target peptide density in primary and metastatic solid tumors; median shown (solid line). Target peptide copy numbers per cell (CpC) measured by quantitative mass spec in paired samples (MAGEA4 vs. MAGEA4/8 in the same tumor); p-value by paired t-test, 3 CpC fold change in A375 cells presenting MAGEA4 and MAGEA4/8 peptides ± IFN-γ (100 U/mL, 48 h; n=3); p-value by paired t-test; HNSCC, head and neck squamous cell carcinoma; IFN-γ, interferon gamma, sqNSCLC, squamous cell non-small cell lung cancer; TPM, transcripts per million.

IMA401 Designed to Improve Efficacy and Reduce Risk of CRS



✓ **Antibody-like format with half-life extension (HLE)**

Long half-life of 2-3 weeks[a]

✓ **Anti-tumor Activity**

High-affinity MAGEA4/8 pHLA binding (K_D = 1.7 nM; BLI)

✓ **Optimized tolerability**

Low binding to TCR/CD3- expressing T cells (EC_{50} ≥ 200 nM; flow cytometry)

IMA401 is an investigational therapy and its use has not been proven to be safe or effective. It has not been approved by the FDA or any other regulatory agency outside of the US.

[a] Median half-life IMA401: ~18 days, see appendix; BLI, biolayer interferometry; CRS, cytokine release syndrome; MAGEA, melanoma-associated antigen gene; pHLA, peptide-human leukocyte antigen; TCR, T-cell receptor.

IMA401 Phase 1 Basket Trial in Solid Tumors: Objectives and Eligibility

Objectives

Primary:

- Determine MTD and/or RP2D in monotherapy and in combination with pembrolizumab

Secondary:

- Assess safety and tolerability
- Evaluate initial anti-tumor activity (RECIST 1.1 and iRECIST)
- Assess pharmacokinetics

Key Eligibility Criteria

- Recurrent and/or refractory **solid tumors**[a]
- HLA-A*02:01 positive
- MAGEA4/8-positive
- ECOG performance status 0-1
- Received or not eligible for all available indicated standard of care treatments

EudraCT No 2021-004326-30; NCT05359445; [a] Basket trial with >15 different tumor indications; ECOG, Eastern Cooperative Oncology Group; (i)RECIST, (immune) response evaluation criteria in solid tumors; MTD, maximum tolerated dose; RP2D, recommended phase 2 dose.

Phase 1 Basket Trial of IMA401 in MAGEA4/8+ Solid Tumors

Phase 1a Dose Escalation
0.0066 mg - 2.5 mg IMA401
(**n=61**)

- **MABEL-based starting dose**
- Dose escalation based on cohorts of 1-6 patients using **adaptive design** (BLRM model)
- Initial q1w step dosing[a] (2-4 doses) up to target dose, q2w after reaching target dose[b]

0.0066 mg
0.02 mg
0.06 mg
0.18 mg
0.54 mg
1.0 mg
1.2 mg
1.5 mg
1.8 mg
2.0 mg
2.5 mg

Phase 1a dose escalation completed

RP2D Selection
1.0 - 2.0 mg IMA401
(**n=32**)

Dose selection:
MTD not reached per adaptive BLRM model[c], RP2D defined at 1-2 mg based on optimal risk-benefit-profile

1.0 mg
1.2 mg
1.5 mg
1.8 mg
2.0 mg

RP2D selection completed

ICI Combination at RP2D
1.0 or 1.5 mg IMA401 with Pembrolizumab
(**n=12**)

ICI combination:
Pembrolizumab started 1 week before IMA401 (400 mg IV q6w)

1.0 mg + Pembrolizumab
1.5 mg + Pembrolizumab

IMA401 + ICI completed

EudraCT No 2021-004326-30; NCT05359445; [a] Step dosing introduced at dose levels ≥1 mg, low-dose dexamethasone partially used as preventive measure for initial doses as applied for other bispecific T-cell engagers; ability to increase dose to previously cleared dose levels; [b] q2w: once every two weeks, weekly (q1w) IMA401 dosing was applied up to 0.54 mg; [c] MTD was not reached at 2.5 mg as defined by the adaptive BLRM model specifying probabilities of DLTs at tested doses. BLRM, Bayesian logistic regression model; ICI, immune checkpoint inhibitor; IV, intravenous; MABEL, minimum anticipated biological effect level; MTD, maximum tolerated dose, RP2D, recommended phase 2 dose; q6w, every 6 weeks.

Baseline Characteristics

Highly heterogenous patient population with >15 different indications

Different Indications (all dose levels)	**# of Patients**
H&N (squamous, adenocarcinoma, others)	16
Melanoma (Cutaneous & Mucosal)	8
Synovial Sarcoma	8
sqNSCLC	4
TNBC	4
adNSCLC	3
Ovarian Carcinoma	3
Gastric Cancer	2
SCLC	2
Urothelial Carcinoma	2
Bladder Carcinoma	1
Esophageal Carcinoma	1
Gallbladder Adenocarcinoma	1
LCNEC Esophageal	1
LCNEC Lung	1
NET CUP	1
Non-melanoma Skin Cancer (Squamous)	1
Penile Cancer	1
Testicular GCT	1

Baseline Characteristics	**All Dose Levels**	**RP2D (1-2 mg)**	
	IMA401 ± Pembrolizumab n=61	IMA401 (Monotherapy) n=32	IMA401 + Pembrolizumab[b] n=12
Age (years), median (min, max)	62 (19, 82)	62 (19, 82)	63 (33, 77)
Sex, male/female n (%)	39 (64)/ 22 (36)	19 (59)/ 13 (41)	12 (100)/ 0 (0)
ECOG performance status			
0, n (%)	21 (34)	11 (34)	6 (42)
1, n (%)	38 (62)	20 (63)	6 (50)
2, n (%)	2 (3)	1 (3)	0
LDH at baseline			
< 1xULN, n (%)	36 (59)	17 (53)	8 (67)
1-2xULN, n (%)	21 (34)	14 (44)	4 (33)
> 2xULN, n (%)	4 (7)	1 (3)	0
Baseline tumor burden Target lesion SLD [cm], median (range)	67 (11.3, 202.8)	60 (11.3, 202.8)	63.1 (15.5, 121.0)
Tumor lesions			
Number of lesions, median (min, max)	4 (1, 10)	4 (1, 10)	4.5 (2, 10)
Liver metastases, n (%)	18 (30)	10 (31)	4 (33)
Brain metastases, n (%)	4 (7)	2 (6)	0
Treatment Experience No. of prior lines of systemic treatment median (min, max)	3 (1, 8)	4 (1, 8)	3 (1, 4)
Prior treatments, n (%)			
Chemotherapy	52 (85)	25 (78)	11 (92)
ICI	40 (66)	18 (56)	11 (92)
Targeted Therapy[a]	41 (67)	22 (69)	9 (75)
Hormone Therapy	4 (7)	2 (6)	0
Others	7 (11)	4 (13)	0

[a] Includes small molecule drugs and antibodies. [b]IMA401 dose in pembrolizumab expansion cohorts were 1 mg (n=8) or 1.5 mg (n=4); adNSCLC, adenocarcinoma non-small cell lung cancer; ECOG, Eastern Cooperative Oncology Group; GCT, germ cell tumor; H&N, head and neck; HNSCC, head and neck squamous cell carcinoma; ICI, immune checkpoint inhibitor; LCNEC, large cell neuroendocrine carcinoma; LDH, lactate dehydrogenase; NET CUP, neuroendocrine tumor of cancer of unknown primary; RP2D, recommended phase 2 dose; SCLC, small cell lung cancer; SLD, sum of longest diameter(s); sqNSCLC, squamous cell non-small cell lung cancer; TNBC, triple-negative breast cancer; ULN, upper limit of normal.

Tolerability of IMA401 Monotherapy

	All treated patients		IMA401 (Monotherapy)			
Treatment-related Adverse Events (safety analysis set)	**All Dose Levels** N=61		**1-2 mg (RP2D)** n=32		**> 2 mg** n=7	
TRAEs[a], n (%)	All Grades	≥ Grade 3	All Grades	≥ Grade 3	All Grades	≥ Grade 3
Any TRAE	54 (89)	31 (51)	28 (88)	16 (50)	7 (100)	7 (100)
Cytokine release syndrome	23 (38)	0	12 (38)	0	3 (43)	0
Lymphopenia	20 (33)	16 (26)	9 (28)	7 (22)	5 (71)	5 (71)
Neutropenia	19 (31)	11 (18)	11 (34)	5 (16)	5 (71)	5 (71)
Thrombocytopenia	10 (16)	2 (3)	5 (16)	0	3 (43)	2 (29)
Leukopenia	9 (15)	5 (8)	7 (22)	4 (13)	1 (14)	1 (14)
Headache	9 (15)	2 (3)	7 (22)	1 (3)	2 (29)	1 (14)
Anaemia	8 (13)	7 (11)	2 (6)	2 (6)	4 (57)	3 (43)
Facial pain	7 (11)	2 (3)	0	0	4 (57)	1 (14)
ALT increased	7 (11)	1 (2)	3 (9)	1 (3)	1 (14)	0
Pyrexia	7 (11)	0	2 (6)	0	1 (14)	0
AST increased	5 (8)	3 (5)	3 (9)	2 (6)	0	0
Hypertension	4 (7)	2 (3)	3 (9)	2 (6)	0	0
GGT increased	2 (3)	1 (2)	0	0	0	0
Hypoxia	2 (3)	1 (2)	0	0	0	0
C-reactive protein increased	1 (2)	1 (2)	1 (3)	1 (3)	0	0
Chest pain	1 (2)	1 (2)	0	0	0	0
Febrile neutropenia	1 (2)	1 (2)	0	0	1 (14)	1 (14)
Pneumonia	1 (2)	1 (2)	0	0	1 (14)	1 (14)
Sinus tachycardia	1 (2)	1 (2)	1 (3)	1 (3)	0	0

Manageable tolerability profile with mostly transient AEs, consistent with MoA

- **Most common AEs:**
  - Low-grade CRS (38% G1-G2, no ≥G3), mainly at first step dose, resolving within 1-3 days
  - Transient, mechanism-related lymphopenia
  - Mostly transient neutropenia, manageable with dexamethasone and G-CSF; not recurring after resolution with continued IMA401 treatment
- **No ICANS observed**
- **MTD not reached**
- Neutropenia-related DLTs in 5 patients (incl. 3 at >RP2D[b])
- **No DLTs at RP2D with dexamethasone premedication**

[a] All TRAEs at least possibly related to IMA401 infusion and/or pembrolizumab infusion with grade 1-2 occurring in at least 10% of all patients, all events with ≥ grade 3; [b] in patients with and without dexamethasone pre-medication, one possibly related death (pneumonia in the context of lung tumor progression and concurrent neutropenia) as previously reported, patient did not receive dexamethasone pre-medication; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CSF, colony-stimulating factor, CRS, cytokine release syndrome, DLT, dose-limiting toxicity; ICANS, immune effector cell-associated neurotoxicity syndrome; GGT, gamma-glutamyltransferase; MoA, mechanism of action; RP2D, recommended phase 2 dose; TRAE, treatment-related adverse event.

Tolerability of IMA401 at RP2D ± Pembrolizumab

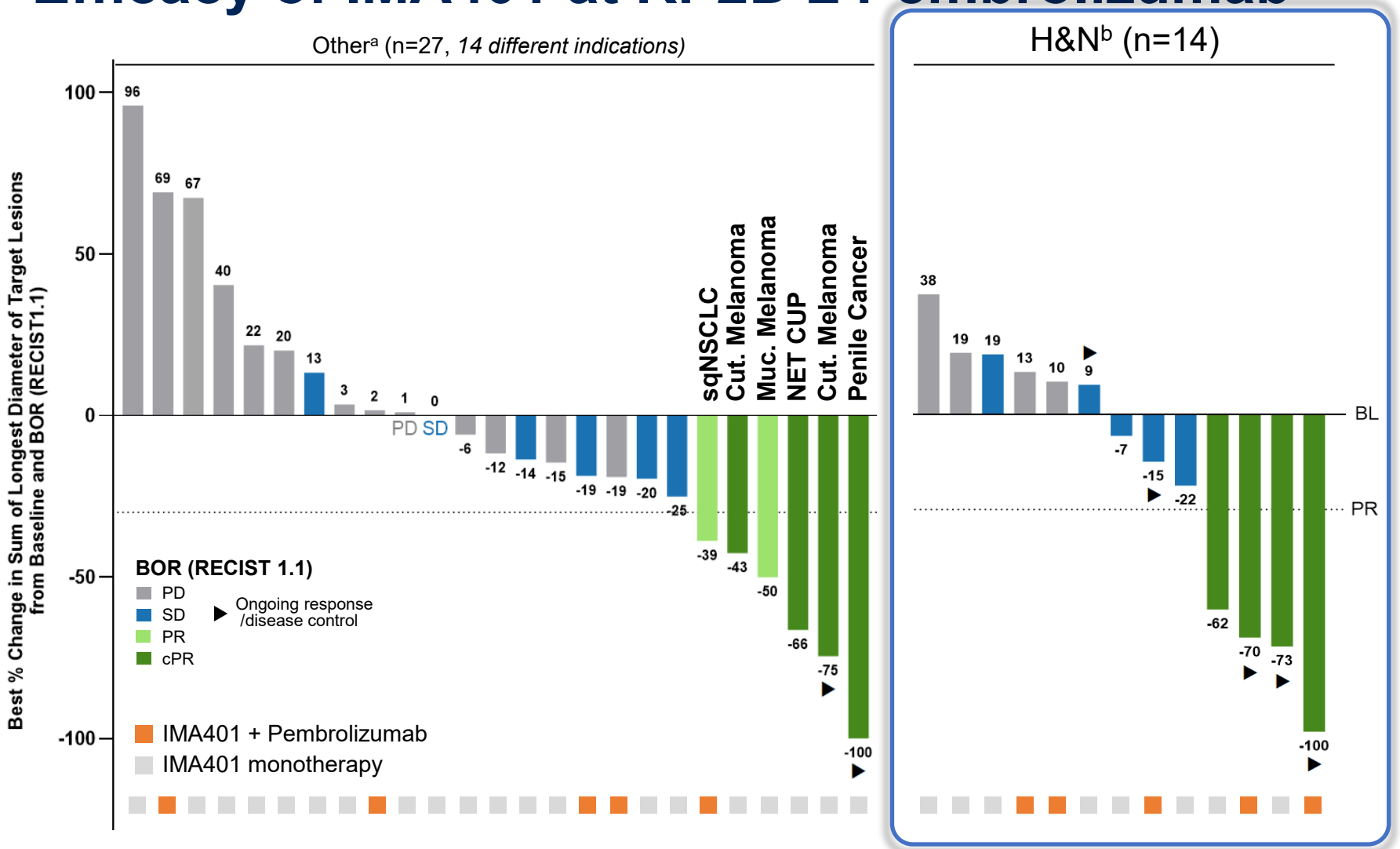
	IMA401 (Monotherapy)		IMA401 + Pembrolizumab	
Treatment-related Adverse Events (safety analysis set)	**1-2 mg (RP2D)** n=32		**1-2 mg (RP2D)[b]** n=12	
TRAEs[a], n (%)	All Grades	≥ Grade 3	All Grades	≥ Grade 3
Any TRAE	28 (88)	16 (50)	11 (92)	3 (25)
Cytokine release syndrome	12 (38)	0	5 (42)	0
Lymphopenia	9 (28)	7 (22)	4 (33)	2 (17)
Neutropenia	11 (34)	5 (16)	1 (8)	0
Thrombocytopenia	5 (16)	0	1 (8)	0
Leukopenia	7 (22)	4 (13)	1 (8)	0
Headache	7 (22)	1 (3)	0	0
Anaemia	2 (6)	2 (6)	0	0
Facial pain	0	0	0	0
Alanine aminotransferase increased	3 (9)	1 (3)	2 (17)	0
Pyrexia	2 (6)	0	3 (25)	0
Aspartate aminotransferase increased	3 (9)	2 (6)	1 (8)	0
Hypertension	3 (9)	2 (6)	0	0
Gamma-glutamyltransferase increased	0	0	1 (8)	1 (8)
Hypoxia	0	0	0	0
C-reactive protein increased	1 (3)	1 (3)	0	0
Chest pain	0	0	0	0
Febrile neutropenia	0	0	0	0
Pneumonia	0	0	0	0
Sinus tachycardia	1 (3)	1 (3)	0	0

ICI-associated toxicities	Any group analyzed
Immune-mediated colitis	0
Immune-mediated pneumonitis	0
Immune-mediated hepatitis	0
Nephritis	0
Adrenal insufficiency	0
Immune-mediated hypophysitis	0

No overlapping and/or additive toxicity observed in the combination cohort, supporting IMA401 combinability with ICIs.

[a] All TRAEs at least possibly related to IMA401 infusion and/or pembrolizumab infusion with grade 1-2 occurring in at least 10% of all patients, all events with ≥ grade 3 and typical ICI-associated toxicities; [b] IMA401 dose in pembrolizumab expansion cohorts were 1 mg (n=8) or 1.5 mg (n=4); ICI, immune checkpoint inhibitor; RP2D, recommended phase 2 dose; TRAE, treatment-related adverse event.

Efficacy of IMA401 at RP2D ± Pembrolizumab



H&N (n=14)

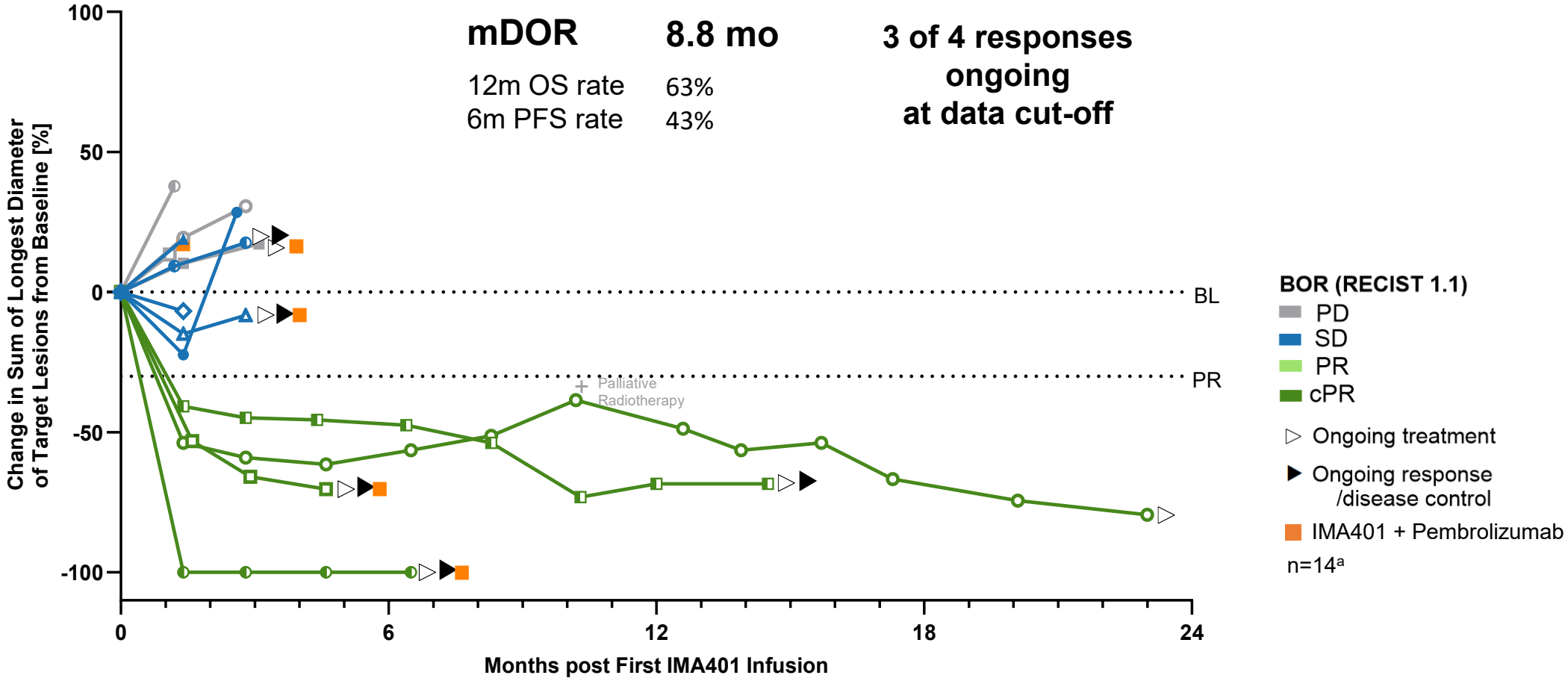
cORR **29%** (4/14)

DCR **64%** (9/14)

All H&N responders achieved deep responses with 60% - 100% tumor reduction

Efficacy population: all patients in the safety set who received 4 IMA401 infusions in monotherapy and in addition at least 1 pembrolizumab infusion in combination therapy and had a post-baseline efficacy assessment, including patients with clinical progression; [a] Two patients not shown in plot due to clinical progression before post-infusion scan. [b] One patient not shown in plot due to clinical progression before post-infusion scan. BOR, best overall response; (c)ORR, (confirmed) objective response rate; (c)PR, (confirmed) partial response; DCR, disease control rate; H&N, head and neck cancer; PD, progressive disease; PFS, progression-free survival; RECIST, response evaluation criteria in solid tumors; RP2D, recommended phase 2 dose; SD, stable disease; OS, overall survival; mDOR, median duration of response.

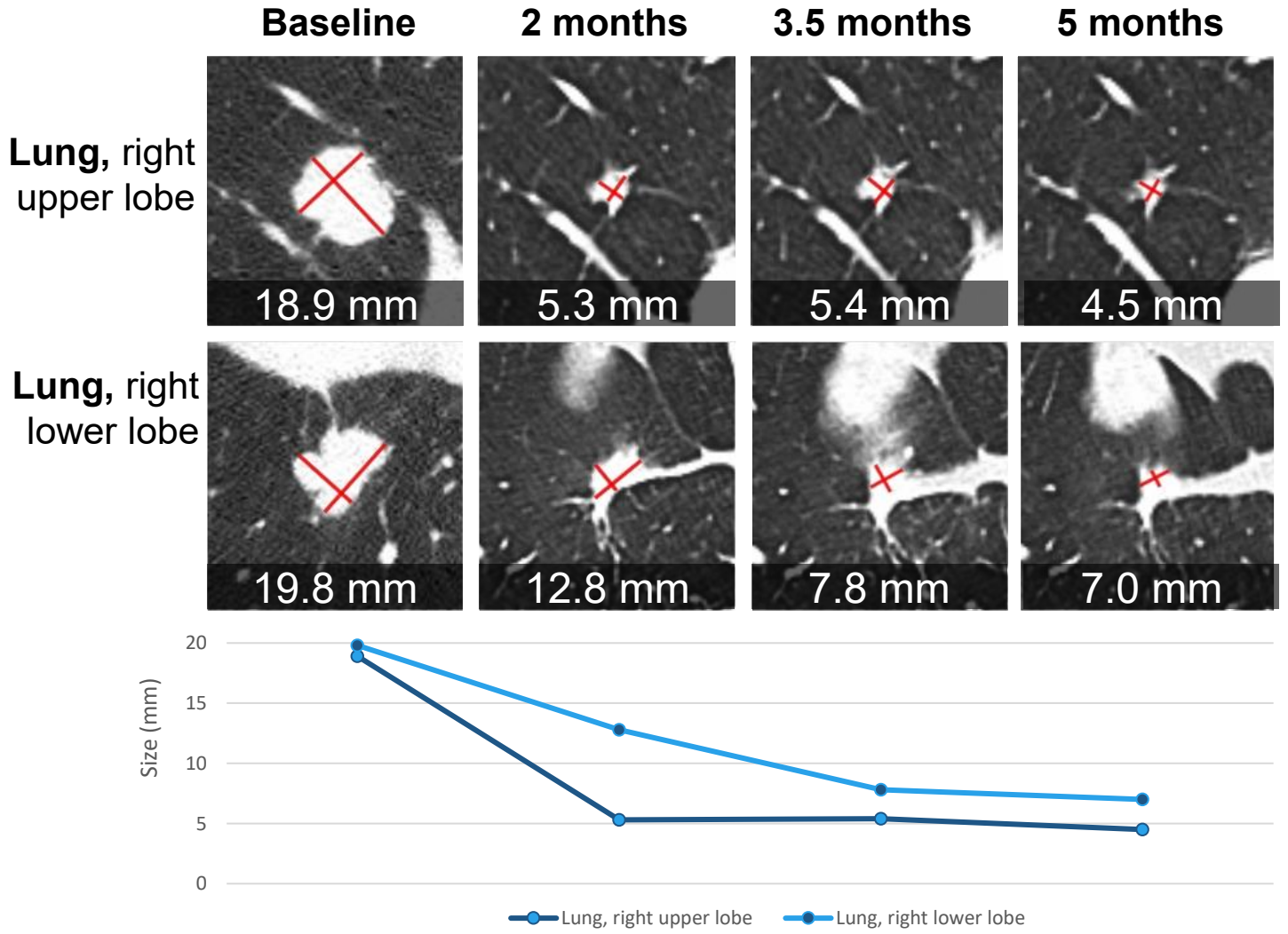
Durable Responses to IMA401 ± Pembrolizumab in Patients with H&N Cancer



Efficacy population: all patients in the safety set who received 4 IMA401 infusions in monotherapy and in addition at least 1 pembrolizumab infusion in combination therapy and had a post-baseline efficacy assessment, including patients with clinical progression; [a] One patient not shown in plot due to clinical progression before post-infusion scan. BOR, best overall response; cPR, confirmed partial response; DOR, duration of response; H&N, head and neck cancer; PD, progressive disease; PR, partial response; RECIST, response evaluation criteria in solid tumors; RP2D, recommended phase 2 dose; SD, stable disease.

Patient Case: Partial Response after IMA401 + Pembrolizumab since 5+ months in H&N Cancer

Patient Characteristics & Outcome	
Patient & Diagnosis	69-year-old male with HNSCC, initial diagnosis in September 2023
Disease at Baseline	**Multiple metastases** in lung and in one lymph node
Prior systemic therapy	**2 prior lines of systemic therapy with BOR SD** • Pembrolizumab, BOR: SD (adjuvant) • Pembrolizumab, carboplatin, 5-fluorouracil, BOR: SD (metastatic) • Progressed prior to IMA401 treatment
Study Treatment	**1.5 mg IMA401 + 400 mg pembrolizumab q6w**
Response Assessment	**Ongoing PR at 5+ months, BOR -70%**

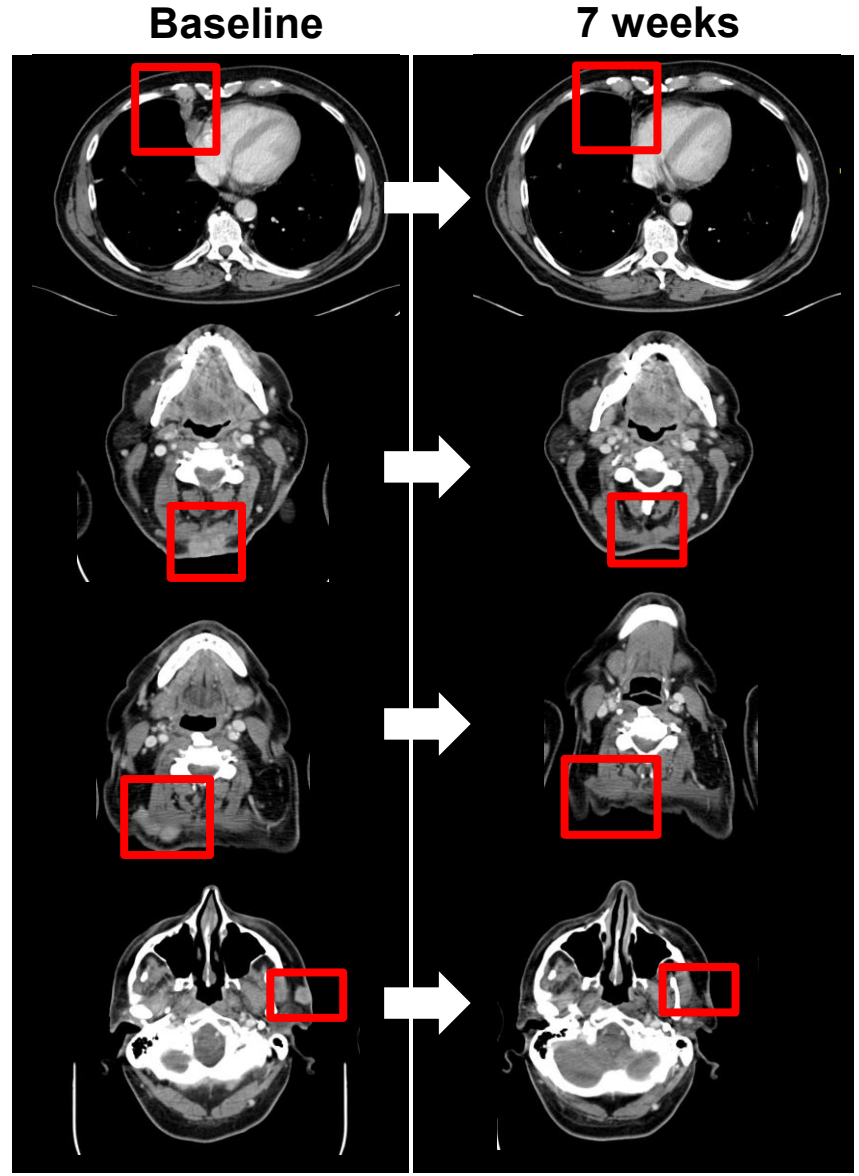


Scans courtesy of treating physician Dr. Moritz Kleemiß, UK Bonn; BOR, best overall response; H&N, head and neck; HNSCC, squamous cell carcinoma of the head and neck PR, partial response; q6w, every 6 weeks; SD, stable disease.

Patient Case: Partial Response after IMA401 + Pembrolizumab in sqNSCLC

Patient Characteristics & Outcome	
Patient & Diagnosis	63-year-old male with ICI-resistant sqNSCLC; initial diagnosis in July 2018
Disease at Baseline	**Multiple metastases** in lymph nodes, skin, lung and bone
Prior systemic therapy	**4 prior lines of systemic therapy with BOR SD** • Adjuvant: cisplatin, vinorelbine • Carboplatin, ipilimumab, nivolumab, paclitaxel, BOR: SD • Docetaxel, ramucirumab, BOR: SD • Progressed after all prior treatments • Carboplatin, gemcitabine, BOR: SD, discontinued early due to toxicity
Study Treatment[a]	**1 mg IMA401 + 400 mg pembrolizumab Q6W;** Pt died during a biopsy due to pulmonary haemorrhage
Response Assessment	**PR at first scan post IMA401 treatment start with -39% tumor reduction**

PR with IMA401 in 5th line ICI-resistant sqNSCLC patient with shrinkage of all target lesions

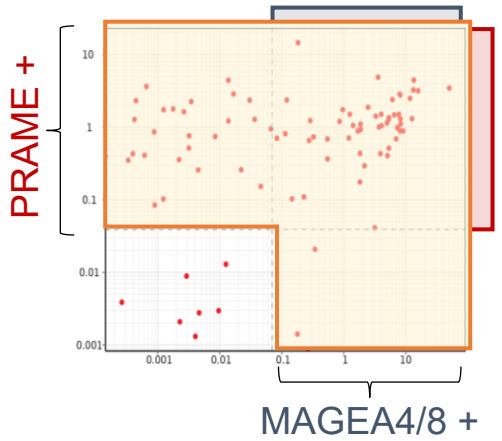


[a] Treatment start 5 weeks after last prior systemic therapy; scans courtesy of treating physician Prof. Dr. Martin Wermke, TU Dresden; BOR, best overall response; ICI, immune checkpoint inhibitor; PR, partial response; Pt, patient; Q6W, once every 6 weeks; SD, stable disease; sqNSCLC, squamous cell non-small cell lung cancer.

IMA401 MAGEA4/8 + IMA402 PRAME Bispecific Dual Targeting in sqNSCLC

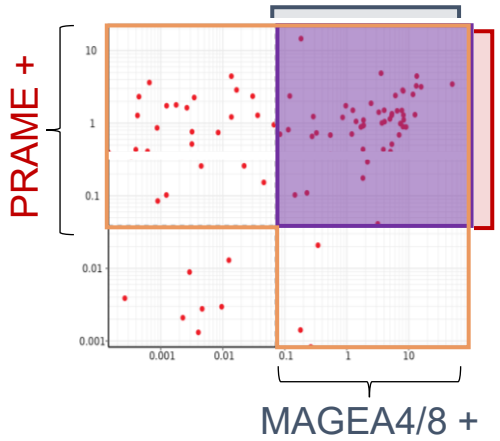
>90% of sqNSCLC

MAGEA4/8 OR PRAME

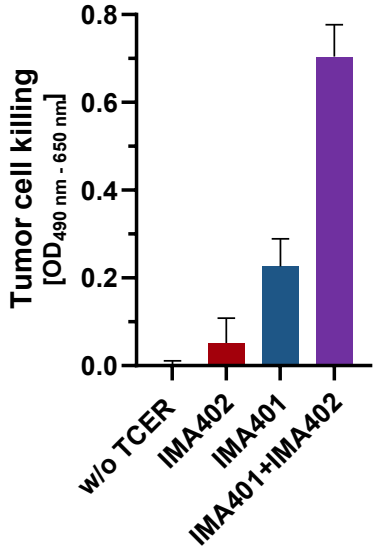


~60% of sqNSCLC

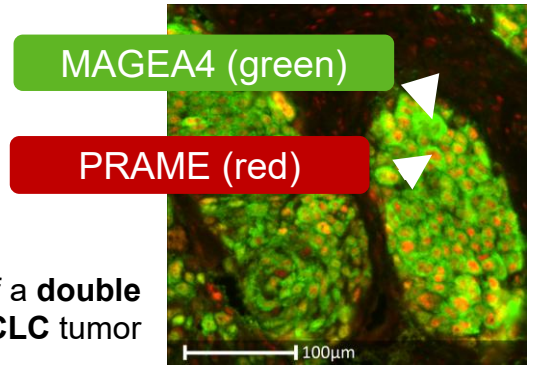
Double Positive



Double Positive Tumors:
Potentially Synergistic Anti-Tumor Activity



In vitro model of PRAME and MAGEA4/8 double positive tumor



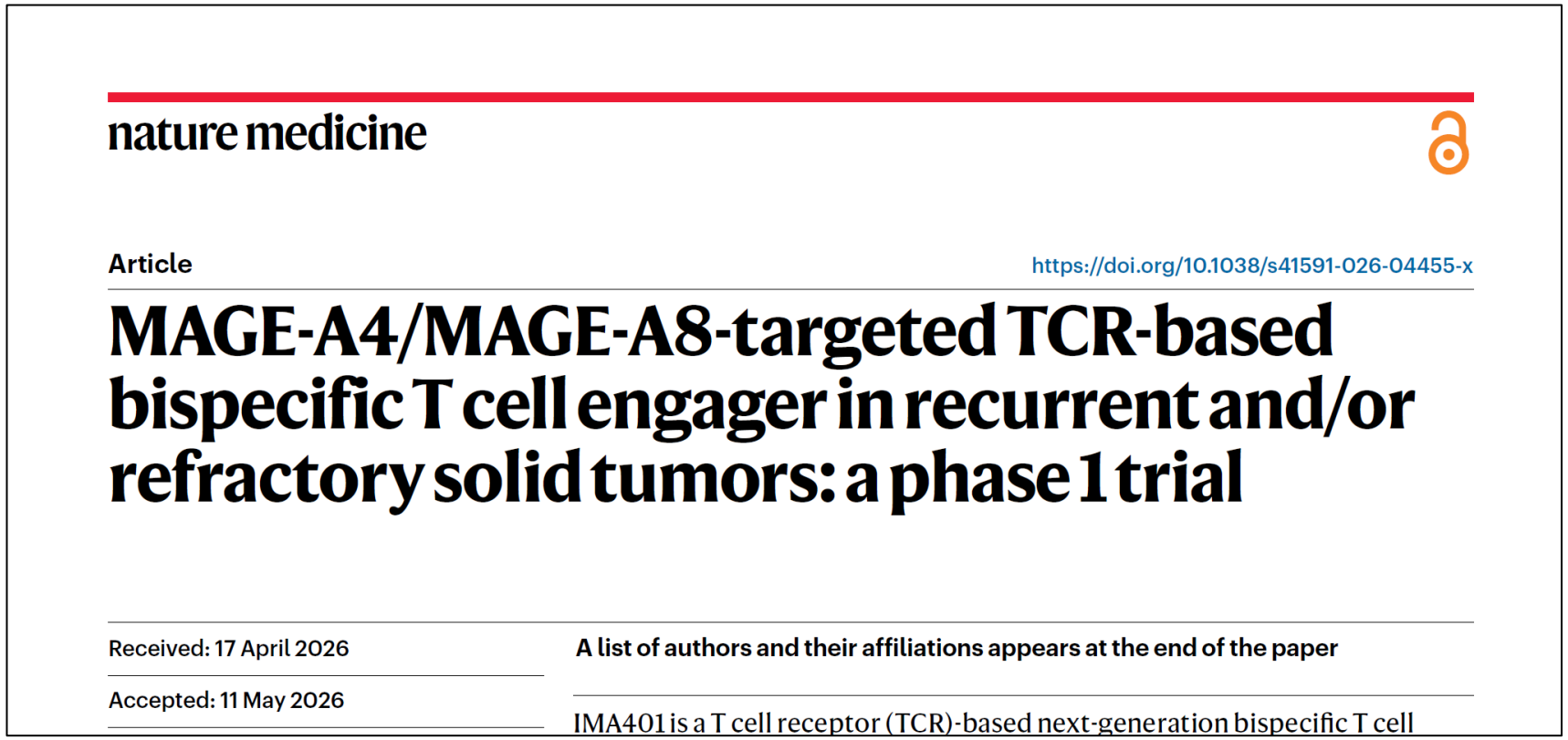
Representative duplex IF image of a **double positive human sqNSCLC** tumor

IMA402 PRAME Bispecific[a]

- PRAME is a cancer testis antigen expressed in more than 50 cancers
- IMA402 PRAME Bispecific Phase 1a dose escalation completed (NCT05958121)
  - Heavily pre-treated last-line patients
  - **Favorable tolerability in RP2D range** with no high-grade CRS, no ICANS
  - **30% (6/20) cORR** across all indications

Data on file - dot plot: PRAME and MAGEA4/8 mRNA expression in stage III/IV sqNSCLC TCGA samples (TPM, log-scale), PRAME and MAGEA4/8 target prevalences are based on an optimized proprietary target expression threshold applied to TCGA data; Bar graph: In vitro LDH-killing assay, A375 tumor cell line with low target density of PRAME (~50 copies per cell) and medium target density of MAGEA4/8 (~250 copies per cell), Bispecific concentration: 1nM IMA401 and 10 nM IMA402; [a] Immatics Corporate Data Release, Nov 2025, data cut-off Sep 26, 2025; cORR, confirmed objective response rate; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; IF, immunofluorescence; RP2D, recommended phase 2 dose; sqNSCLC, squamous cell non-small cell lung cancer.

Simultaneous Publication in Nature Medicine



nature medicine

Article

https://doi.org/10.1038/s41591-026-04455-x

MAGE-A4/MAGE-A8-targeted TCR-based bispecific T cell engager in recurrent and/or refractory solid tumors: a phase 1 trial

Received: 17 April 2026

Accepted: 11 May 2026

A list of authors and their affiliations appears at the end of the paper

IMA401 is a T cell receptor (TCR)-based next-generation bispecific T cell

Wermke et al., Nat. Med. 2026

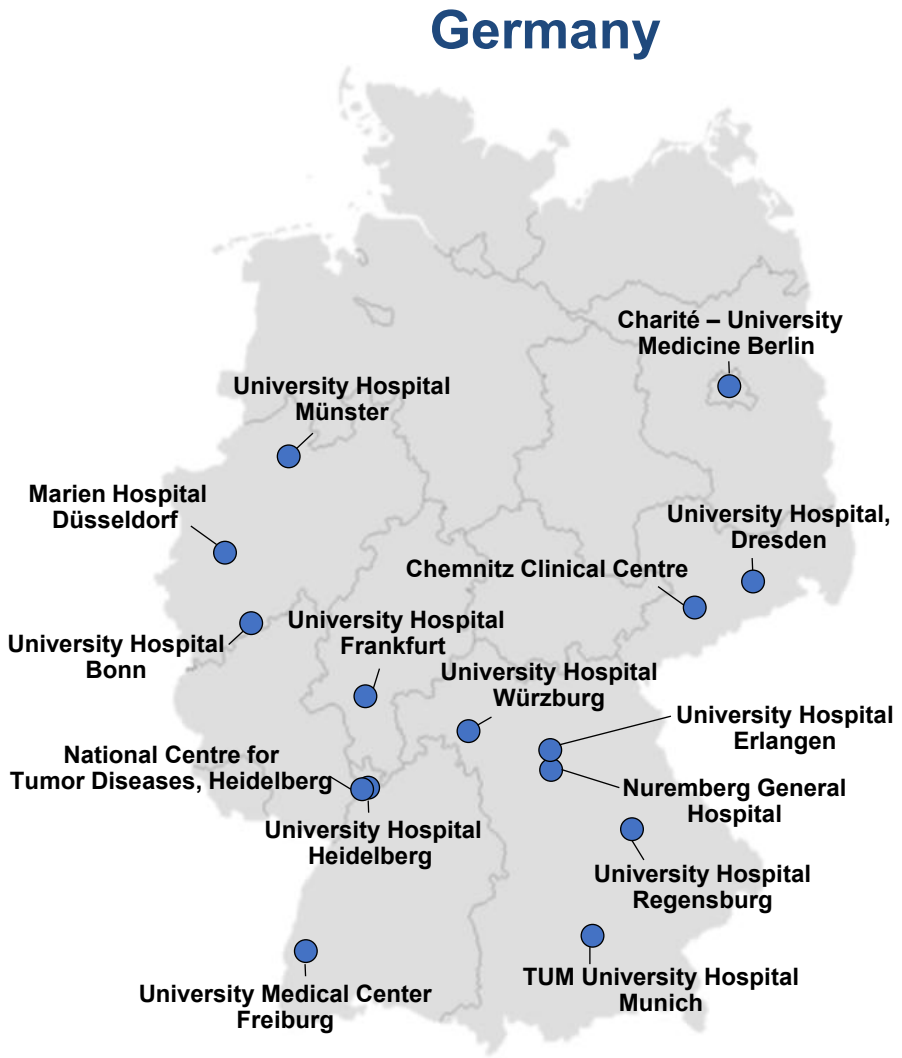
Key Takeaways

- TCR-based therapies enable immune recognition of intracellular tumor antigens presented by cell-surface HLA, expanding the therapeutic landscape beyond targets accessible to conventional immunotherapies
- **IMA401** is a novel TCR-based bispecific T-cell engager targeting MAGEA4/8, expressed in multiple cancers incl. head & neck cancer and sqNSCLC
- **IMA401** demonstrates a manageable tolerability profile and encouraging efficacy as monotherapy or in combination with ICI
- **Next steps** include a combination with a PRAME-directed TCR-based T-cell engager (IMA402) for >90% prevalence in sqNSCLC

HLA, human leukocyte antigen; head and neck (H&N) cancer (squamous cell and adenocarcinoma); ICI, immune checkpoint inhibitor; MAGE, melanoma-assicated antigen; PRAME, preferentially expressed in melanoma; sqNSCLC, squamous cell non-small cell lung cancer; TCR: T-cell receptor;

Dose escalation data presented by Wermke et al., ESMO 2024.

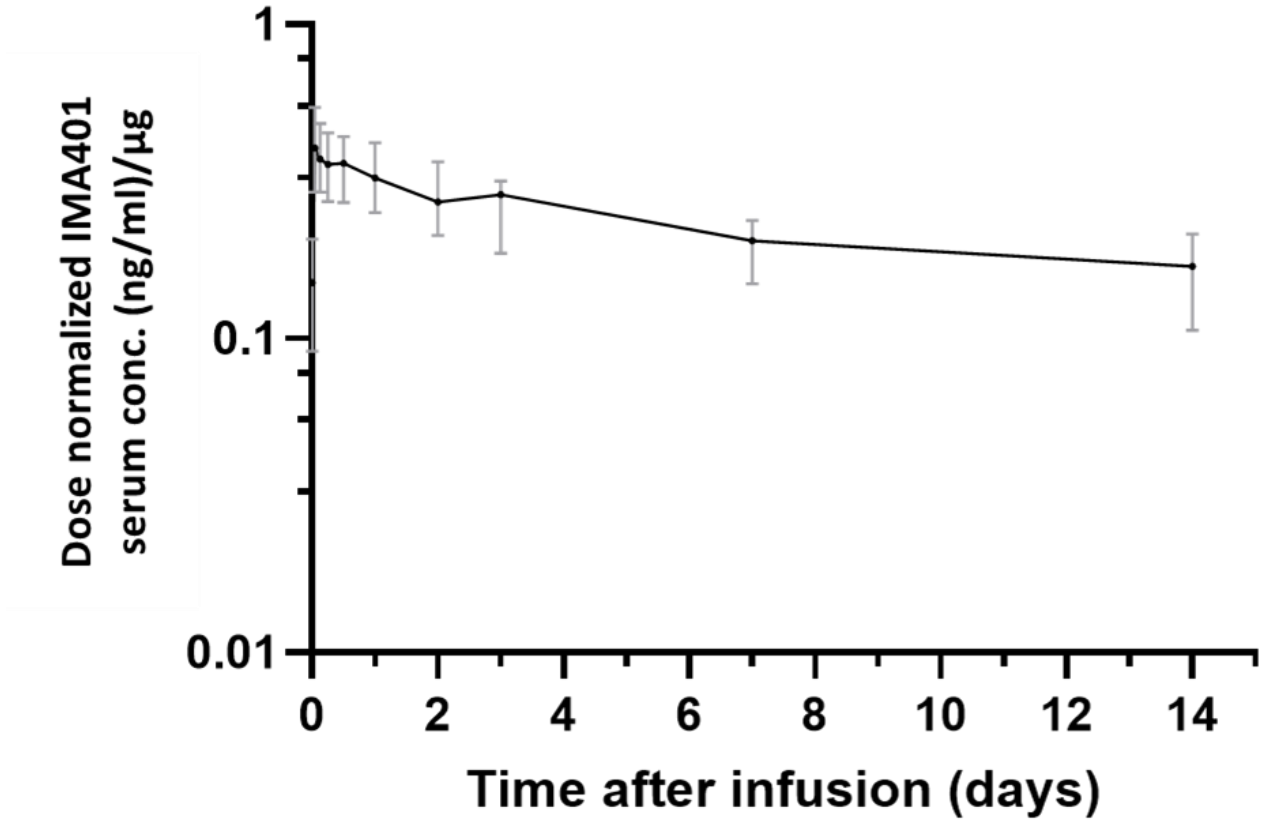
Thank You – Trial Participants & Caregivers



IMA401 Phase 1 Trial
Sponsor: Immatics

Appendix

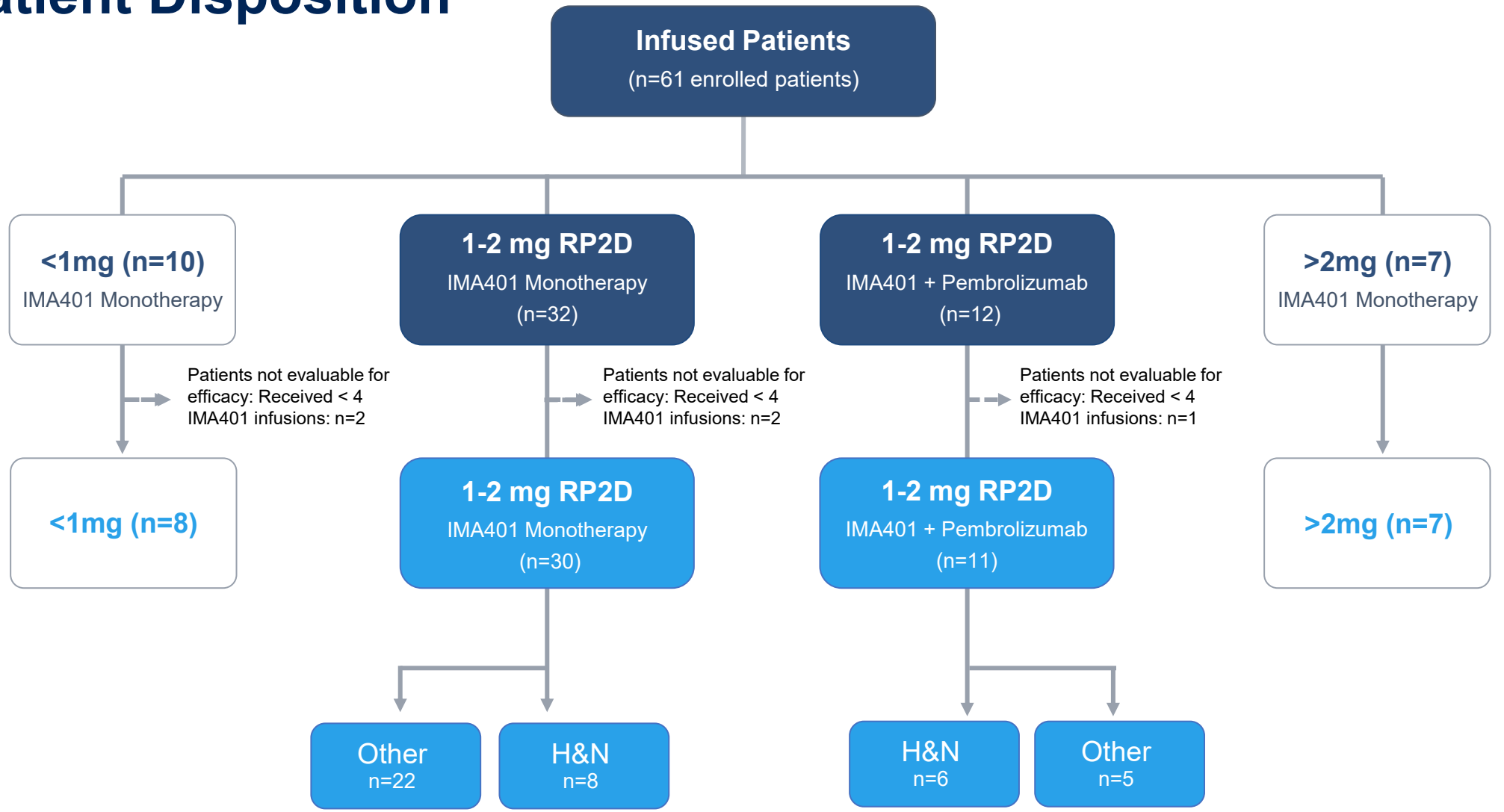
IMA401 Bispecific Pharmacokinetics in Patients



Median half-life:
17.5 days
(n=22)

Shown are the median and interquartile ranges (25-75%) for all patients with evaluable PK samples that received biweekly target doses at or above 1 mg.

Patient Disposition



Dose groups are shown according to highest actual IMA401 dose received at any time point, as initial target dose or via intrapatient dose escalation and as monotherapy or combination with pembrolizumab. Efficacy population: all patients in the safety set who received 4 IMA401 infusions in monotherapy and in addition at least 1 pembrolizumab infusion in combination therapy and had a post-baseline efficacy assessment, including patients with clinical progression; H&N, head and neck cancer; RP2D, recommended phase 2 dose.

Baseline Characteristics for IMA401 at RP2D ± Pembrolizumab in Patients with H&N Cancer

Baseline Characteristics (safety analysis set)	**H&N** RP2D (1-2mg) n = 14
Age (years), median (min, max)	62.5 (35, 70)
Sex, male/female n (%)	12 (86)/ 2 (14)
ECOG performance status	
0, n (%)	6 (43)
1, n (%)	8 (57)
2, n (%)	0 (0)
LDH at baseline	
< 1xULN, n (%)	9 (64)
1-2xULN, n (%)	5 (36)
> 2xULN, n (%)	0 (0)
Baseline tumor burden	
Median target lesion sum of diameter (mm) (min, max)	54.1 (15.5, 129.0)
Tumor lesions	
Number of lesions, median (min, max)	3 (2, 10)
Liver metastases, n (%)	3 (21)
Brain metastases, n (%)	0 (0)
Treatment Experience	
No. of prior lines of systemic treatment median (min, max)	2.5 (1, 8)
Prior treatments, n (%)	
Chemotherapy	12 (86)
ICI	11 (79)
Targeted Therapy[a]	10 (71)
Hormone Therapy	1 (7)
Others	0 (0)

Baseline Characteristics (safety analysis set)	**H&N** RP2D (1-2mg) n = 14
Main tumor location, n (%)	
Oral cavity	8 (57)
Larynx	2 (14)
Hypopharynx	1 (7)
Other	3 (21)
p16, n (%):	
p16-positive	3 (21)
p16-negative	2 (14)
p16 unknown	9 (64)

All H&N patients treated in the IMA401 + pembrolizumab combination cohort received prior ICI

This Phase 1 basket trial was not specifically designed for H&N cancer; therefore, some H&N subclassification data may be limited or not fully conclusive. ECOG, Eastern Cooperative Oncology Group; H&N, head and neck; ICI, immune checkpoint inhibitor; LDH, lactate dehydrogenase; RP2D, recommended phase 2 dose; ULN, upper limit of normal.

Summary of AEs in Patients treated with IMA401 ± Pembrolizumab

Safety Summary (safety analysis set)	**All treated patients**	**IMA401 (Monotherapy)**		**IMA401 + Pembrolizumab**
	All DL N=61	**1-2 mg (RP2D) n=32**	**>2 mg n=7**	**1-2mg (RP2D)[a] n=12**
Any SAE	24 (39)	8 (25)	6 (86)	4 (33)
Treatment-related SAEs	11 (18)	5 (16)	3 (43)	1 (8)
Dose reduction due to AE	4 (7)	3 (9)	1 (14)	0
Dose interruption due to AE	4 (7)	3 (9)	0	1 (8)
Dose delayed due to AE	13 (21)	6 (19)	4 (57)	1 (8)
Dose discontinuation due to AE	4 (7)	1 (3)	1 (14)	1 (8)
Deaths due to AE[b]				
due to related AEs	1 (2)	0	1 (14)	0
due to unrelated AEs	2 (3)	0	0	2 (17)
AEs of special interest				
CRS	23 (38)	12 (38)	3 (43)	5 (42)
ICANS	0	0	0	0

[a] IMA401 dose in pembrolizumab expansion cohorts were 1 mg (n=8) or 1.5 mg (n=4); [b] Two of the three deaths were unrelated to IMA401 and/or pembrolizumab. One treatment-unrelated death was due to pulmonary hemorrhage (biopsy-related) and the other was due to respiratory failure (unrelated). AE, adverse event; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; RP2D, recommended phase 2 dose; SAE, serious adverse events.

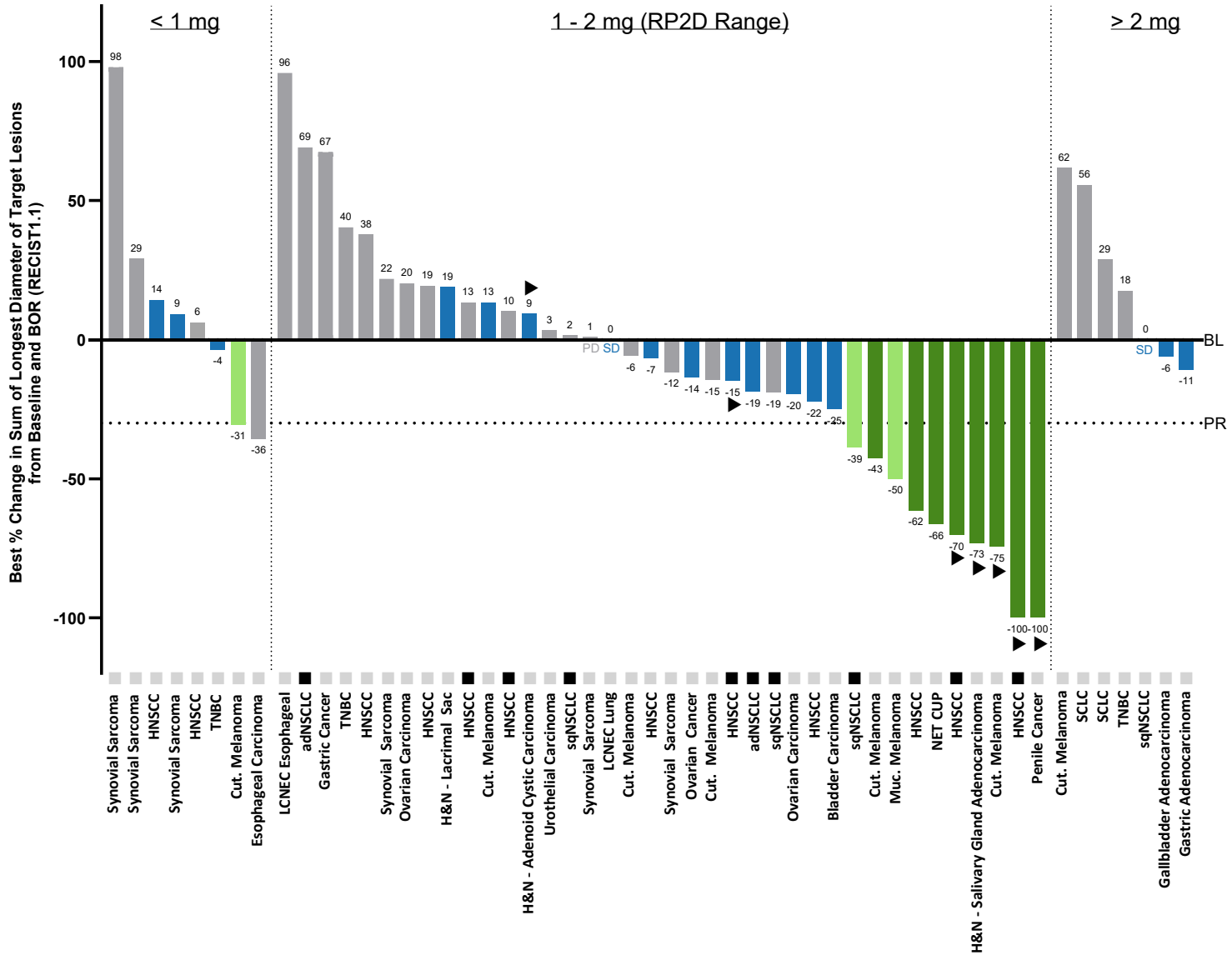
Tolerability of IMA401 at RP2D ± Pembrolizumab in all Indications and in Patients with H&N Cancer

	IMA401 RP2D (1-2 mg) ± Pembrolizumab		IMA401 RP2D (1-2 mg) ± Pembrolizumab	
Treatment-related Adverse Events (safety analysis set)	**all indications** n=44		**H&N** n=14	
TRAEs[a], n (%)	All Grades	≥ Grade 3	All Grades	≥ Grade 3
Any TRAE	39 (89)	19 (43)	14 (100)	5 (36)
Cytokine release syndrome	17 (39)	0	6 (43)	0
Lymphopenia	13 (30)	9 (20)	4 (29)	2 (14)
Neutropenia	12 (27)	5 (11)	4 (29)	1 (7)
Thrombocytopenia	6 (14)	0	2 (14)	0
Leukopenia	8 (18)	4 (9)	1 (7)	0
Headache	7 (16)	1 (2)	2 (14)	0
Anaemia	2 (5)	2 (5)	0	0
Facial pain	0	0	0	0
Alanine aminotransferase increased	5 (11)	1 (2)	1 (7)	0
Pyrexia	5 (11)	0	2 (14)	0
Aspartate aminotransferase increased	4 (9)	2 (5)	0	0
Hypertension	3 (7)	2 (5)	1 (7)	1 (7)
Gamma-glutamyltransferase increased	1 (2)	1 (2)	1 (7)	1 (7)
Hypoxia	0	0	0	0
C-reactive protein increased	1 (2)	1 (2)	0	0
Chest pain	0	0	0	0
Febrile neutropenia	0	0	0	0
Pneumonia	0	0	0	0
Sinus tachycardia	1 (2)	1 (2)	0	0

Data cutoff Mar 02, 2026.

[a] All TRAEs at least possibly related to IMA401 infusion and/or pembrolizumab infusion with grade 1-2 occurring in at least 10% of all SAS patients, all events with ≥ grade 3; CSF, colony-stimulating factor, CRS, cytokine release syndrome, H&N, head and neck; RP2D, recommended phase 2 dose; TRAE, treatment-related adverse event.

BOR of IMA401 at all DLs ± Pembrolizumab



BOR (RECIST 1.1)
- PD
- SD
- PR
- cPR
- ▶ Ongoing response/ disease control

- ■ IMA401 + Pembrolizumab
- ■ IMA401 monotherapy

Three patients treated at RP2D not shown in plot due to clinical progression before post-infusion scan; BOR, best overall response; cPR, confirmed partial response; H&N, head and neck cancer; sq/adNSCLC, squamous cell/adenocarcinoma non-small-cell lung cancer; LCNEC, large cell neuroendocrine carcinoma; NET CUP, neuroendocrine cancer of unknown primary; PD, progressive disease; PR, partial response; RP2D, recommended phase 2 dose; RECIST, Response Evaluation Criteria in Solid Tumors; SCLC, small cell lung cancer; SD, stable disease; TNBC, triple-negative breast cancer.

Clinical Responses of IMA401 at RP2D ± Pembrolizumab in Patients with H&N Cancer

Indication	No of prior treatment lines	List of prior treatment lines	Highest dose received (mg)	Pembrolizumab (≥ one dose)	Baseline Tumor Burden (mm)[a]	BOR (RECIST 1.1)	BOR (Max % change of target lesions)	PFS (months)	Ongoing treatment
H&N – HNSCC	3	Carboplatin/ Cetuximab/ Pembrolizumab/ Nivolumab Nivolumab/ Cisplatin Cetuximab/ Fluorouracil/ Carboplatin	1.5	Yes	16	cPR	-100	7.6 (ongoing)	Yes
H&N – Salivary gland adenocarcinoma	1	Cisplatin	2	No	32	cPR	-73	14.9 (ongoing)	Yes
H&N – HNSCC	2	Pembrolizumab Pembrolizumab/ Carboplatin/ Fluorouracil	1.5	Yes	39	cPR	-70	5.3 (ongoing)	Yes
H&N – HNSCC	3	Cisplatin/ Carboplatin Pembrolizumab/ Fluorouracil/ Carboplatin Cetuximab/ Docetaxel	2	No	39	cPR	-62	10.2	Yes
H&N – HNSCC	3	Cisplatin/ Carboplatin Nivolumab Cisplatin/ Cetuximab/ Docetaxel	1.5	No	67	SD	-22	2.6	No
H&N – HNSCC	3	Cisplatin Cisplatin/ Fluorouracil sodium/ Pembrolizumab Cetuximab/ Paclitaxel	1	Yes	121	SD	-15	2.8 (ongoing)	Yes
H&N – HNSCC	2	Cisplatin Carboplatin/ Paclitaxel/ Cetuximab	1.2	No	59	SD	-7	2.4	No
H&N – Adenoid cystic carcinoma of submandibular gland	1	Axitinib	1	No	55	SD	9	3.7 (ongoing)	Yes
H&N – Squamous cell carcinoma right lacrimal sac	1	Cemiplimab	1.5	No	53	SD	19	2.2	No
H&N – HNSCC	2	Cisplatin Carboplatin/ Fluorouracil/ Pembrolizumab	1	Yes	29	PD	10	1.4	Yes
H&N – HNSCC	2	Pembrolizumab/ Cisplatin/ Fluorouracil Cetuximab	1	Yes	82	PD	13	1.1	No
H&N – HNSCC	3	Pembrolizumab Docetaxel Cetuximab	1.2	No	129	PD	19	1.4	No
H&N - HNSCC	8	Cisplatin Carboplatin/ Paclitaxel Tipifarnib Tipifarnib/ Bicalutamide/ Triptorelin VB-N-10-NEO/ Atezolizumab Trastuzumab deruxtecan/ Darolutamide Abiraterone/ Trastuzumab deruxtecan Sacituzumab govitecan	1.8	No	37	PD	38	1.2	No
H&N – HNSCC	3	Cisplatin Dostarlimab/ Nelistotug Carboplatin/ Paclitaxel/ Cetuximab	1	Yes	110	N/A	N/A[b]	1.4	No

[a] Target lesion sum of diameter; [b] Max change not shown due to clinical progression before post-infusion scan; BOR, best overall response; (c)PR, (confirmed) partial response; H&N, head and neck cancer; PD, progressive disease; RP2D, recommended phase 2 dose; SD, stable disease.

Data cutoff Mar 02, 2026

Thank you