

2024 ASCO Annual Meeting

1100 Data Update

June 2nd, 2024

(Database cutoff: 17 April 2024)

NANOBIOTI

2024 ASCO

Annual Meeting

Abstract #6035

“Early signs of efficacy in patients with anti-PD-1 naïve and anti-PD-1 resistant HNSCC treated with NBTXR3/SBRT in combination with nivolumab or pembrolizumab in the phase I trial Study 1100”

Colette Shen¹, Jessica Frakes², Trevor Hackman¹, Jiaxin Niu³, Jared Weiss¹, Jimmy Caudell², George Yang², Tanguy Seiwert⁴, Paul Chang⁵, Septimiu Murgu⁵, Siddharth Sheth¹, Shetal Patel¹, Kedar Kirtane², David Rolando⁶, Pavel Tyan⁶, Omar I. Vivar⁶, Zhen Gooi⁵, Aditya Joolori⁵, Ari Rosenberg⁵

¹University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA; ²Moffitt Cancer Center, Tampa, Florida, USA; ³Banner MD Anderson Cancer Center, Gilbert, Arizona, USA;

⁴Johns Hopkins Medicine, Baltimore, Maryland, USA; ⁵The University of Chicago, Chicago, Illinois, USA; ⁶Nanobiotix, SA, Paris, France

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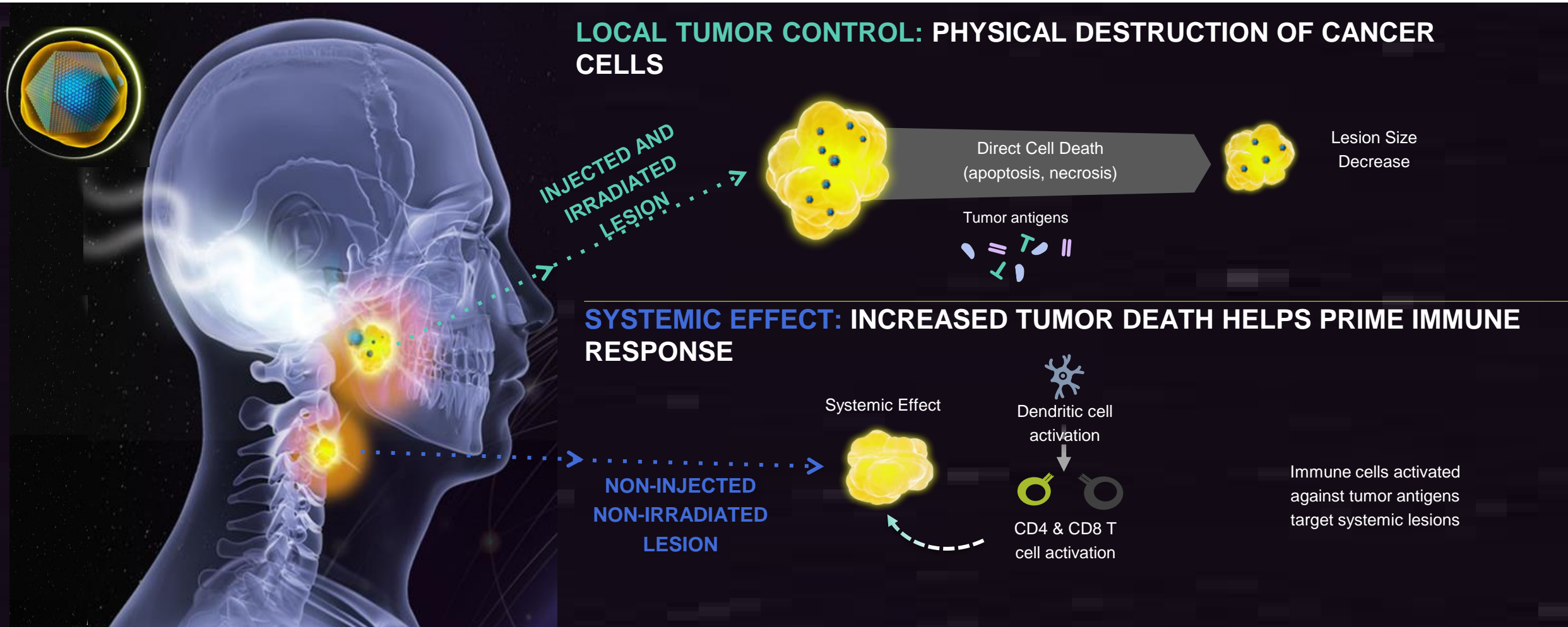
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Local Cell Destruction Induced by NBTXR3 Activates Immune Priming

Local and systemic benefits through cell death and immune activation against tumor antigens



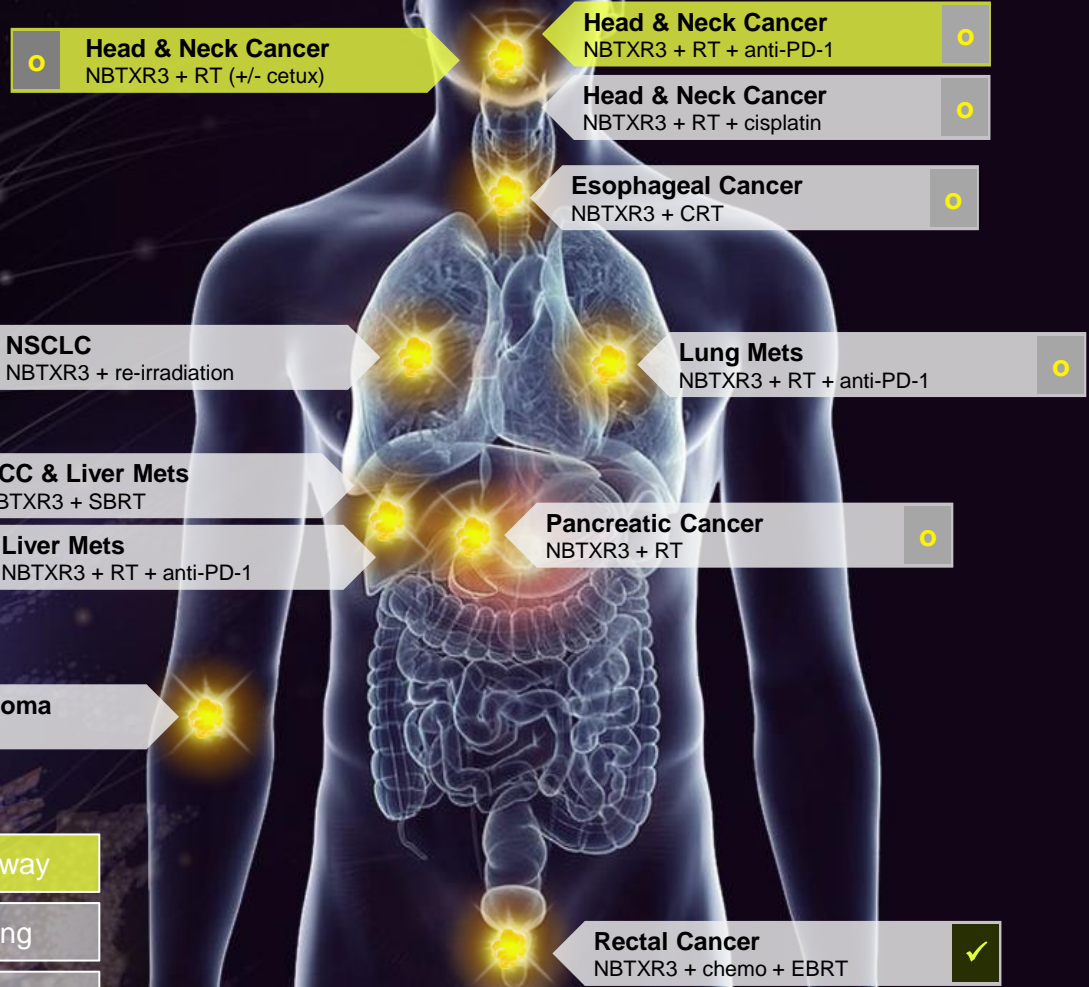
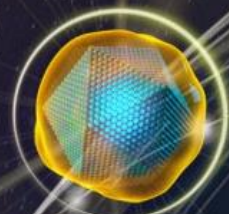
Potential Tumor-Agnostic, Combination-Agnostic Treatment

PoC when activated by RT alone, positive Ph 3 in STS

Potential for multiple SOC, including IO

100+ Clinical sites worldwide

Hundreds of patients treated, showing safety, feasibility and consistent tumor response



- Priority Pathway
- Trial Ongoing
- Trial Completed

Evaluating Tumor Agnostic, Combination Agnostic NBTXR3 Capabilities

Patients (Current Study)	N	Phase 1	Phase 2	Phase 3	Operational Sponsor	Milestone
Head & Neck						
Elderly Cisplatin-ineligible (NANORAY-312, RT-R3 ± cetuximab vs RT ± cetuximab)	500				Nanobiotix Janssen*	Last Patient Recruited 1H26
R/M IO Naïve (Study 1100, RT-R3 fb anti-PD-1)	35+				Nanobiotix	New Data 1H24
R/M IO Resistant (Study 1100, RT-R3 fb anti-PD-1)	35+				Nanobiotix	New Data 1H24
R/M (MDA-0541, RT-R3 fb anti-PD-1)	60				MD Anderson Cancer Center	–
Lung						
Inoperable, Stage 3	NA				Janssen	First Patient Randomized
Inoperable, Recurrent (MDA-0123, Reirradiation RT-R3)	24				MD Anderson Cancer Center	First Data 1H25
Expansion Opportunities						
Soft Tissue Sarcoma (Act.In.Sarc, RT-R3 fb resection)	180				Nanobiotix	Completed
Rectal (Study 1001, RT-R3 concurrent CT)	32				Nanobiotix	Completed
Advanced Solid (MDA-0618, RT-R3 with anti-PD-1)	40				MD Anderson Cancer Center	–
Cisplatin-eligible H&N (Study 1002, RT-R3 concurrent CT)	12				Nanobiotix	Completed
HCC & Liver Mets (Study 103, RT-R3)	23				Nanobiotix	Completed
Pancreas (MDA-1001, RT-R3)	24				MD Anderson Cancer Center	Updated Data 2H24
Esophageal (MDA-0122, RT-R3 concurrent CT)	24				MD Anderson Cancer Center	First Data FY25
IO Resistant Multiple Primary Tumors (Study 1100, RT-R3 fb anti-PD-1)	35+				Nanobiotix	First Data FY25

Head and Neck Squamous Cell Carcinoma Cancer Care

Head and Neck Cancer Treatment With Check Point Inhibitors

A circular infographic with a teal border and a light grey center. The number '90%' is written in teal inside the circle.

90%

90% of H&N patients
are diagnosed with local / loco-regional disease

1st line treatment is often chemotherapy, radiation and surgery in combination

When patients fail those front-line treatments, they are eligible to anti-PD-1 treatment as 2nd treatment line or more (e.g. Keynote 040¹, CheckMate-141²)

A circular infographic with a blue border and a light grey center. The number '10%' is written in blue inside the circle.

10%

10% of H&N patients
are diagnosed with mets and are eligible for anti-PD-1 as 1st line (e.g. Keynote-048³)

Important parameters defining outcomes when treated with anti-PD-1:

- CPS score: below 1%, 1 to 20%, and above 20%
- HPV status for oropharynx
- Number of prior line of treatment, and exposure to previous systemic treatment

Post anti-PD-1 failure

There is no established standard of care leading to poor outcome for patients in 3rd line

Head and Neck Cancer Treatment With Check Point Inhibitors

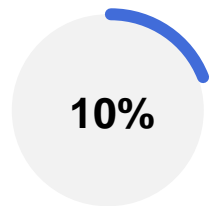


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NBTXR3
Study 1100

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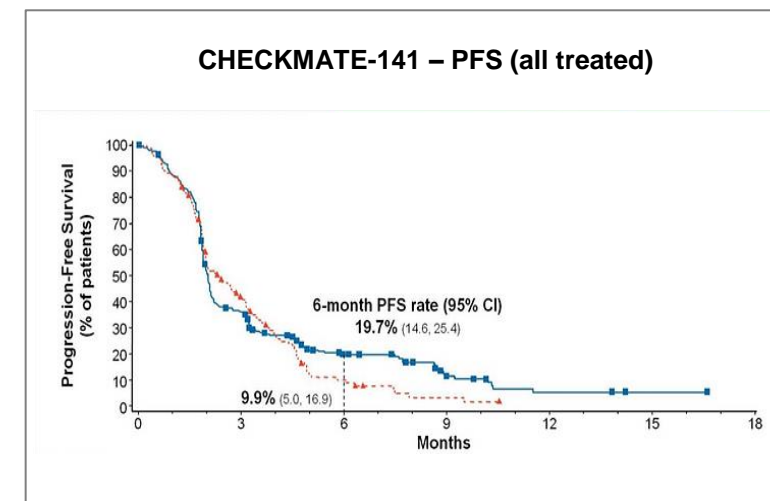
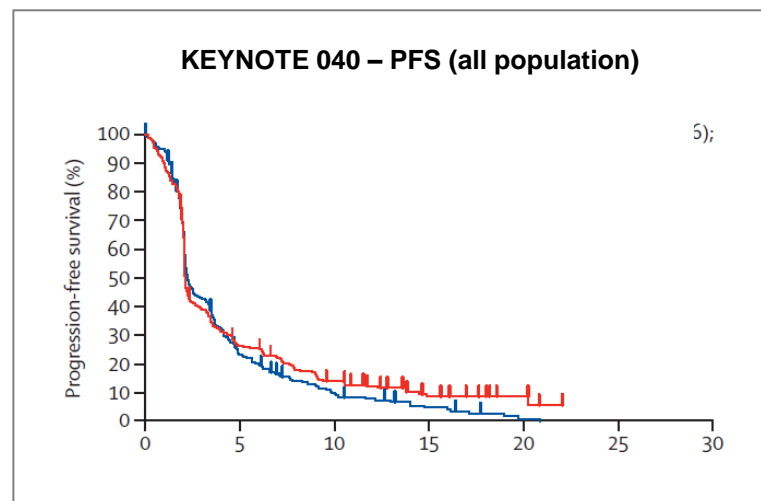
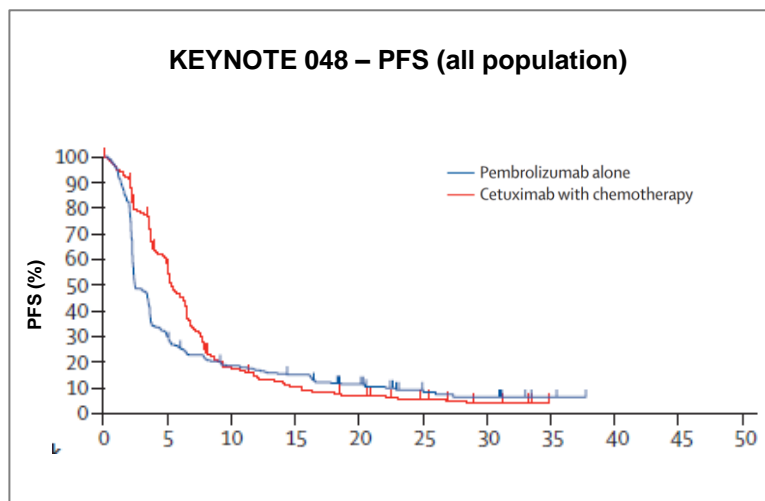
NBTXR3
Study 1100

Outcomes Remain Limited for Patients Treated With Anti-PD-1 in 1st, 2nd or Further Lines of Treatment: PFS is Short and Many Patients do not Respond

Line of anti-PD-1 therapy	1 st line treatment	2 nd or further line treatment	
Study	Keynote 048 ⁽³⁾	Keynote 040 ⁽¹⁾	CheckMate-141 ⁽²⁾
	Pembrolizumab N=301	Pembrolizumab N=247	Nivolumab N=240
ORR	16.9%	14.6%	13.3%
PFS	2.3	2.1	2.0
OS	11.5	8.4	7.5

Populations enrolled in reference trials have overall similar baseline characteristics as patients enrolled in Study 1100 with R/M HNSCC

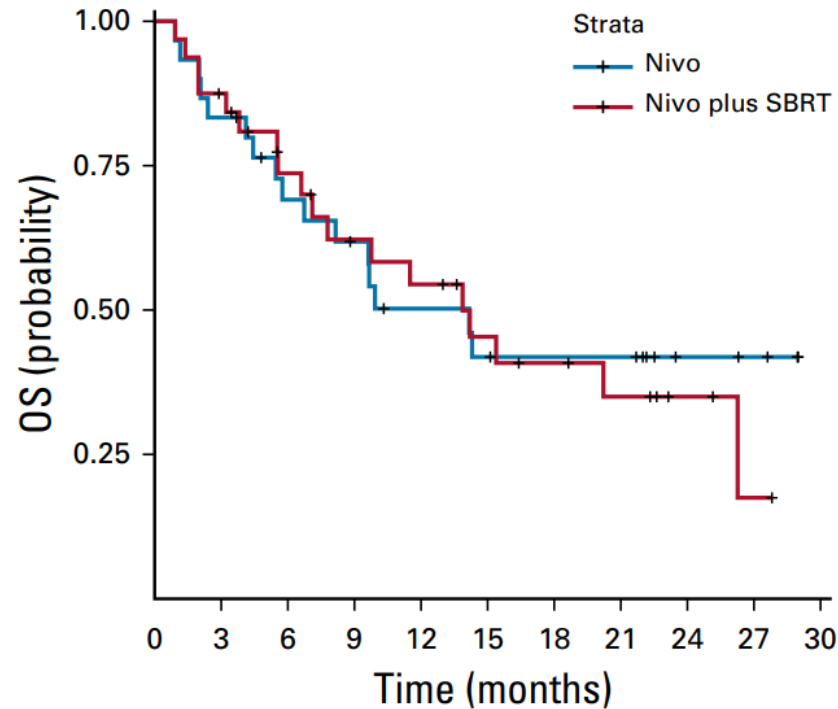
(1) Burtness B., 2019: « Participants were excluded if they had progressive disease within 6 months of curatively intended systemic treatment given for locoregionally advanced disease[...]; (2) Ezra, 2018; (3) Ferris, 2016



MSKCC Phase 2 Trial Exploring Nivolumab vs Nivolumab + SBRT¹

Addition of RT to Nivolumab does not improve OS in Naïve patient to PD-1

Overall Survival



No. at risk:

Nivo	30	25	19	16	12	10	9	9	4	3	0
Nivo plus SBRT	32	27	20	16	14	10	8	6	3	1	0

1100 Study – Data Update

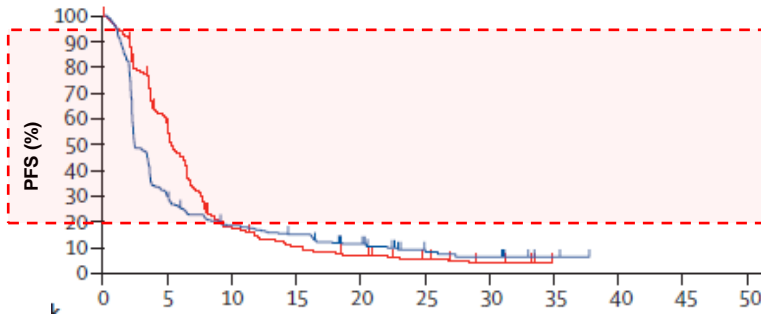
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Outcomes Remain Limited for Patients Treated With Anti-PD-1 in 1st, 2nd or Further Lines of treatment: PFS is Short and Many Patients do not Respond

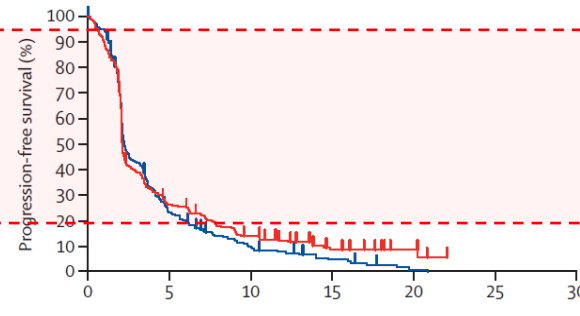
Anti-PD-1 treatment as 1st line of treatment

KEYNOTE 048³ – PFS (all population)

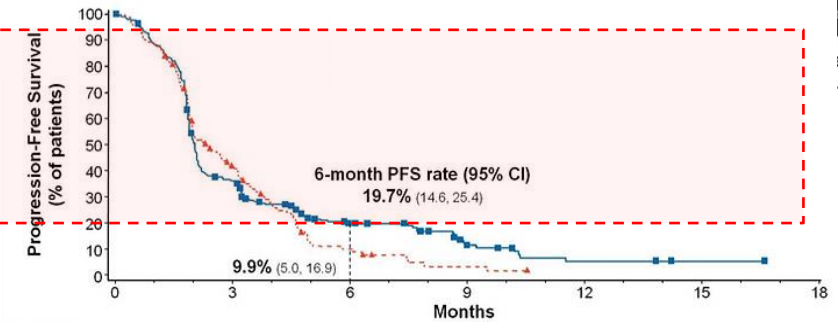


Anti-PD-1 treatment as 2nd or further line of treatment

KEYNOTE 040¹ – PFS (all population)



CHECKMATE-141² – PFS (all treated)



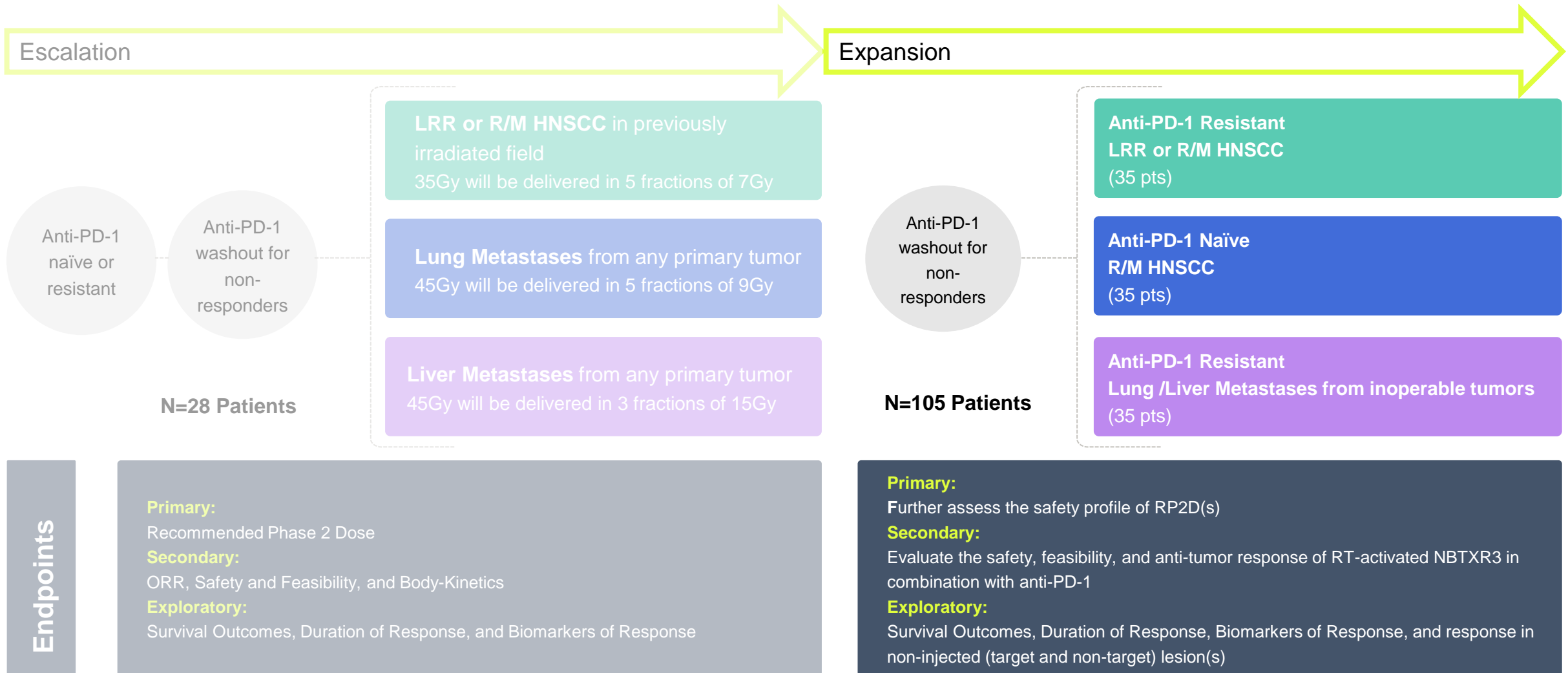
Primary and secondary non-responders to anti-PD-1 treatment

By providing local control and priming an immune response with NBTXR3 + RT, we intend to:

1. Improve responses and deepness of immune responses for patients naive to anti-PD-1
2. Reverse resistance to anti-PD-1 for refractory patients

Study 1100 Potential Immunotherapy Combination

Study design



Baseline Characteristics

1100 Data Update

Baseline Characteristics of R/M HNSCC Patients in Study 1100

	ICI Naive N=33	ICI Resistant N=35	All N=68
Age (years)			
Missing	0	0	0
n	33	35	68
Mean (SD)	64.1 (8.6)	63.5 (9.5)	63.8 (9.0)
Median	63.0	64.0	63.5
Min ; Max	46 ; 80	45 ; 85	45 ; 85
ECOG Performance status			
Missing	1	0	1
n	32	35	67
0	13 (40.6)	16 (45.7)	29 (43.3)
1	17 (53.1)	19 (54.3)	36 (53.7)
2	2 (6.3)		2 (3.0)
Prior anti-PD-1			
Missing	5	3	8
n	28	32	60
Yes	2 (7.1) ⁽¹⁾	32 (100)	34 (56.7)
No	26 (92.9)		26 (43.3)
Number of prior treatment lines			
Missing	5	4	9
n	28	31	59
1-2	25 (89.3)	11 (35.5)	36 (61.0)
3-4	2 (7.1)	12 (38.7)	14 (23.7)
5+		8 (25.8)	8 (13.6)

* 10 ICI naive patients have Oropharynx cancer and HPV+

** 12 ICI resistant patients have Oropharynx cancer and HPV+

	ICI Naive N=33	ICI Resistant N=35	All N=68
Number of lesions			
Missing	4	1	5
n	29	34	63
1	10 (34.5)	7 (20.6)	17 (27.0)
2-3	12 (41.4)	7 (20.6)	19 (30.2)
4+	7 (24.1)	20 (58.8)	27 (42.9)
HPV status			
Missing	1	0	1
n	32	35	67
Negative	17 (53.1)	13 (37.1)	30 (44.8)
Positive	11 (34.4)*	18 (51.4)**	29 (43.3)
Unknown	4 (12.5)	4 (11.4)	8 (11.9)
Smoking status			
Missing	0	0	0
n	33	35	68
Former smoker	16 (48.5)	22 (62.9)	38 (55.9)
Nonsmoker	8 (24.2)	10 (28.6)	18 (26.5)
Current smoker	9 (27.3)	3 (8.6)	12 (17.6)
Combined Positive Score (CPS) testing (%)			
Missing	17	9	26
n	16	26	42
< 1%		4 (15.4)	4 (9.5)
[1%-20%]	12 (75.0)	11 (42.3)	23 (54.8)

⁽¹⁾Two patients were included approximately two years after having finished ICI therapy as part of definitive/adjuvant therapy: one patient received 4 month Durvalumab treatment, one patient received 10 month nivolumab treatment.

Safety

1100 Data Update

Safety – Few Treatment Emergent Adverse Events (TEAE) Related to NBTXR3

Confirmed safety profile of NBTXR3 activated by RT in both ICI naïve and ICI resistant patients

	ICI Naïve N=33 Patients (%) [AEs]	ICI Resistant N=35 Patients (%) [AEs]	All treated N=68 Patients (%) [AEs]
All TEAEs	24 (72.7) [122]	31 (88.6) [221]	55 (80.9) [343]
Grade ≥ 3 TEAEs:			
related to NBTXR3	1 (3.0) [2] ¹	1 (2.9) [1] ¹	2 (2.9) [3]
related to injection procedure	2 (6.1) [2]	2 (5.7) [2] ¹	4 (5.9) [4]
related to radiotherapy	1 (3.0) [1]	6 (17.1) [6] ¹	7 (10.3) [7]
TEAEs related to anti-PD1	2 (6.1) [5] ¹	2 (5.7) [2]	4 (5.9) [7]
Grade ≥ 3 Serious TEAEs related to radiotherapy or injection procedure or anti-pd-1 or NBTXR3, or a combination	3 (9.1) [5] ^{1,2}	3 (8.6) [3]	6 (8.8) [8]

¹ Same TEAEs reported several times in each category by investigators due to multiple causalities

² 1 patient experienced Grade 5 pneumonitis related to anti-PD-1 and possibly to NBTXR3; this patient did not receive injection in the lungs

- A single NBTXR3 intra-tumoral injection followed by SBRT activation was safe and feasible
- Less than 10% of Grade ≥ 3 serious TEAEs related to NBTXR3, injection procedure, radiotherapy or anti-PD-1
- Approximately 10% of Grade ≥ 3 TEAEs were related to radiotherapy, which is in line with reported data
- No unexpected side effect emerged related to radiotherapy/NBTXR3 or anti-PD-1 or injection procedure

AE occurrences are grouped in episodes when there is a chronologic continuity and no change in relationship to NBTXR3, injection, radiotherapy, anti-PD1, disease or other

Patients = number of patients with at least one TEAE and AEs = number of events.

Events are considered treatment related when reported as 'Possibly related' or 'Related' to NBTXR3, injection procedure, radiotherapy and/or anti-PD1

Efficacy

Patients Naïve to Anti-PD-1

1100 Data Update

Baseline Characteristics of R/M HNSCC Patients Naive to Anti-PD-1

Similar population as in the Keynote 040 (pembrolizumab) and CheckMate-141 (nivolumab)^

33 patients treated evaluable for safety
25 evaluable for efficacy at the cutoff date

Heavy tumor burden

Highly pre-treated patients

CPS score

- 75% of patients* **below 20%**

HPV status:

- 10 patients* with oropharynx with HPV+ status among the 33 patients

Number of lesions	ICI Naive (N=33)
Missing	4
n	29
1	10 (34.5)
2-3	12 (41.4)
4+	7 (24.1)

Number of prior treatment lines	ICI Naive (N=33)
Missing	5
n	28
1-2	25 (89.3)
3-4	2 (7.1)

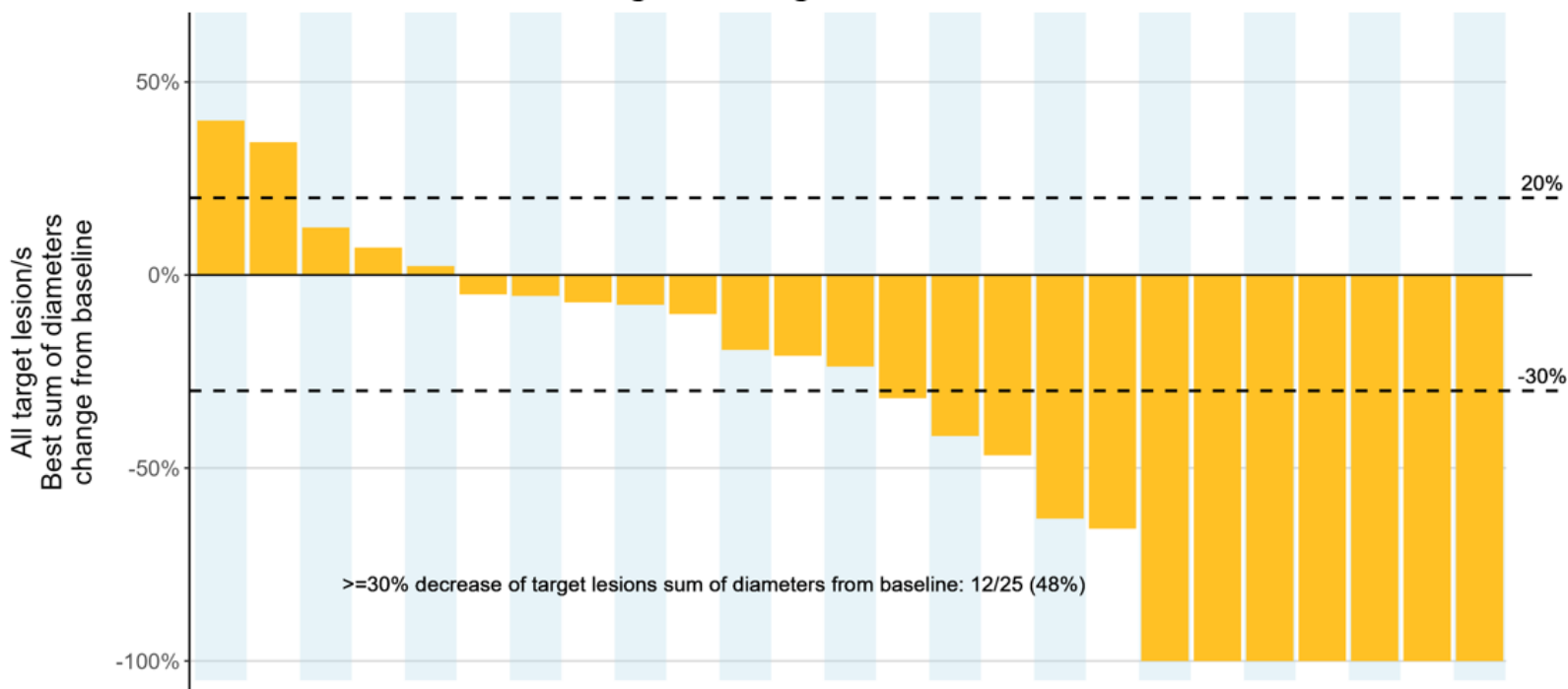
*among available data at cutoff

^Note: Study 1100 is a ph. I trial assessing safety as primary endpoint and exploring signals of efficacy as secondary endpoints. The sample size is small, and the trial is ongoing – some of the efficacy data will mature along with new data comes in.

Best Change in Diameter Sum From Baseline and RECIST Response

ICI Naïve, Evaluable Patients (N=25)

Best Change in All Target Lesions Diameter Sum from Baseline



Overall Response (RECIST 1.1)	ICI Naïve N=25
Complete Response	3 (12.0)
ORR (CR + PR)	12 (48.0)
95% CI	[27.8 - 68.7]
Median duration (days) ⁽¹⁾	54.0
DCR (CR + PR + SD)	19 (76.0)
95% CI	[54.9 - 90.6]
Median duration (days) ⁽²⁾	65.0

(1) Number of days from first to last RECIST assessment with CR or PR
(2) Number of days from first to last RECIST assessment with CR, PR or SD
 Best overall response have been derived as single best overall response observed for 11 subjects, either ongoing or with missing data (1 CR, 7 PR, 3 SD and 0 PD)

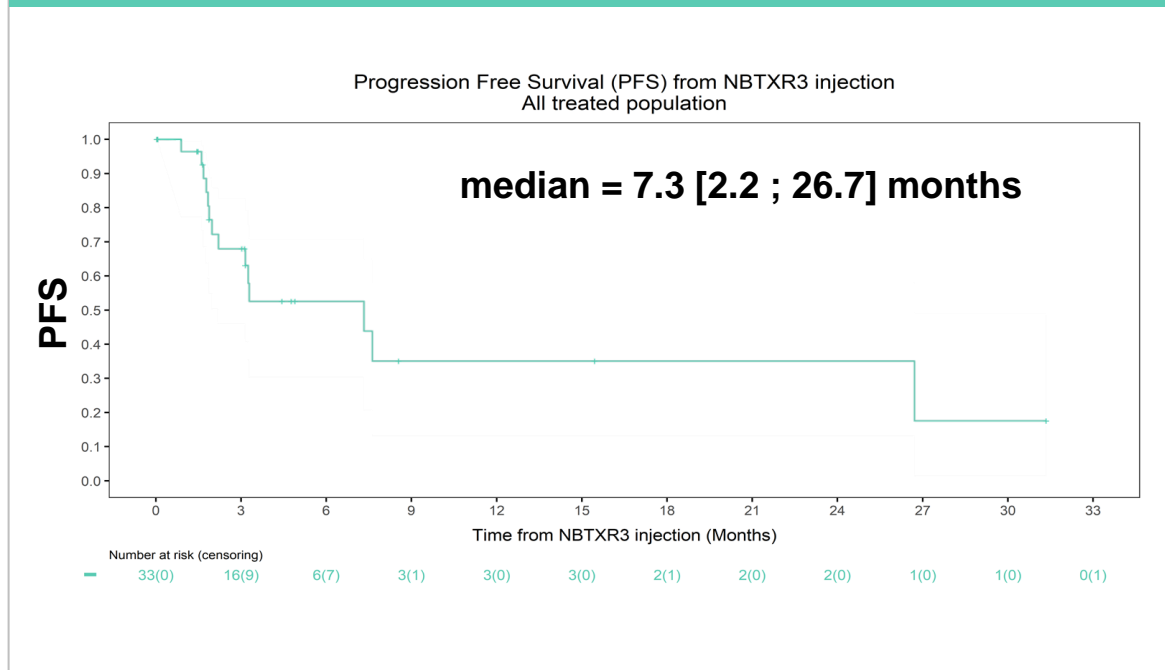
Systemic Control in anti-PD-1 naïve patients with high disease burden
 (24% of patients have 4+ lesions; 66% have 2+ lesions)

Progression Free Survival (PFS) and Overall Survival (OS)

All treated R/M HNSCC ICI Naïve patients

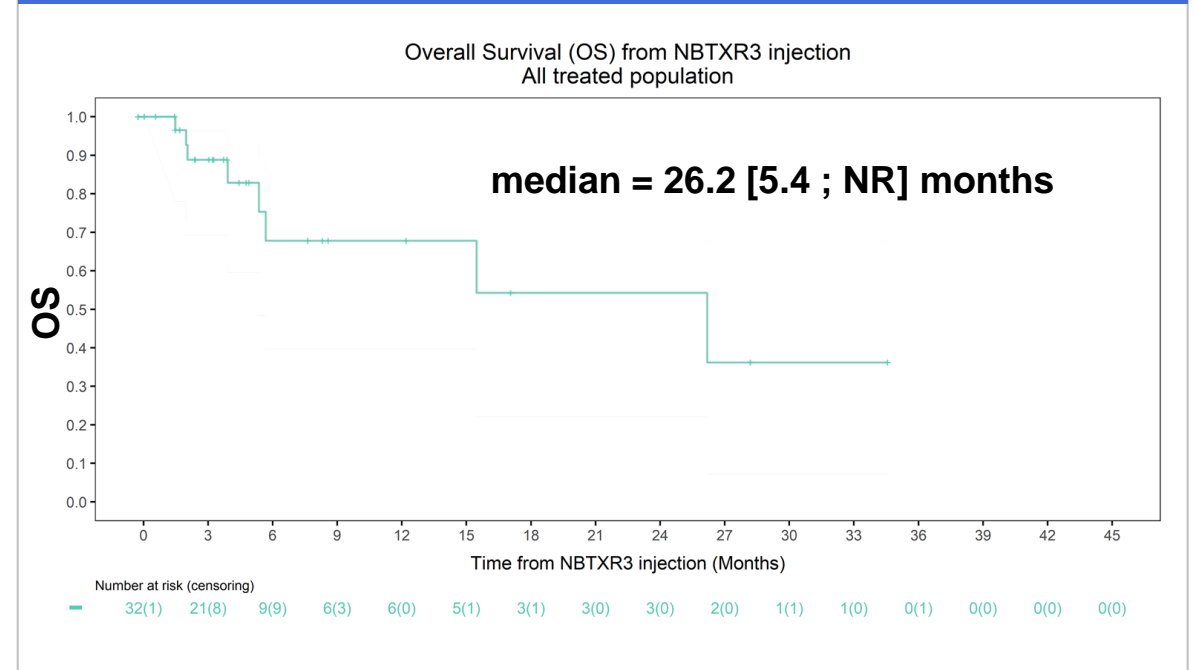
PFS from NBTXR3 injection

All treated population (N=33)



OS from NBTXR3 injection

All treated population (N=32*)



* Ongoing query related to survival data for 1 patient: censored at T = 0 month.

Illustration / Response and Survival Results for Study 1100 and Reference Studies Keynote 040 and Checkmate-141

ICI-Naïve patient population

	1100 Study – Naïve to Anti-PD-1		Keynote 040	CheckMate-141
	All Treated: N=33 evaluable for efficacy: N=25		Pembrolizumab N=247	Nivolumab N=240
Response	<i>All target</i> (N=25) 48%	<i>ORR</i> (N=25) 48,0%	<i>ORR</i> 14.6%	<i>ORR</i> 13.3%
PFS	7.3 [2.2 ; 26.7] months (N=33)*		2.1	2.0
OS	26.2 [5.4 ; NR] months (N=32)*		8.4	7.5

* Ongoing trial – PFS and OS expected to mature with new data coming in

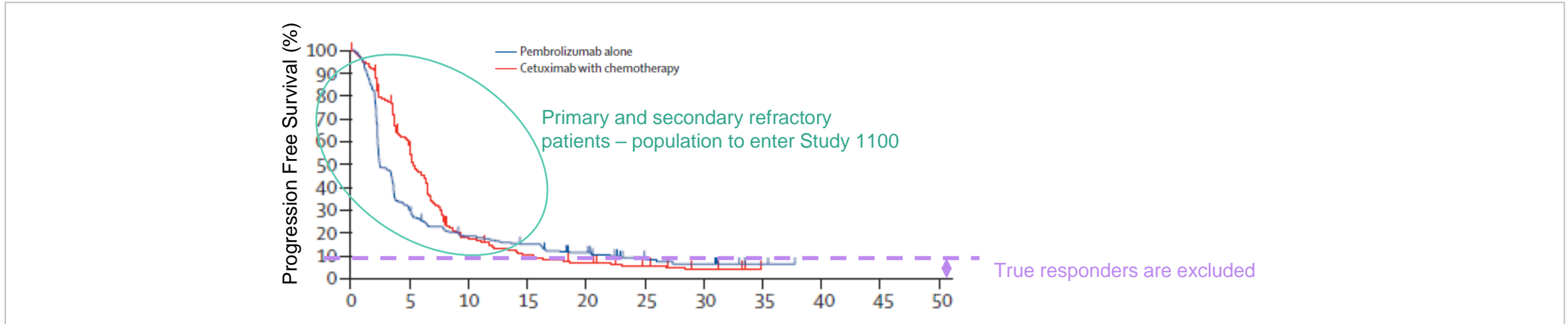
Efficacy

Patients Resistant to Anti-PD-1

1100 Data Update

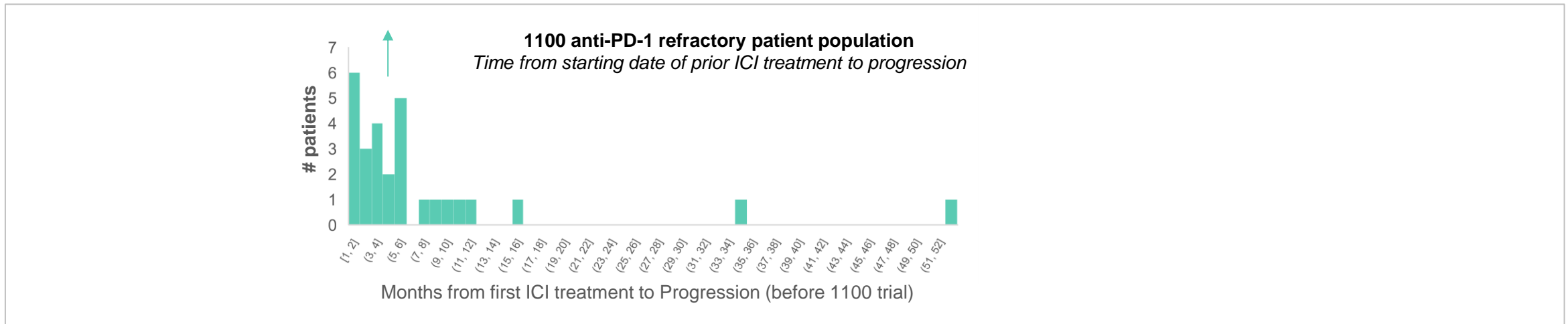
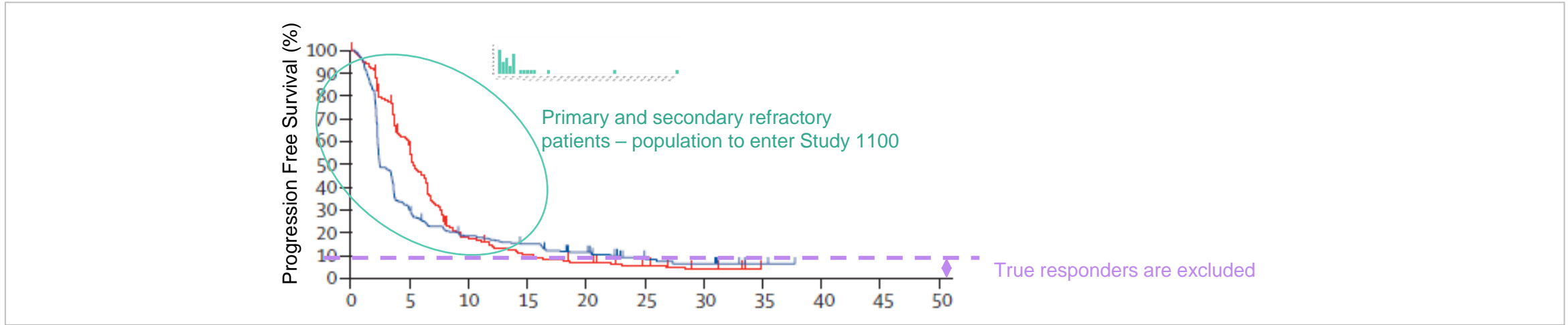
1100 Study – Treatment of Anti-PD-1 Resistant Patient Population

83% of H&N resistant patients entered the 1100 study after having been recorded in progression in their last treatment line
17% have unknown status before entering the study, but supposed to be considered as in progression



1100 Study – Treatment of Anti-PD-1 Resistant Patient Population

83% of H&N resistant patients entered the 1100 study after having been recorded in progression in their last treatment line
 17% have unknown status before entering the study, but supposed to be considered as in progression



Baseline Characteristics of R/M HNSCC Patients Resistant to Anti-PD-1

35 patients treated evaluable for safety

25 evaluable for efficacy at the cutoff date

83% of patients entered the 1100 study « in progression » in their last treatment line (17% have unknown status but supposed to be in progression (not recorded yet))

Heavy tumor burden

Highly pre-treated patients

CPS score

- 15% of patients* have a CPS score < 1%
- 58% of patients* below 20%

HPV status:

- 12 patients* with oropharynx with HPV+ status among the 35 patients

Number of lesions	ICI Resistant (N=35)
Missing	1
n	34
1	7 (20.6)
2-3	7 (20.6)
4+	20 (58.8)

Number of prior treatment lines	ICI Resistant (N=35)
Missing	4
n	31
1-2	11 (35.5)
3-4	12 (38.7)

Similar population as **Keynote-040 treatment beyond progression** (pembrolizumab), and **CheckMate-141 treatment post-failure** (nivolumab)[^]

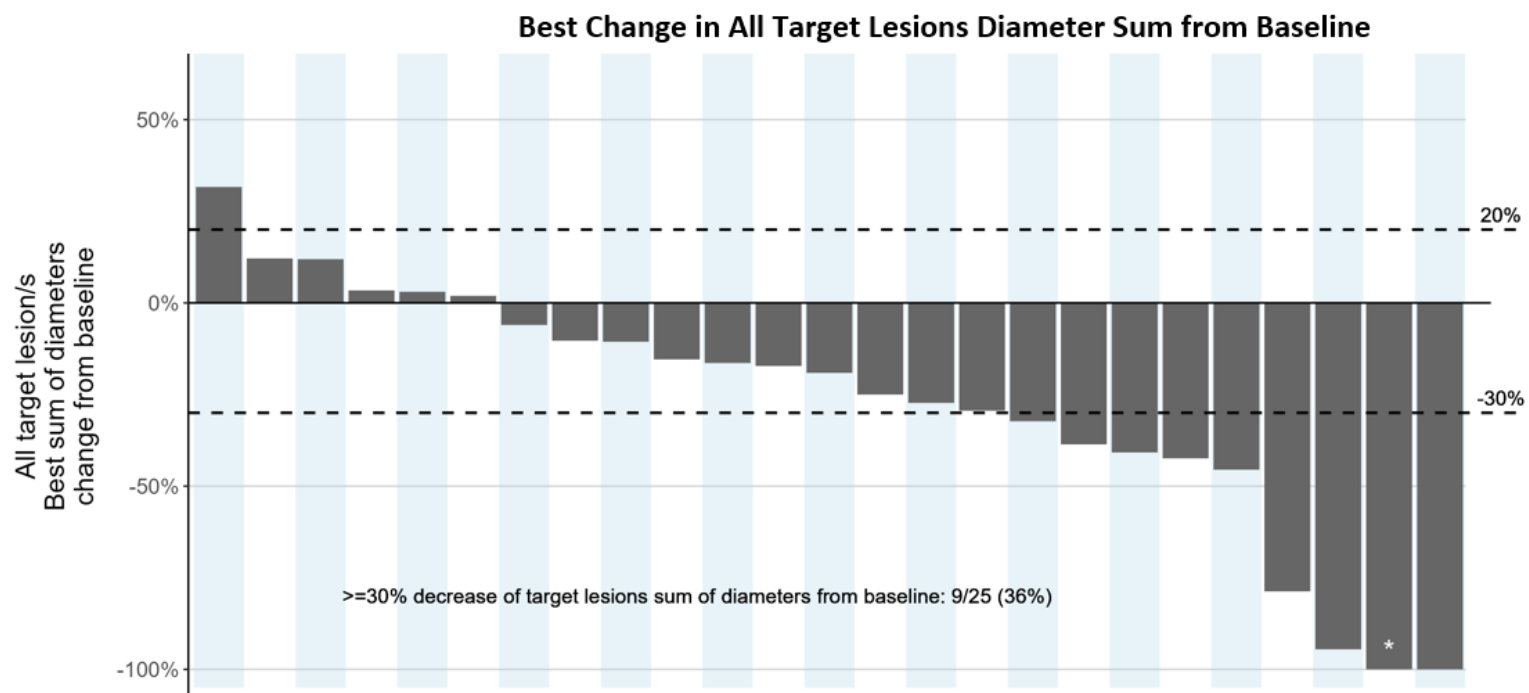
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[^]Note: Study 1100 is a ph. I trial assessing safety as primary endpoint and exploring signals of efficacy as secondary endpoints.

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Best Change in Diameter Sum From Baseline and Study Duration

ICI Resistant, Evaluable Patients (N=25)



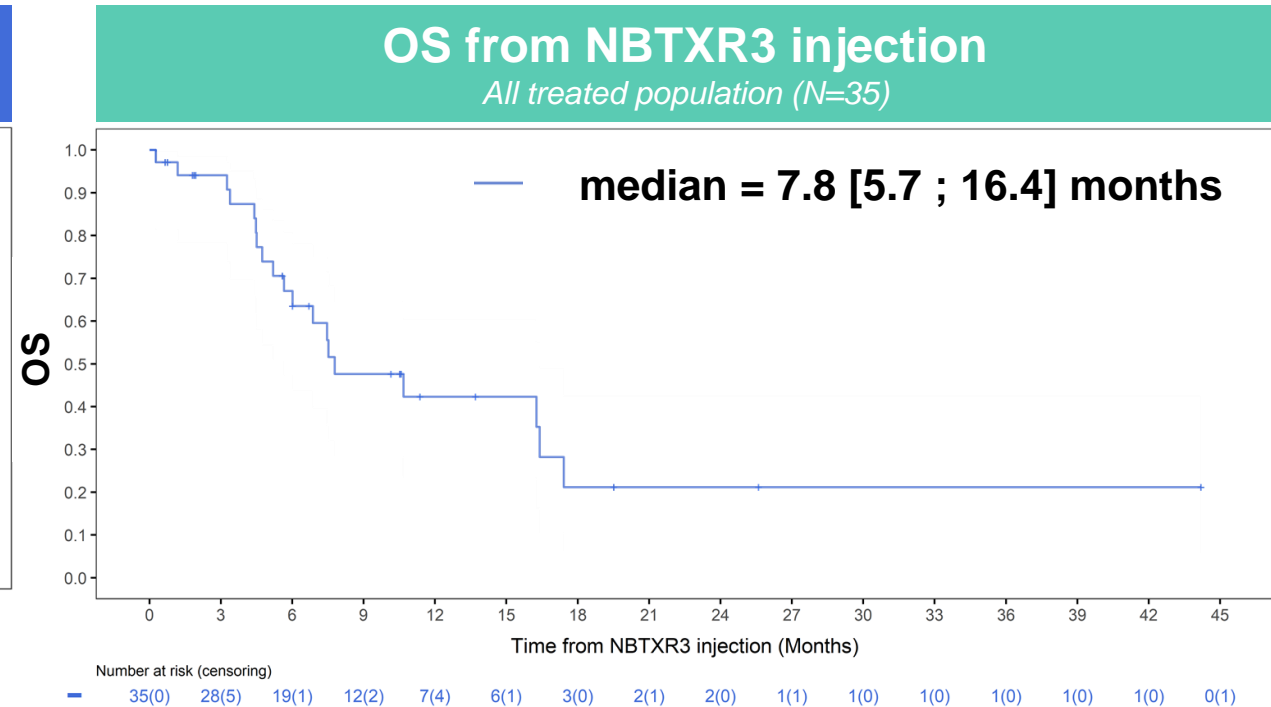
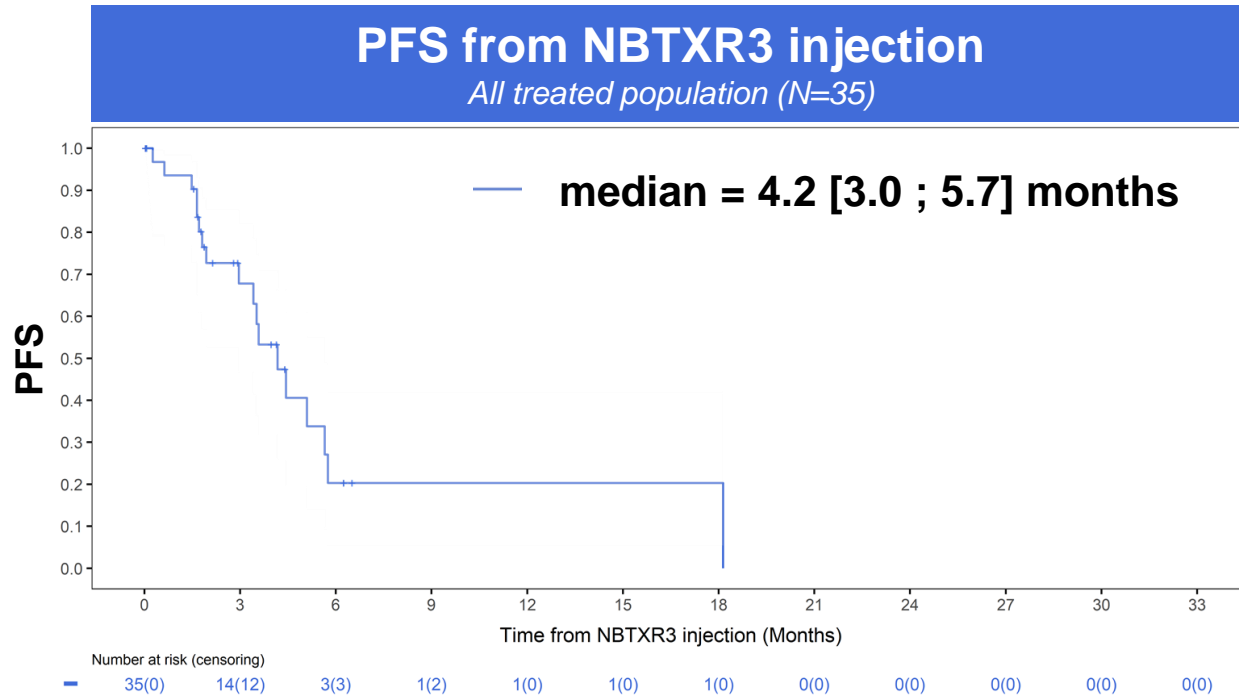
	ICI Resistant N=25
Overall Response (RECIST 1.1)	
Complete Response	2 (8.0)
ORR (CR + PR)	7 (28.0)
95% CI	[12.1 - 49.4]
Median duration (days) ⁽¹⁾	128.0
DCR (CR + PR + SD)	17 (68.0)
95% CI	[46.5 - 85.1]
Median duration (days) ⁽²⁾	58.0

(1) Number of days from first to last RECIST assessment with CR or PR
(2) Number of days from first to last RECIST assessment with CR, PR or SD
 One subject is in complete pathological response (pCR) and has been included in the CR category of this table
 Best overall response have been derived as single best overall response observed for 7 subjects, either ongoing or with missing data (0 CR, 3 PR, 2 SD and 2 PD)

Systemic Control in resistant to anti-PD-1 and in progression metastatic patients with high disease burden (58% of patients have 4+ lesions; 78% have 2+ lesions)

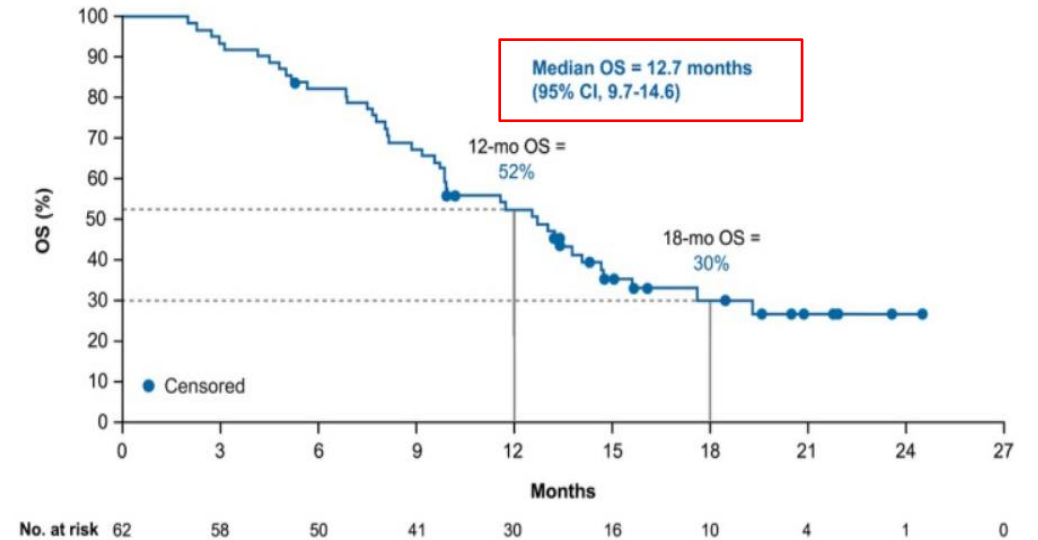
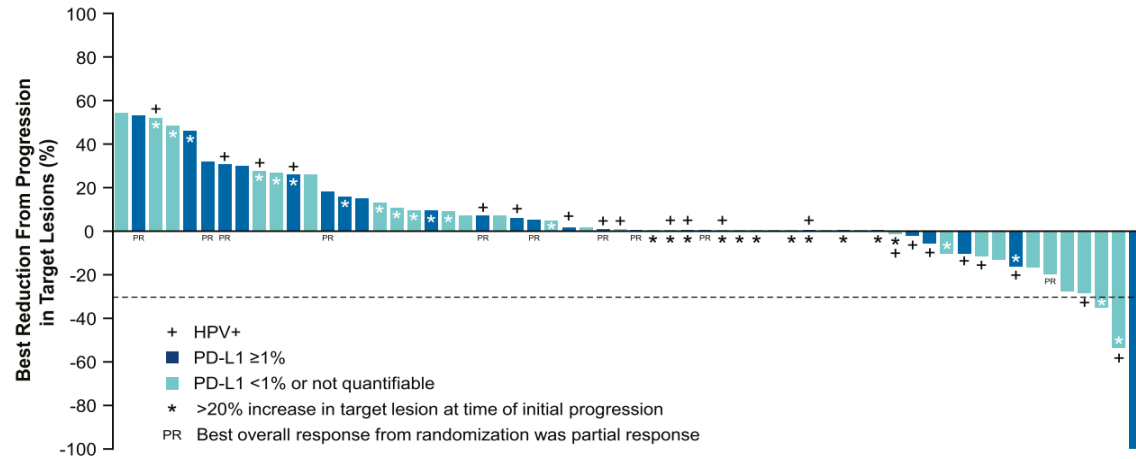
Progression Free Survival (PFS) and Overall Survival (OS)

ICI resistant, all treated HNSCC patients



R/M HNSCC Immune Checkpoint Inhibitor Refractory Populations

CheckMate 141 Nivolumab Trial – patients treated with anti-PD-1 beyond progression¹



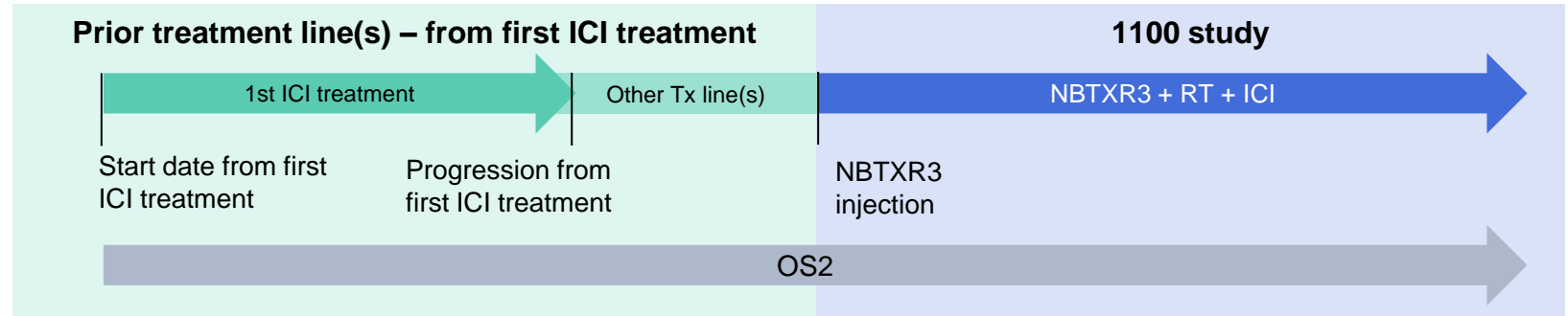
Overall Survival 2 (OS2)

From first ICI treatment

ICI resistant
All treated HNSCC
patients

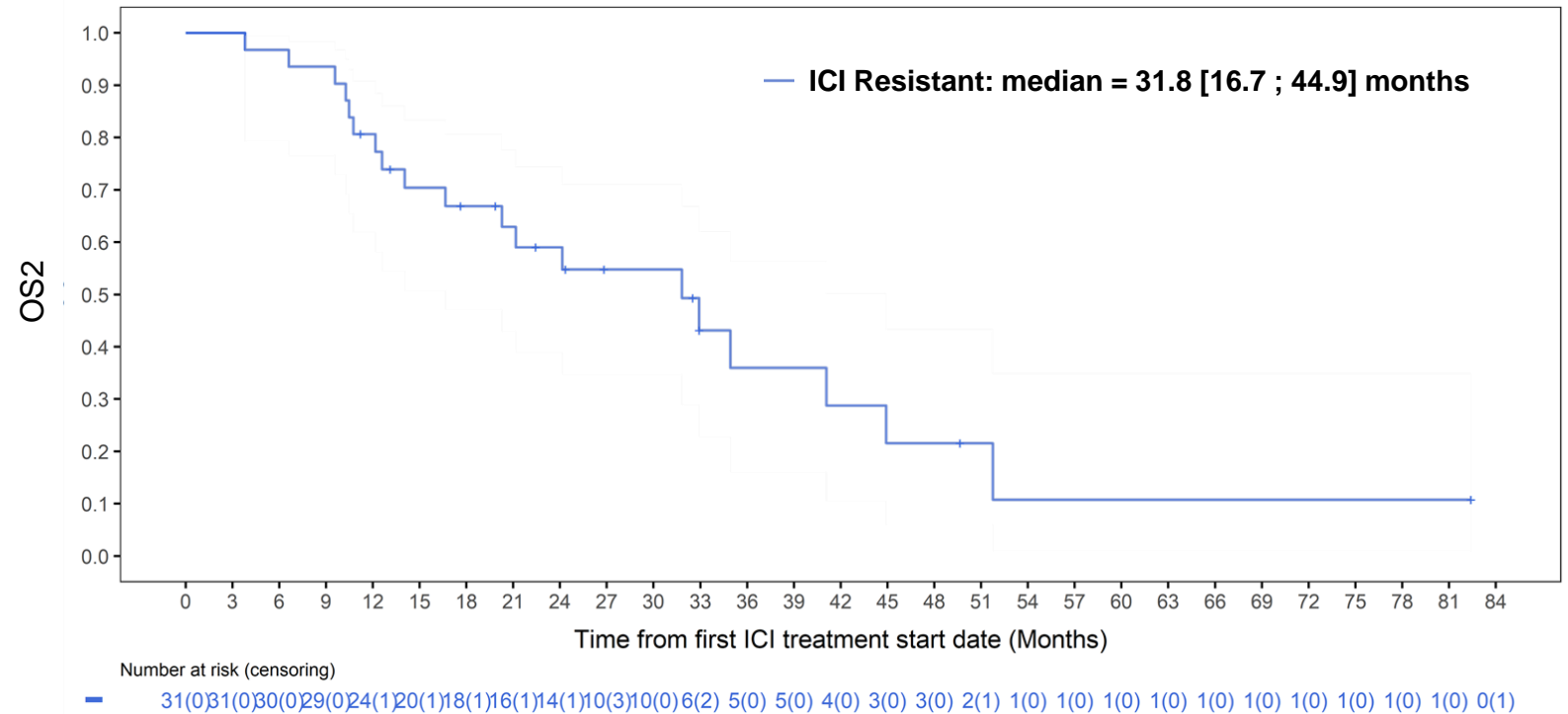
Cut-off: 17 April 2024
N=31*

**4 patients have missing data for prior treatment*



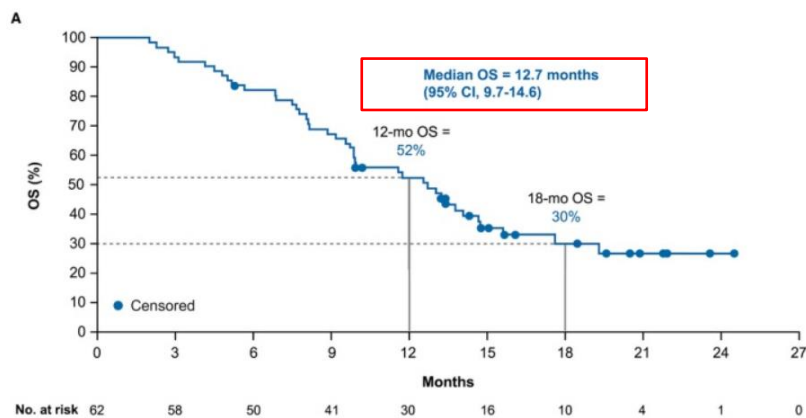
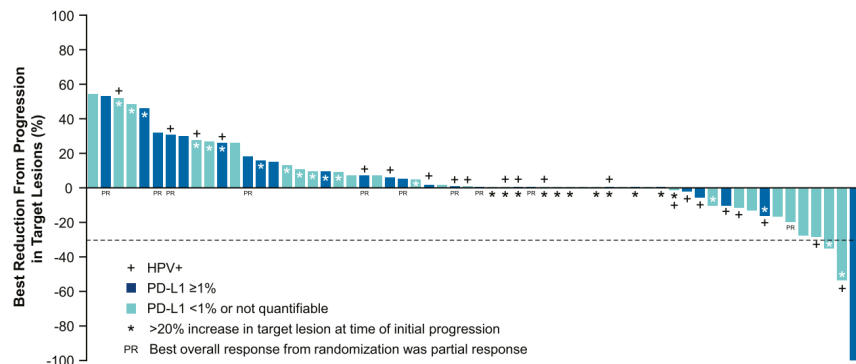
OS2: Overall Survival From First ICI Treatment Start Date

*All treated population (N=31)**



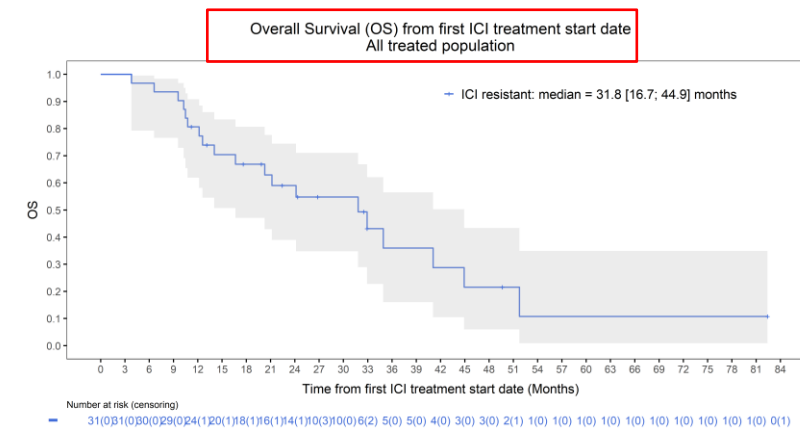
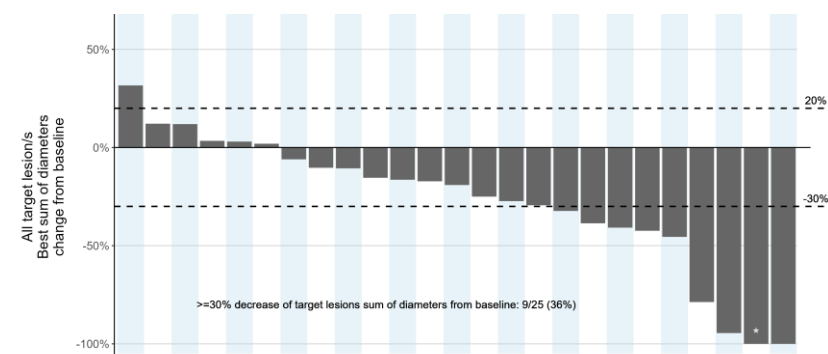
R/M HNSCC Immune Checkpoint Inhibitor Refractory Populations

CheckMate 141 – Nivolumab Trial¹ Anti-PD-1 treatment beyond progression



Study 1100 – ICI Resistant Patients

RT+NBTXR3 and anti-PD-1 treatment beyond progression



Response and Survival Results for Study 1100 and Reference Studies Keynote-048 TBP and Checkmate-141 TBP in ICI Resistant Patients

	1100 Study – Refractory to Anti-PD-1		Post-Checkmate-141	Keynote 048 Post-Progression – <i>patients TBP with pembro and continued treatment</i>
	All treated: N=35 Evaluable for efficacy: N=25		TBP – N=62	N=112
Response	All target (N=25) 36%	ORR (N=25) 28,0%	All target: 5%	All target 8.9%
PFS	4.2 [3.0 ; 5.7] months* (N=35)		-	-
OS	7.8 [5.7 ; 16.4] months* (N=35)		-	-
OS2	31.8 (N=31)**		12.7	-

* Ongoing trial – PFS and OS expected to mature with new data coming in

**4 refractory pts have missing data related to their prior IO treatment

Study 1100 Results Warrant Further Exploration in Randomized Trials for Both ICI Naïve and Resistant Patients with HNSCC

Feasible and safe with no unexpected findings

- NBTXR3 intra-tumoral injection **was feasible and safe** in heavily pretreated patients with R/M HNSCC
- **Less than 10% of Grade \geq 3 serious TEAEs** related to radiotherapy, injection procedure, anti-PD-1 or NBTXR3
- No specific or unexpected adverse event emerging

High response rate with metastatic patients (naïve or refractory to anti-PD-1) suggests systemic control of NBTXR3

	ICI Naïve patients	ICI Resistant patients
ORR	48% (12/25)	28% (7/25)
DCR	76% (19/25)	68% (17/25)
mPFS	7.3 months	4.2 months
mOS	26.2 months	7.8 months
mOS from first ICI treatment	--	31.8 months

Q&A

THANK YOU