ENCORE 601 Update

Syndax

MAY 17, 2018

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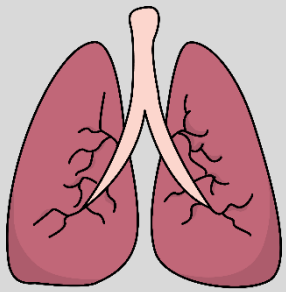
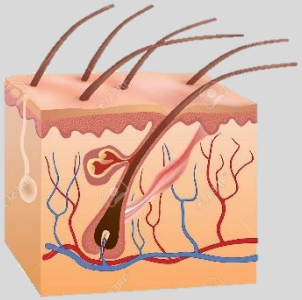
ENCORE Clinical trial program: Evaluating entinostat's potential to enhance anti-PD-(L)1 efficacy

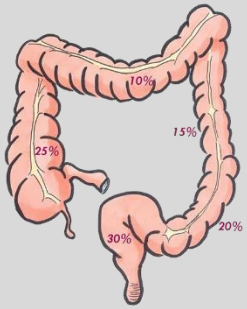
PD-(L)1	Immune cells	Tumor mutational burden (TMB)	Nanostring



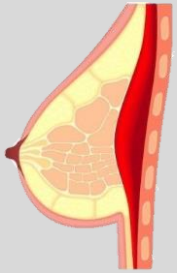
NSCLC



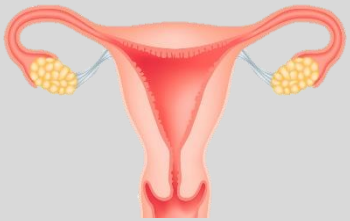
MEL



CRC



TNBC
HR+ BC

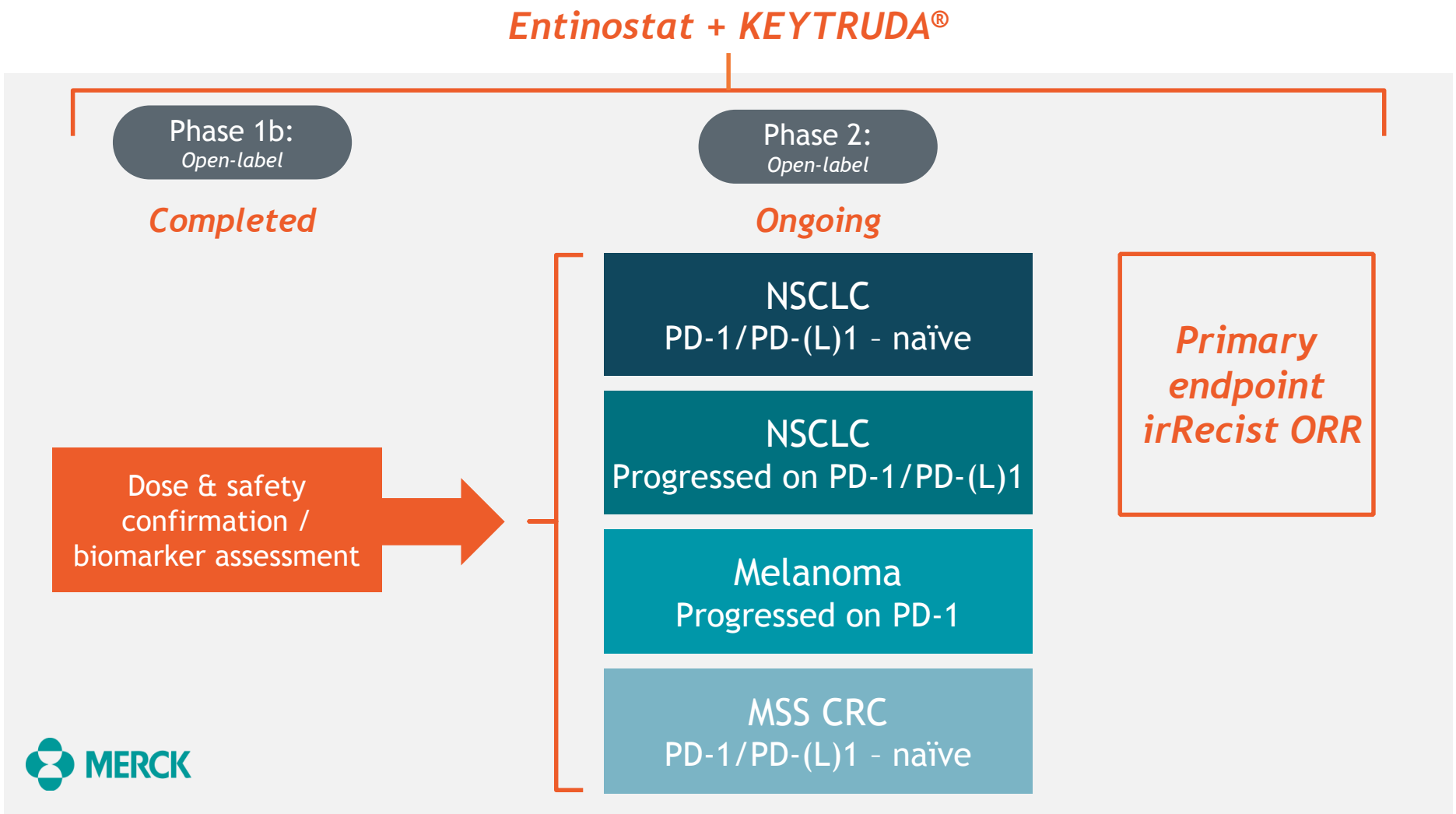


OVAR

Focused on early signs of efficacy and biomarkers that predict clinical benefit

NSCLC - non-small cell lung cancer, MEL - melanoma, CRC - colorectal cancer, TNBC - triple negative breast cancer, HR+ BC - hormone receptor positive breast cancer, OVAR - ovarian cancer

ENCORE 601 / KEYNOTE 142 study design



MSS CRC - Microsatellite stable colorectal cancer, irRecist - immune related response evaluation criteria solid tumors

PD-(L)1 Pre-Treated NSCLC patients

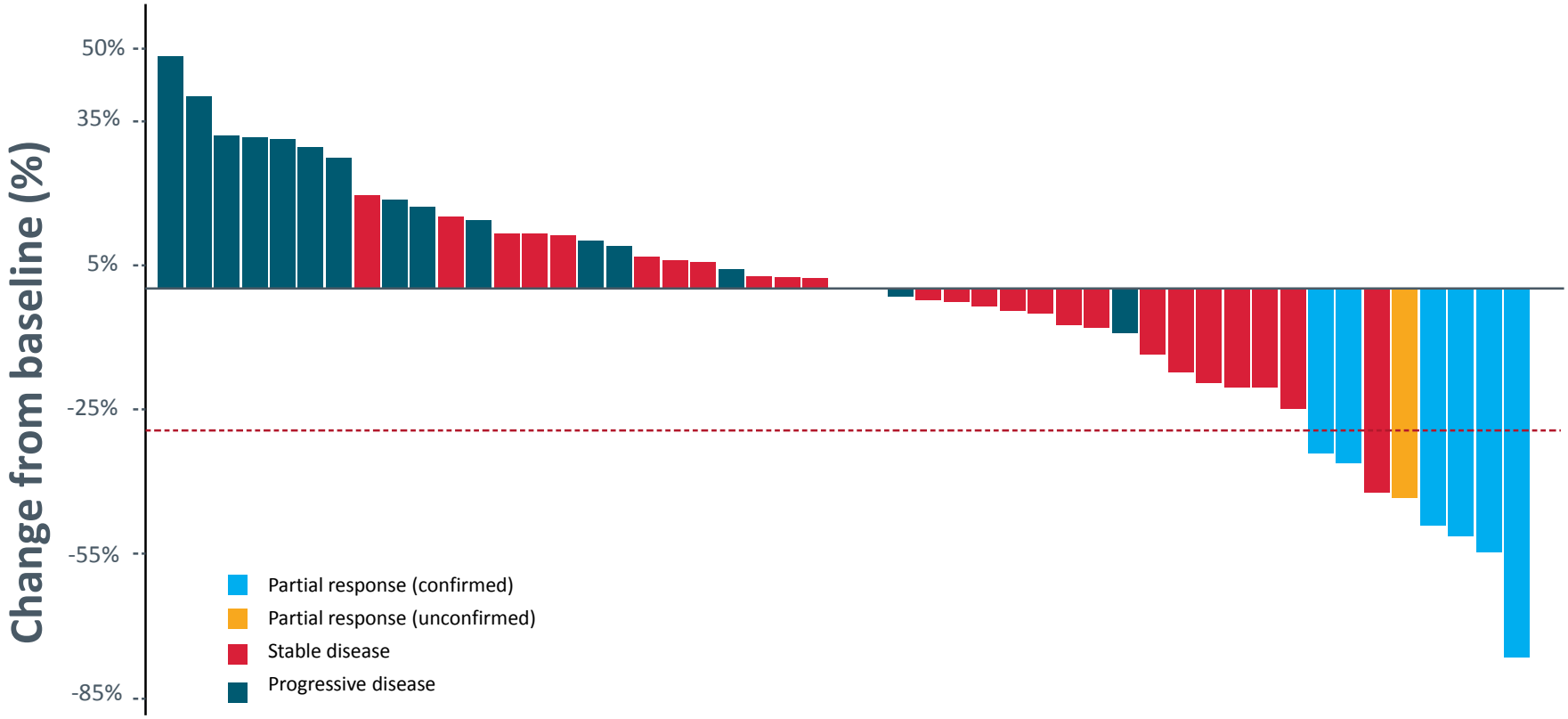
ENCORE 601 PD-(L)1 Pre-treated NSCLC: patient demographics

KEYTRUDA® + entinostat

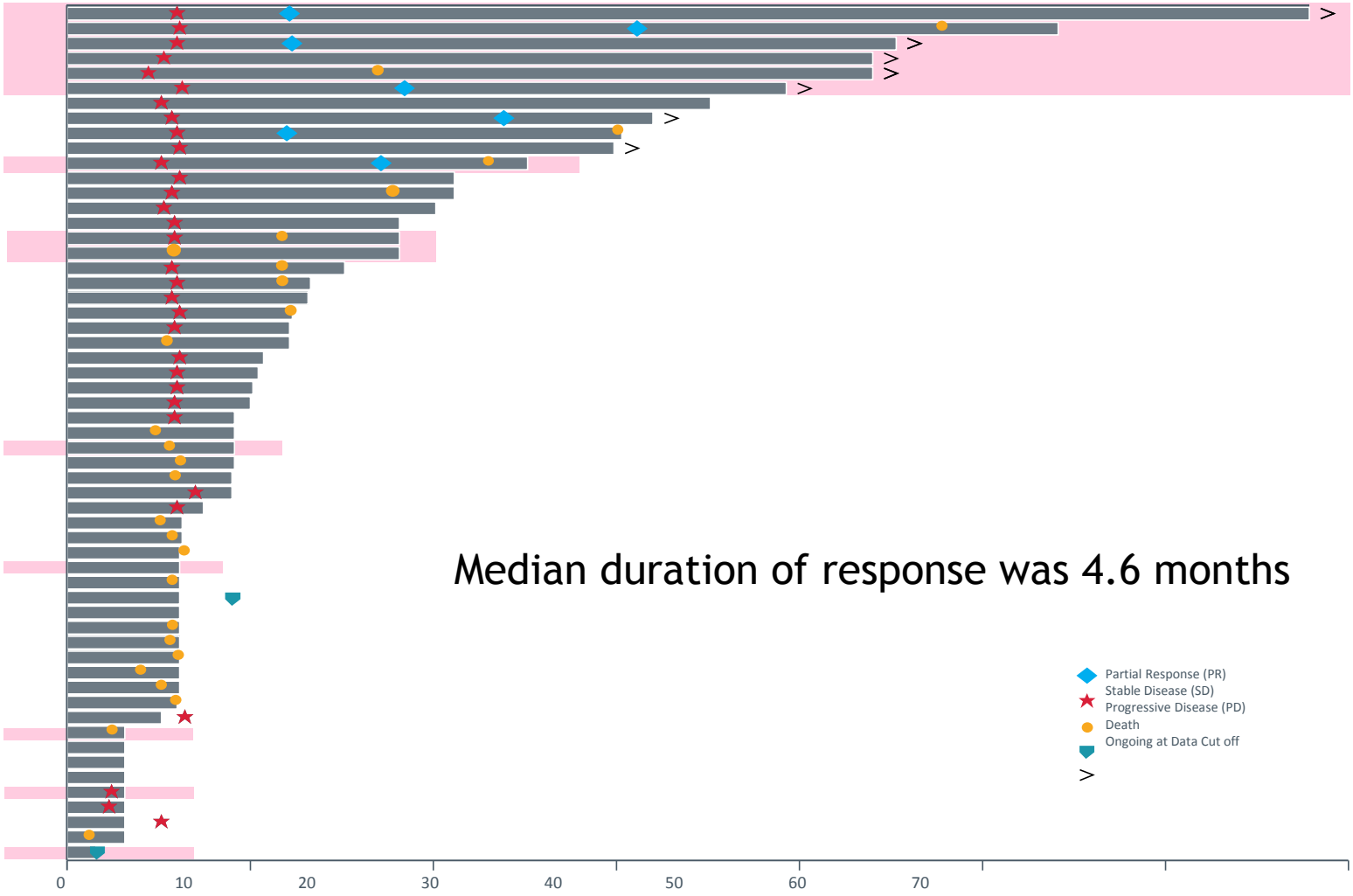
Characteristic, n (%)	Total (n=57)
Male / Female	33 (58%) / 24 (42%)
Age, median (range), years	66 (48-85)
ECOG performance status 0 / 1 / missing	14 (25%) / 42 (74%) / 1 (2%)
PD-L1 expression: <1%/ 1-49%/ ≥50%/ unknown	21 (37%)/ 20 (35%)/ 8 (14%)/ 8 (14%)
Smoking status: current/former/never	2 (4%) / 50 (88%) / 5 (9%)
Best Response on Prior PD-(L)1 Therapy: CR/PR/SD/ PD/unknown	1 (2%) /3 (5%) / 27 (47%) / 22 (39%) / 4 (7%)
Median duration on prior PD-(L)1 Therapy	162 days
Median duration between last dose of prior PD-(L)1 and first of dose on ENCORE 601	65 days

ENCORE 601 pretreated NSCLC: 11% response rate observed in patients with PD-(L)1 refractory NSCLC

Primary Endpoint: Overall Response Rate = 11% [95% CI (4% - 21%)]



ENCORE 601 NSCLC: Results show meaningful durable benefit in treated patients



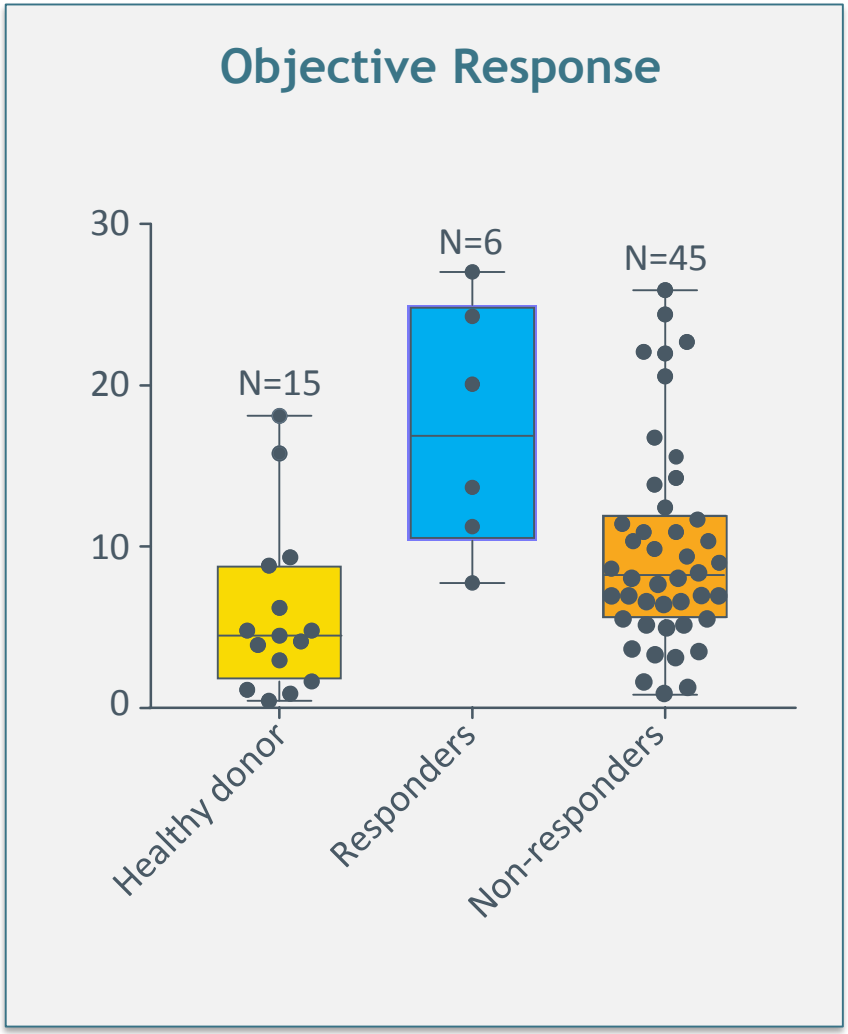
ENCORE 601 PD-(L)1 pretreated NSCLC: Manageable toxicity profile for this combination

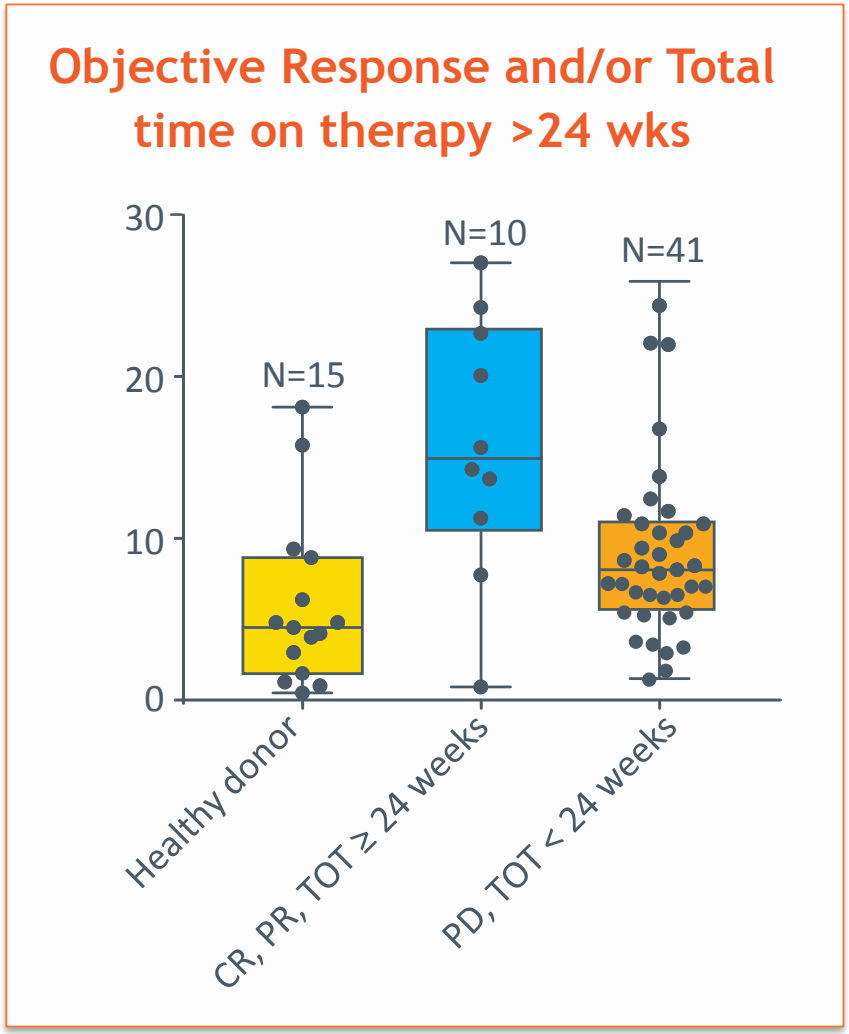
Related AEs occurring in >10% of patients	Total (n=57)	
	All Grades	Grade ≥3
Subjects w/ ≥1 related AE	**44 (77%)**	**24 (42%)**
Fatigue	23 (40%)	5 (9%)
Decreased appetite	12 (21%)	-
Anemia	11 (19%)	4 (7%)
Diarrhea	11 (19%)	2 (4%)
Decreased platelets	10 (18%)	1 (2%)
Nausea	7 (12%)	-
Hypophosphatemia	6 (11%)	4 (7%)
Vomiting	6 (11%)	1 (2%)
Weight decrease	6 (11%)	-
Hyponatraemia	6 (11%)	3 (5%)
Pneumonitis	5 (9%)	2 (4%)
Colitis	2 (4%)	2 (4%)

12 (21%) pts discontinued due to TEAE:

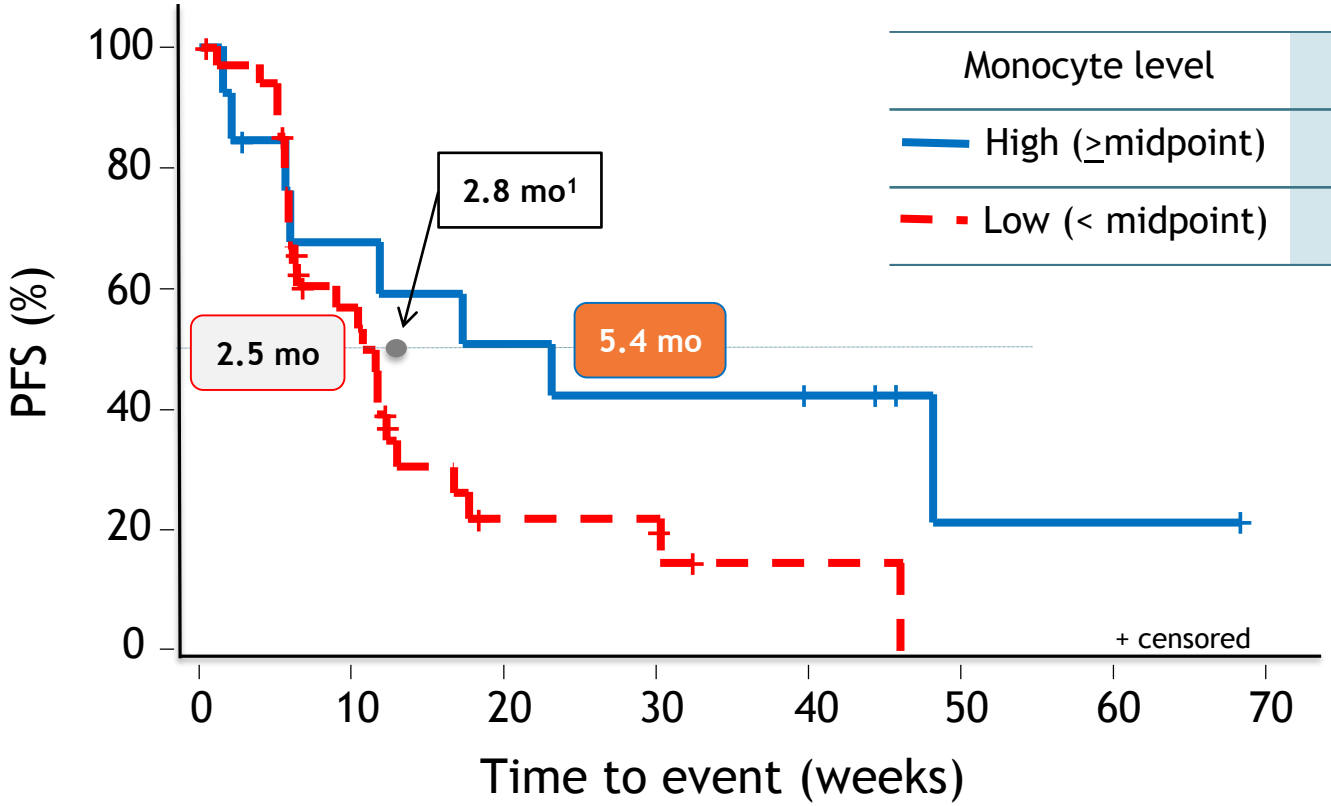
- Fatigue (3)
- Encephalitis
- Acute respiratory failure
- Hyponatremia
- Ventricular arrhythmia
- Asthenia
- Pneumonitis (2)
- Colitis
- Vomiting/diarrhea

Entinostat - pembrolizumab clinical benefit after PD-1 associated with higher baseline monocyte levels





Higher baseline levels of classical monocytes associated with PFS, ORR benefit in ENCORE 601 NSCLC cohort



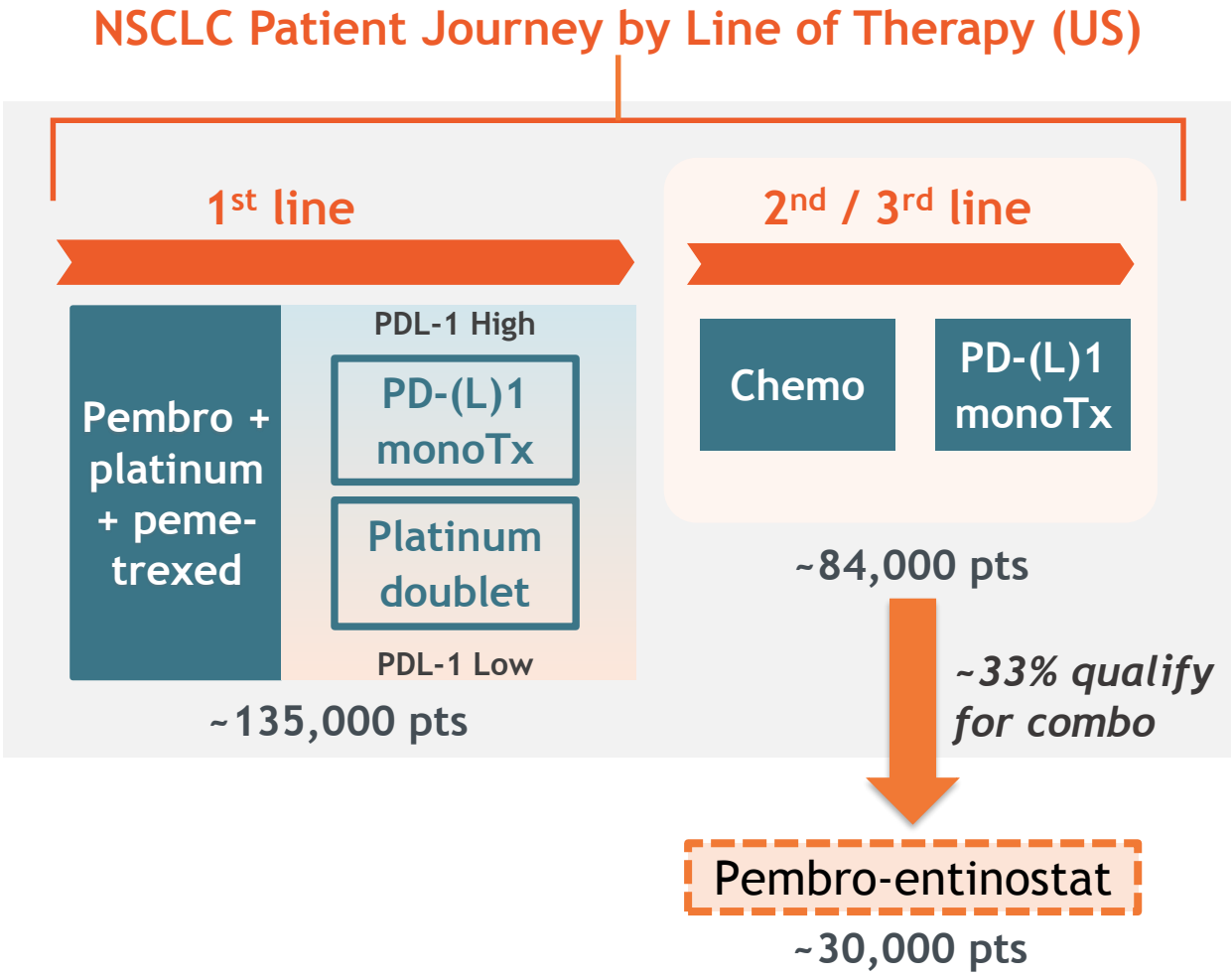
Monocyte level	mPFS	ORR
High (≥midpoint)	5.4 mo	28.6%
Low (< midpoint)	2.5 mo	5.4%

Monocyte High	14	8	6	5	4	1	1	0
Monocyte Low	37	16	4	3	1	0		

1. Costantini et al. ERJ Open Res 2018; 4:00120-2017

Patient segmentation common in NSCLC therapy

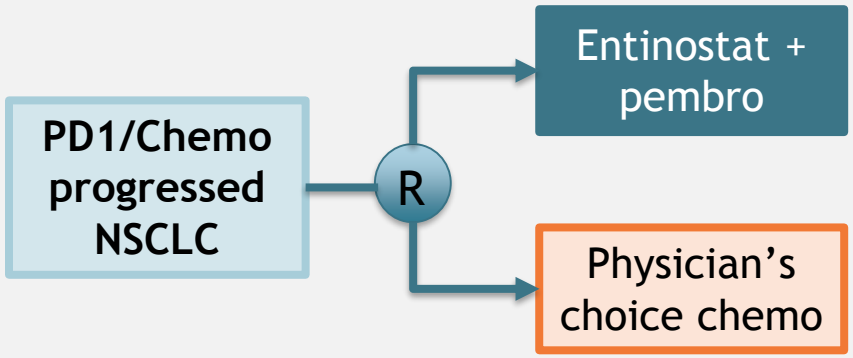
- Biomarkers used to identify responders (EGFR, ALK, PD-(L)1; TMB?, etc.)
- Selection may enable **entinostat-KEYTRUDA** to provide meaningful benefit for a subset of 2L / 3L NSCLC



Source: Kantar 2016 Treatment Architecture report; Trial Trove, SEER data

Potential registration path in patients with NSCLC who have progressed on a PD-(L)1

Conduct a randomized trial to test hypothesis:



- Confirm clinical benefit in high monocyte population (est. cutoff)

AND

- Compare to Physician's choice Chemo (SOC)

Stratify by baseline classical monocyte level

Anticipate topline data 1H20

- Continue monitoring ENCORE 601 PD-(L)1 PreTx cohort to determine utility of monocyte biomarker, and potential for OS benefit
- Validate and industrialize the classical monocyte assay
- Continue to explore additional biomarkers

PD-(L)1 Pre-Treated Melanoma Patients

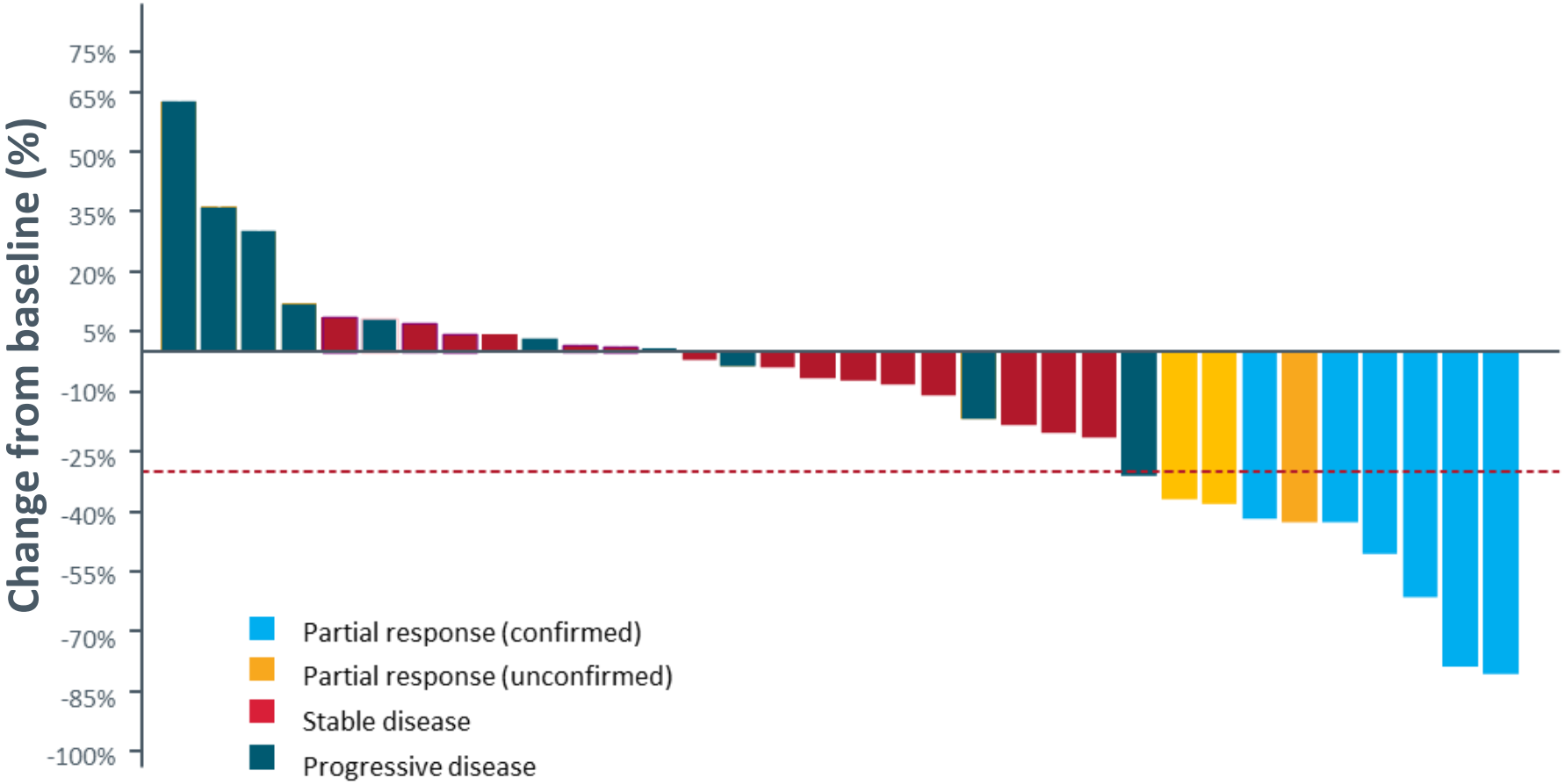
ENCORE 601 Melanoma: patient demographics

KEYTRUDA® + entinostat

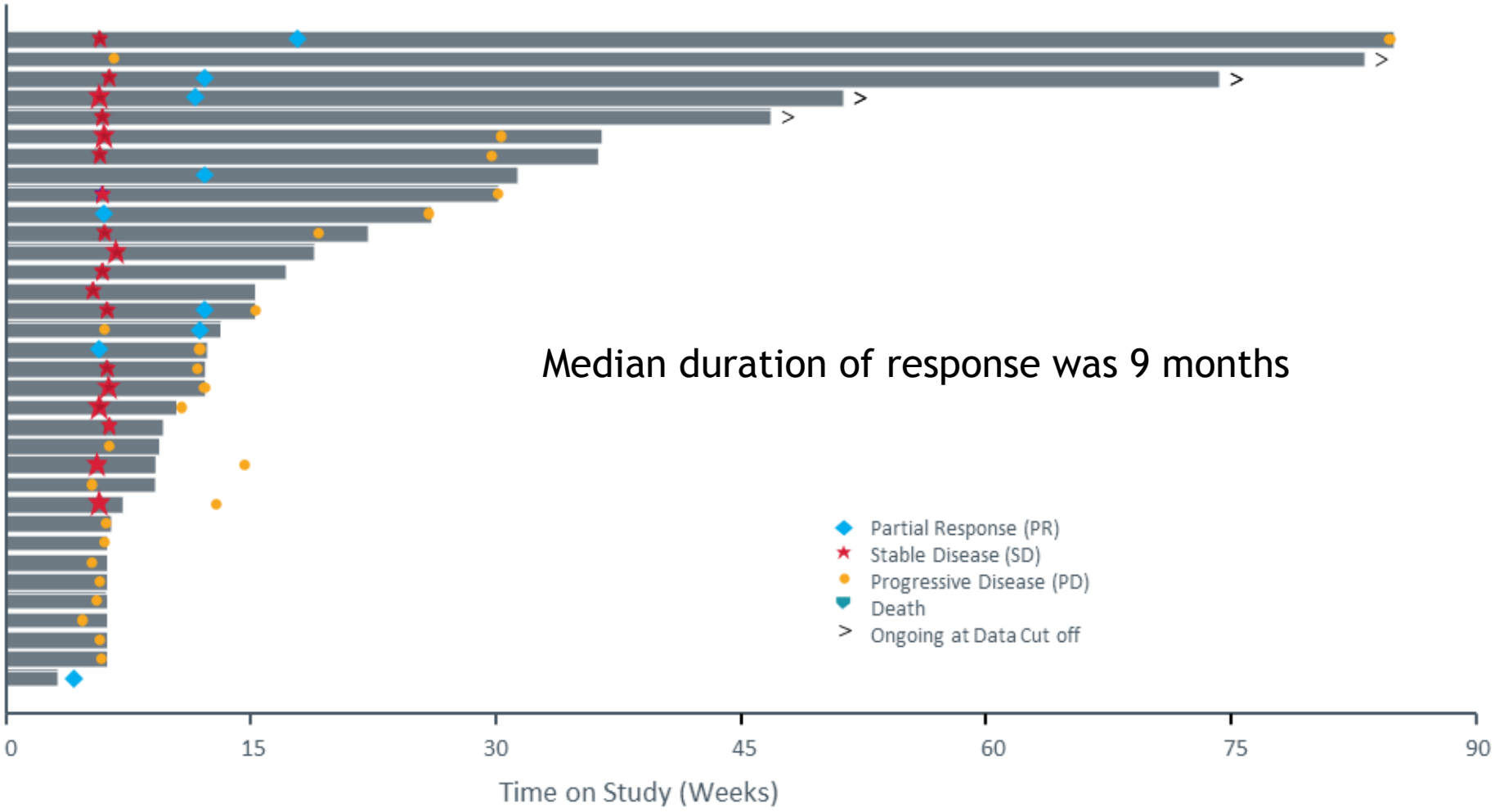
Characteristic, n (%)	Total (n = 34)
Male / Female	22 (65%) / 12 (35%)
Age, median (range), years	64 (20 - 86)
ECOG performance status 0 / 1	19 (56%) / 15 (44%)
PD-L1 expression: negative /positive /unknown	9 (26%)/ 17 (50%)/ 8 (24%)
Metastases: Visceral / Non-visceral / unknown	15 (44%) / 17 (50%) / 2 (6%)
Prior CTLA-4	22 (65%)
Best Response on Prior PD-(L)1 Therapy: CR/PR/SD PD/unknown	1 (3%) / 1 (3%) / 13 (38%) 16 (47%) / 3 (9%)
Median duration on Prior PD-(L)1 Therapy	162 days
Median duration Between Last Dose of Prior PD-(L)1 and First of Dose on ENCORE 601	64 days

ENCORE 601 Melanoma: 18% response rate observed in first 34 patients

Primary Endpoint: Overall Response Rate = 18% [95% CI (7% - 35%)]



ENCORE 601 Melanoma: Shows meaningful durable benefit in treated patients



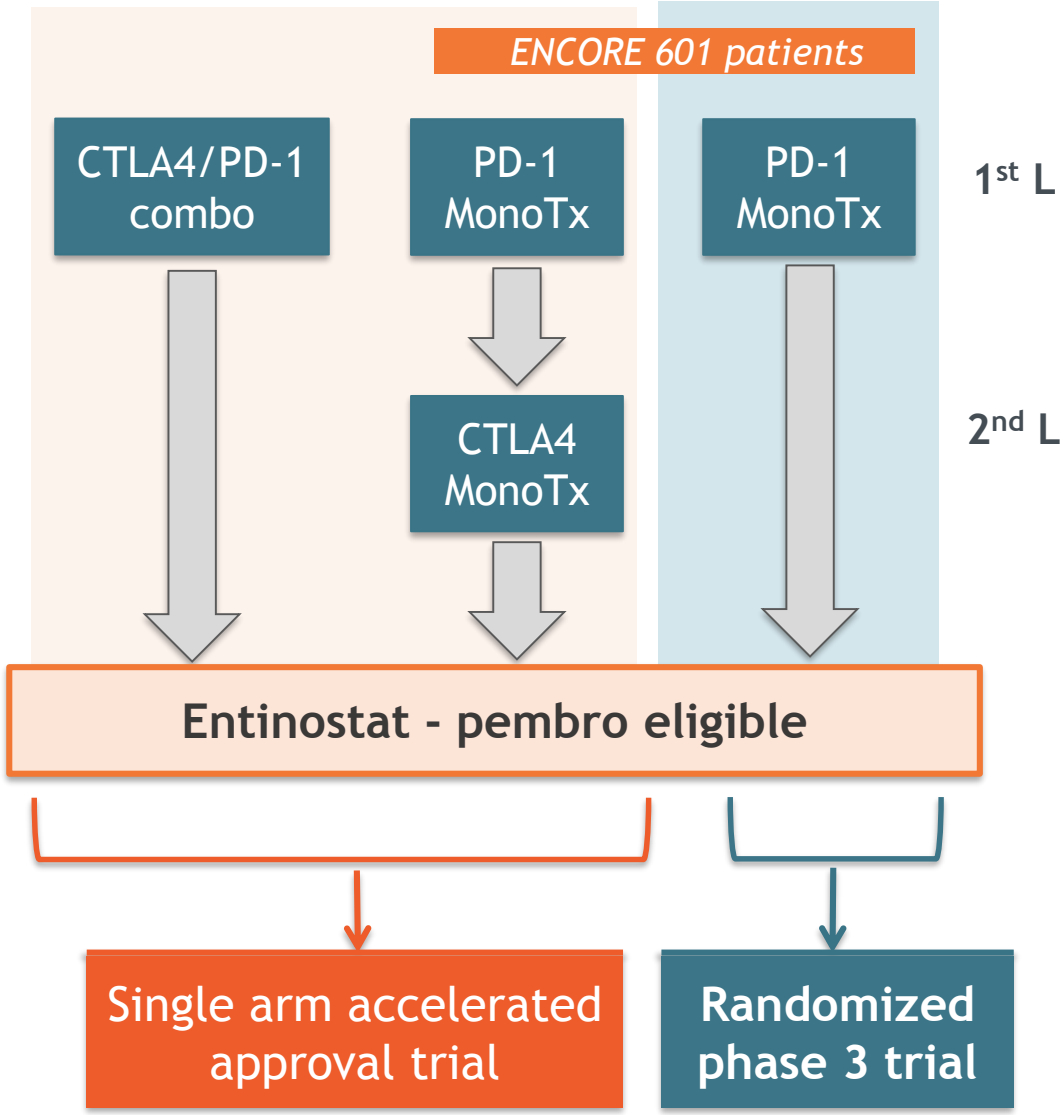
ENCORE 601 PD-(L)1 pretreated Melanoma: Manageable toxicity profile for this combination

Related AEs occurring in >10% of patients	Total (n = 34)	
	All Grades	Grade ≥3
Subjects w/ ≥1 related adverse event	**30 (88%)**	**14 (41%)**
Nausea	18 (53%)	-
Fatigue	12 (35%)	1 (3%)
Diarrhea	7 (21%)	-
Pruritus	6 (18%)	-
Decreased neutrophils	5 (15%)	-
Anemia	4 (12%)	2 (6%)
Arthralgia	4 (12%)	-
Myalgia	4 (12%)	-
Decreased platelets	4 (12%)	-
Rash	4 (12%)	2 (6%)

4 (12%) pts discontinued due to TEAE:

- Liver enzyme increase
- Mucosal inflammation
- Colitis
- Autoimmune hepatitis

Unmet need: Patients progressed on CTLA-4 and PD-1



Potential Registration path:

MSS-CRC

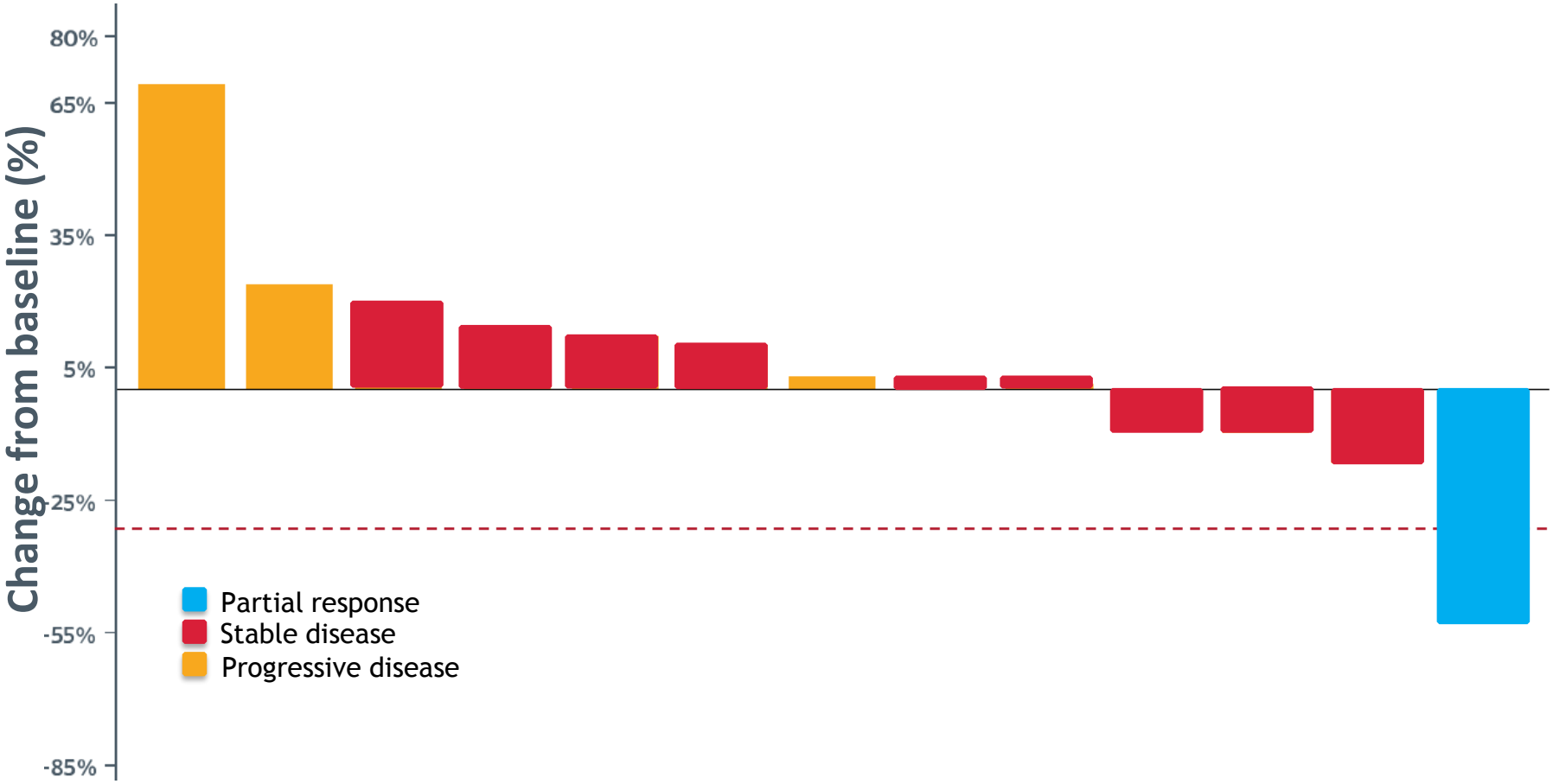
ENCORE 601 CRC: Patient demographics

KEYTRUDA® + entinostat

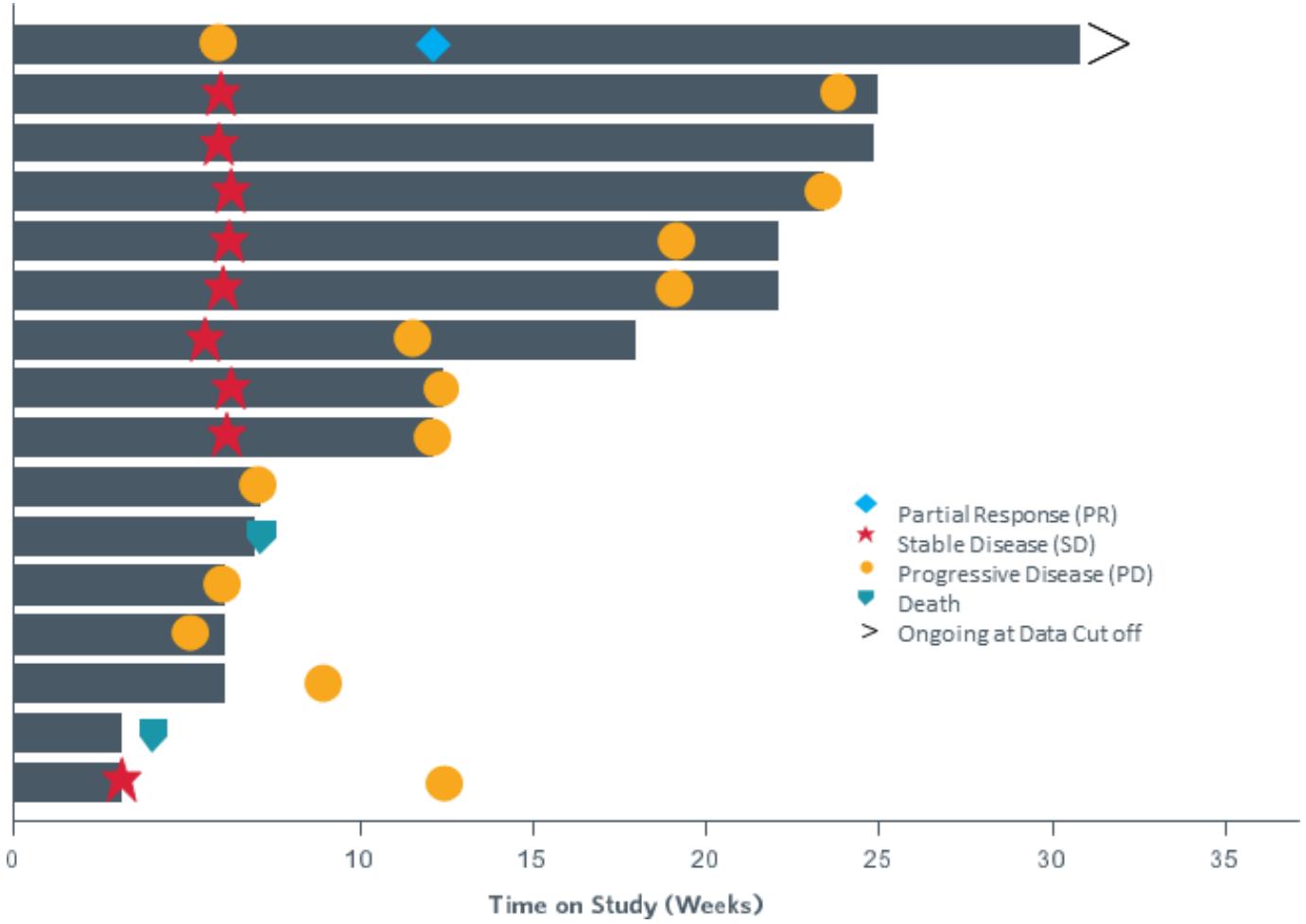
Characteristic, n (%)	Total (n = 16)
Male / Female	8 (50%) / 8 (50%)
Age, median (range), years	58 (36 - 69)
ECOG performance status 0 / 1 / Unknown	7 (44%) / 8 (50%) / 1 (6%)
CEA > ULN: Yes/ No/ Unknown	8 (50%)/ 2 (13%)/ 6 (38%)
Prior lines of therapy: 1 / ≥2	3 (19%) / 13 (81%)

ENCORE 601 CRC: 1 partial response observed in first 16 patients

Primary Endpoint: Overall Response Rate = 6% [95% CI (0% - 30%)]



ENCORE 601 CRC: Shows meaningful durable benefit in treated patients



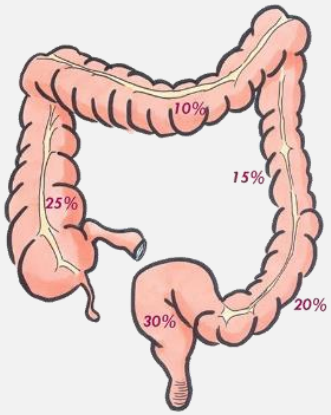
ENCORE 601 PD-(L)1 MSS-CRC: Manageable toxicity profile for this combination

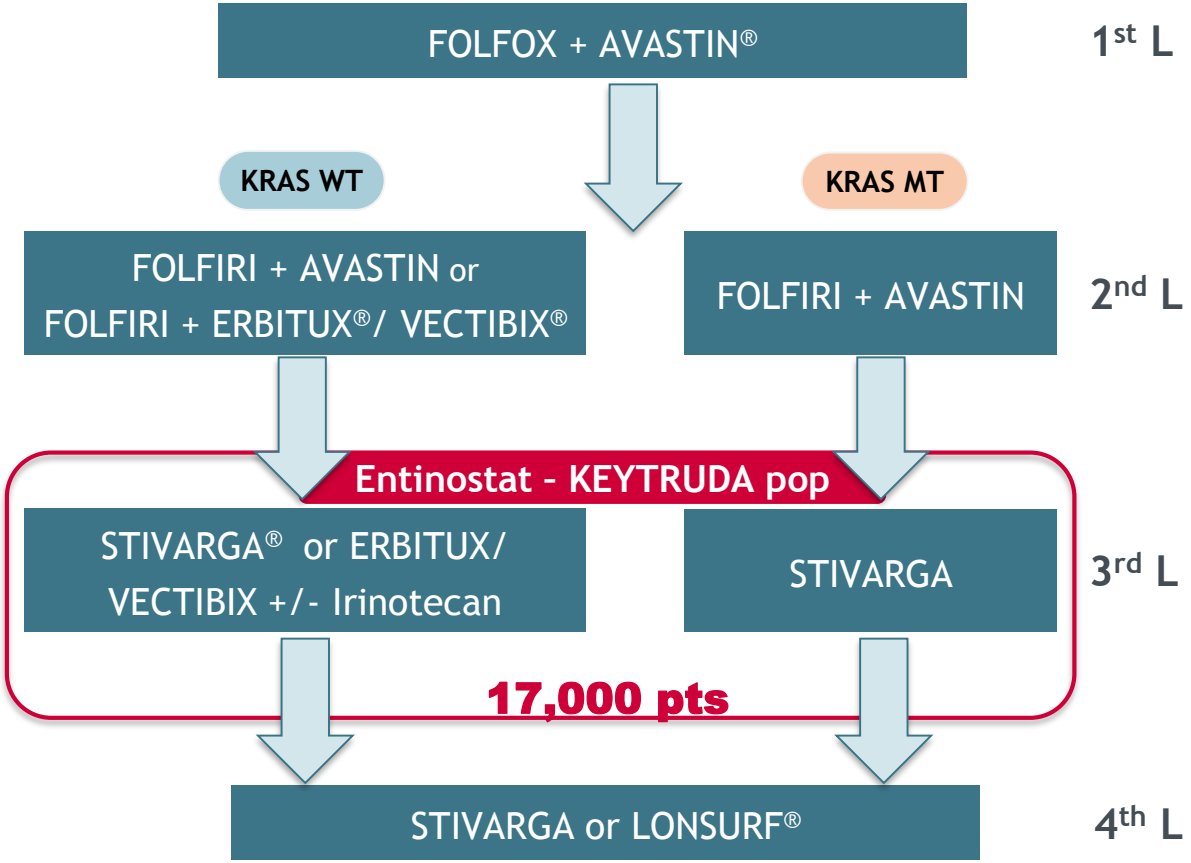
Related AEs occurring in >4 patients	Total (n = 16)	
	All Grades	Grade ≥3
Subjects w/ ≥1 related AE	**16 (100%)**	**8 (50%)**
Fatigue	8 (50%)	1 (6%)
Blood alk phos increase	6 (38%)	2 (13%)
Asp increase	5 (31%)	1 (6%)
Nausea	5 (31%)	-
Anemia	4 (25%)	2 (13%)
Arthralgia	4 (25%)	1 (6%)
Diarrhea	4 (25%)	1 (6%)
Myalgia	4 (25%)	-
Vomiting	4 (25%)	-
Hypothyroidism	2(13%)	-
Pneumonitis	2 (13%)	1 (6%)

2 (13%) pts discontinued due to TEAE:

- Liver enzyme increase
- Pneumonitis

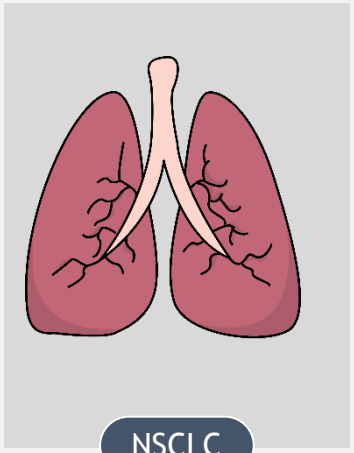
Significant need remains for patients with MSS-CRC

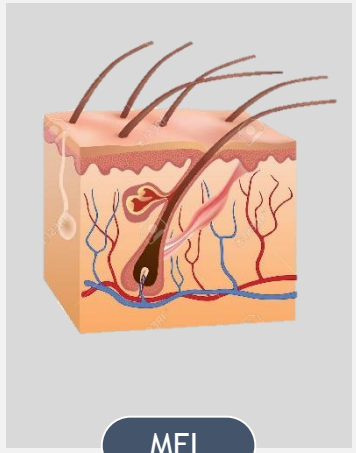


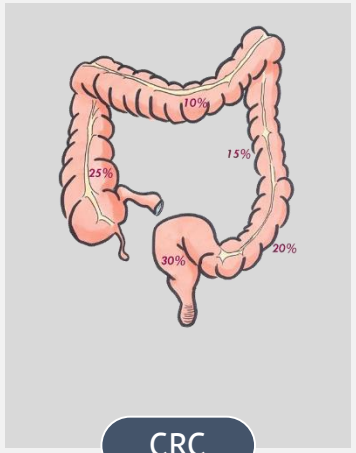


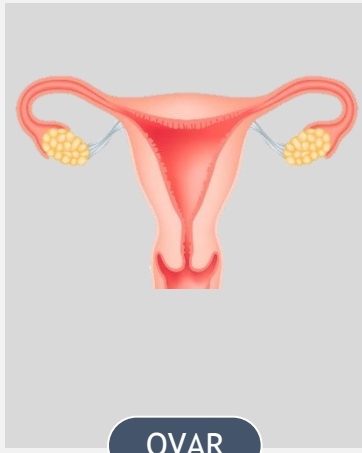
ENCORE Clinical Trial Program: Evaluating entinostat's potential to enhance anti-PD-(L)1 efficacy

PD-(L)1	Immune cells	Tumor mutational burden (TMB)	Nanostring









NSCLC	MEL	CRC	TNBC HR+ BC	OVAR
Progress	Awaiting final phase 2 results	Await data	Await data	Await data