



Bristol-Myers Squibb

AACR 2018 Investor Meeting

April 16, 2018

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In addition, any forward-looking statements represent our estimates only as of the date hereof and should not be relied upon as representing our estimates as of any subsequent date. While we may elect to update forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our estimates change.



Tom Lynch

Chief Scientific Officer

AACR 2018 – Continued Progress in 1L NSCLC

- **CM-227: Important result in 1L NSCLC**
 - Highly statistically significant and clinically meaningful
 - Benefit independent of PD-L1 status and histology
- **Data supports TMB as a potential important new biomarker**
 - Significant advance in the understanding of tumor biology
 - Demonstrates strength of translational research capabilities
 - Supports continued patient segmentation
- **Third tumor with benefit demonstrated for Opdivo+Yervoy in randomized trial**
 - Clear contribution of parts from combination over monotherapy
 - Offers potential for chemo-sparing regimen

CM-227: Clinically Meaningful Result

- PFS HR of 0.58 and $p = 0.0002$ using a chemo-sparing regimen
 - Consistent benefit across key subgroups
- Benefit being driven by deep and durable responses
 - 1 year DoR close to 70% compared to 25% on chemotherapy
 - 1 year PFS rate for Opdivo/Yervoy > 3x chemotherapy
- Preliminary analysis of OS is encouraging in >10mut/mb
- Opdivo and low dose Yervoy safety consistent with previous trials

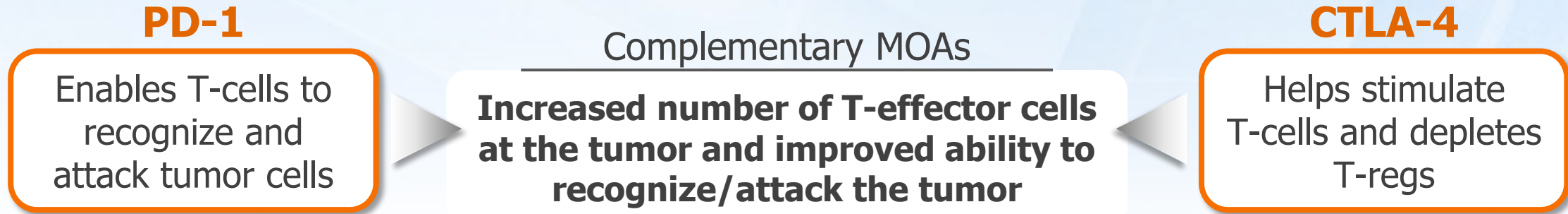
Data supports the potential importance of assessing TMB status

A laboratory setting with a multi-well plate in the foreground containing several test tubes. The background is filled with more test tubes in a rack, all under a blue and purple light. A white semi-transparent banner is overlaid on the center of the image.

Fouad Namouni

Head of Oncology Development

Rationale for Evaluating Opdivo/Yervoy in Patients with High TMB

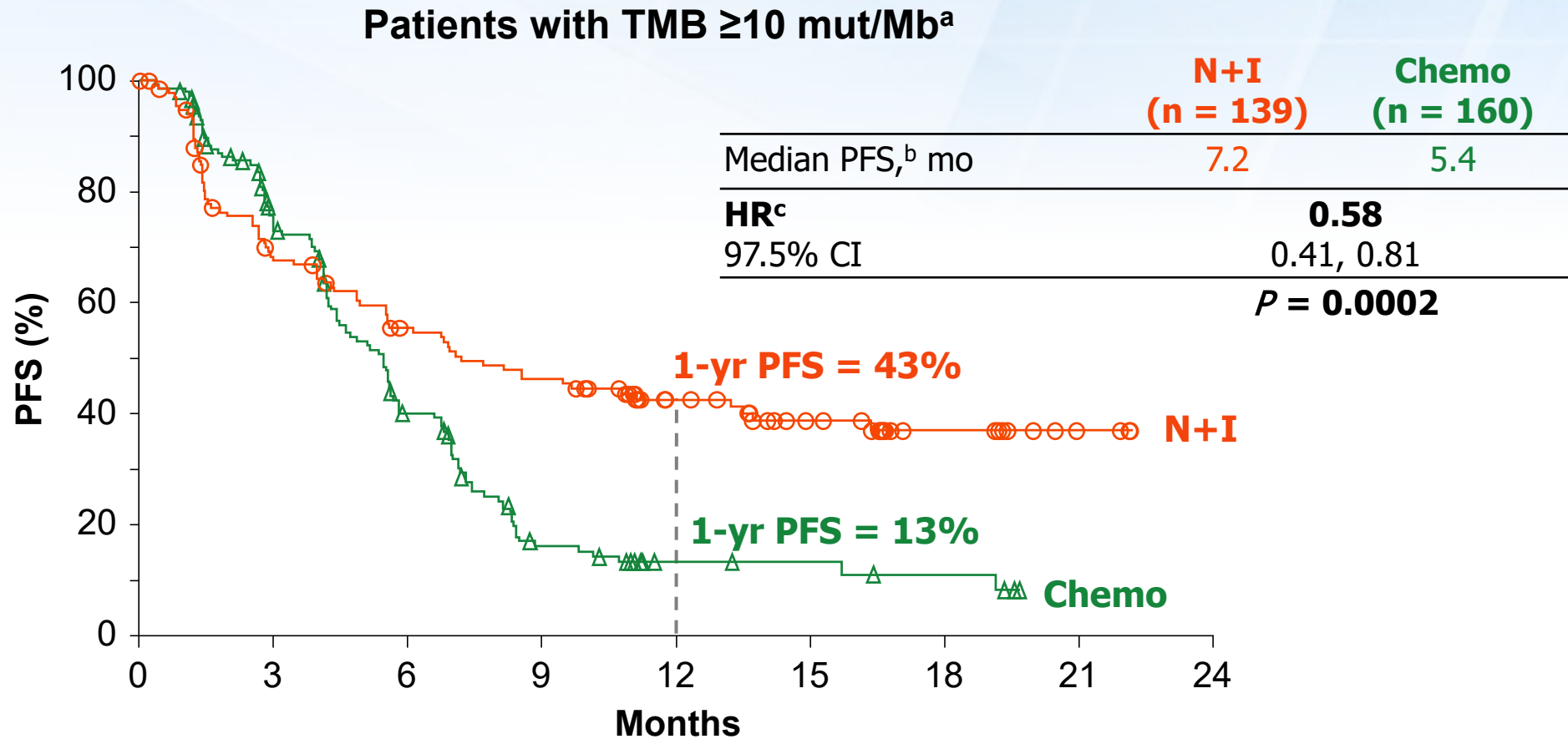


Hypothesized TMB Mechanism



TMB identifies different and independent populations from PD-L1

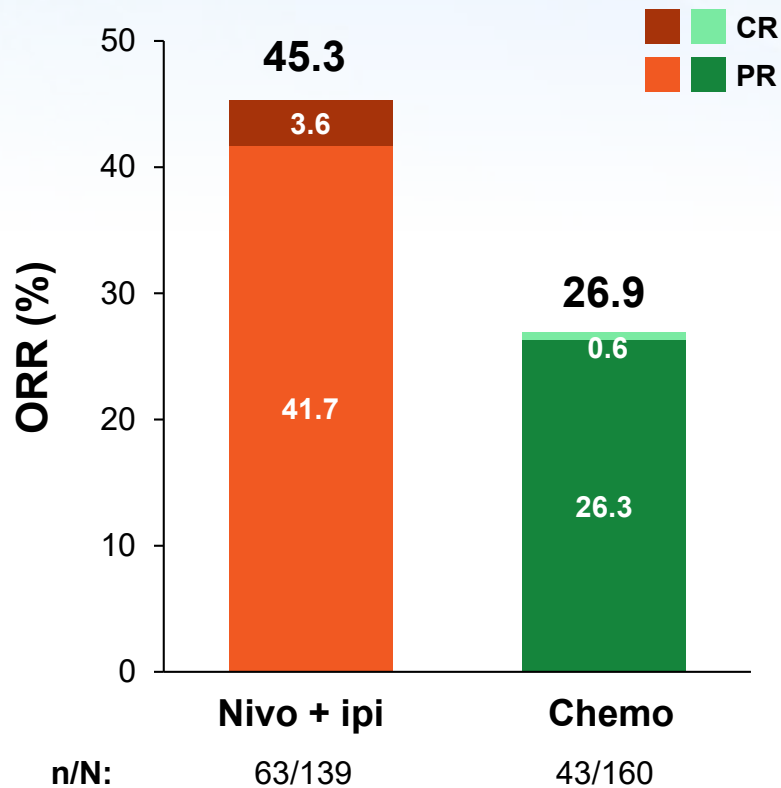
Co-primary Endpoint: PFS with Nivolumab + Ipilimumab vs Chemotherapy in Patients with High TMB (≥ 10 mut/Mb) per BICR



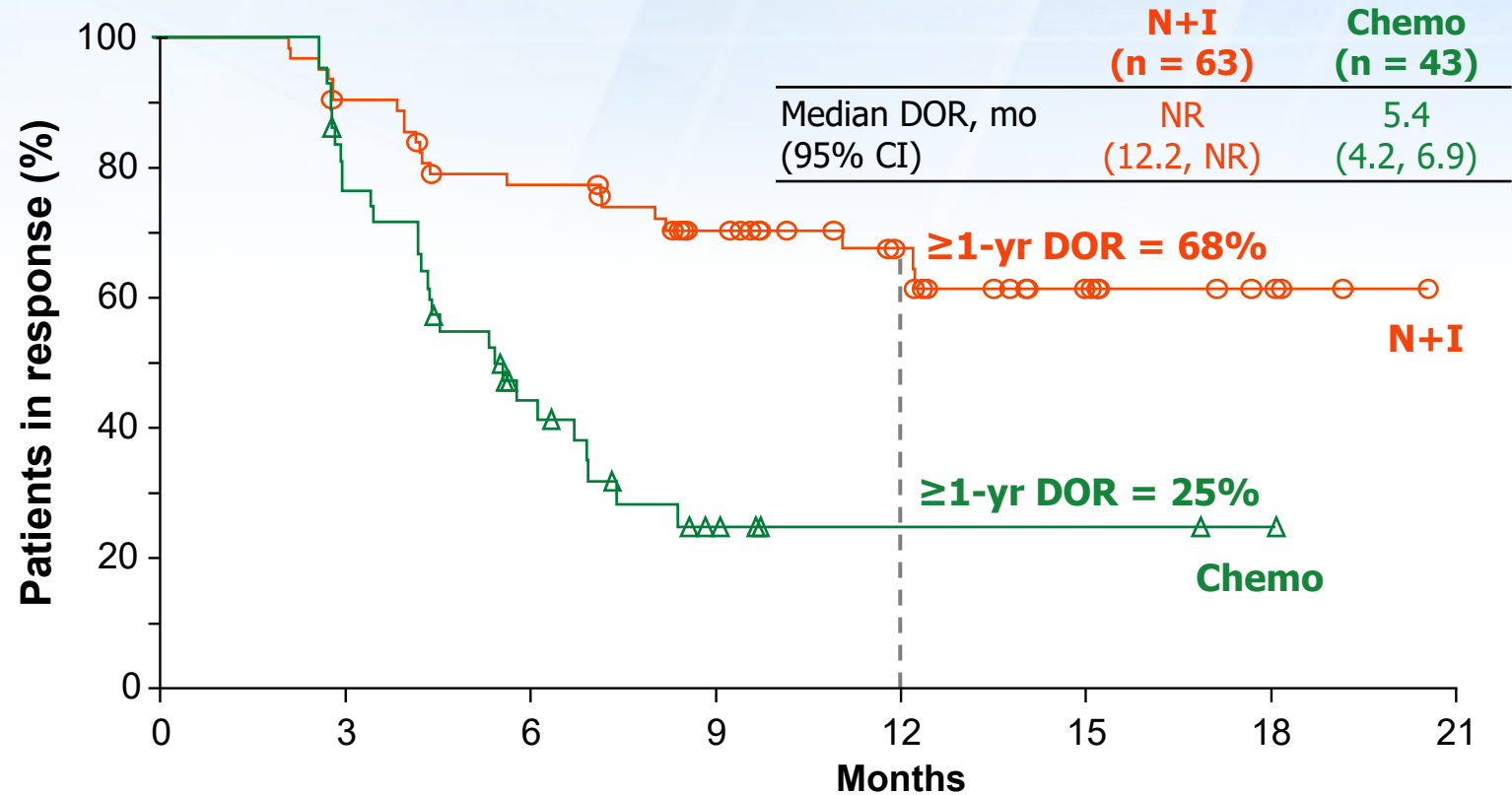
^aIn patients with TMB <10 mut/Mb treated with nivo + ipi vs chemo, the HR was 1.07 (95% CI: 0.84, 1.35); ^b95% CI: nivo + ipi (5.5, 13.2 mo), chemo (4.4, 5.8 mo); ^c95% CI: 0.43, 0.77 mo

Improved ORR with More Durable Responses

ORR (TMB ≥ 10 mut/Mb)^a

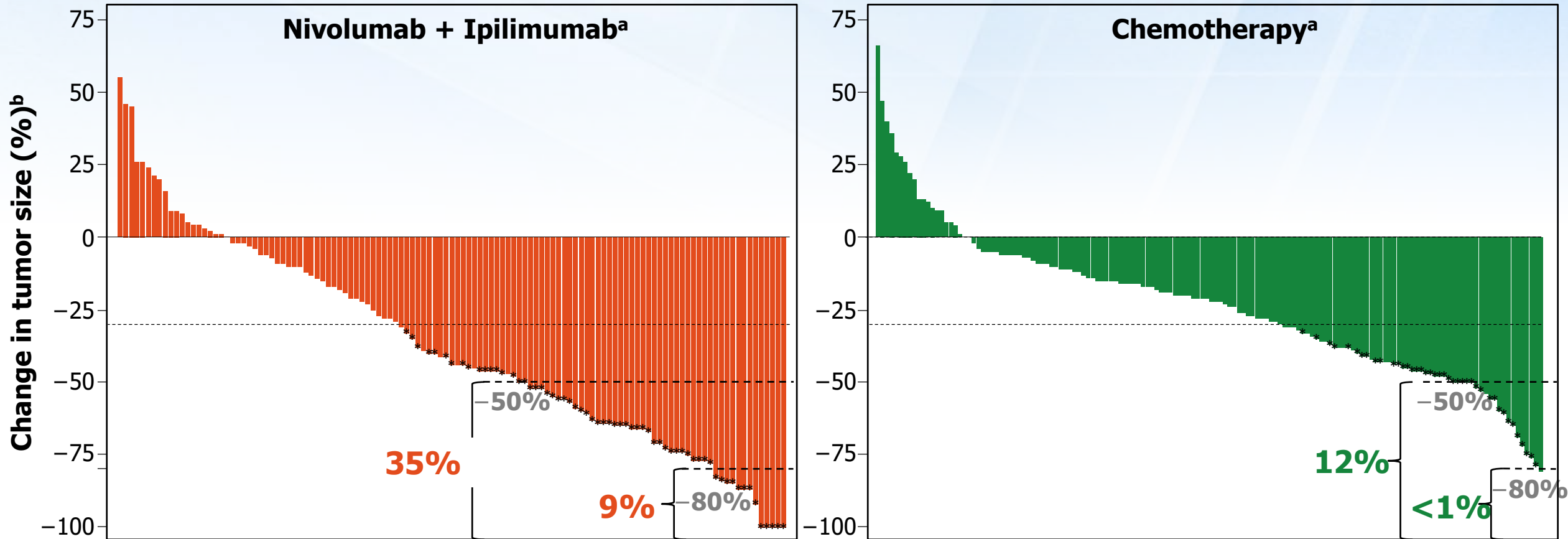


DOR (TMB ≥ 10 mut/Mb)



^aORR in patients with TMB <10 mut/Mb was 24.6% in nivo + ipi arm and 25.9% in chemo arm

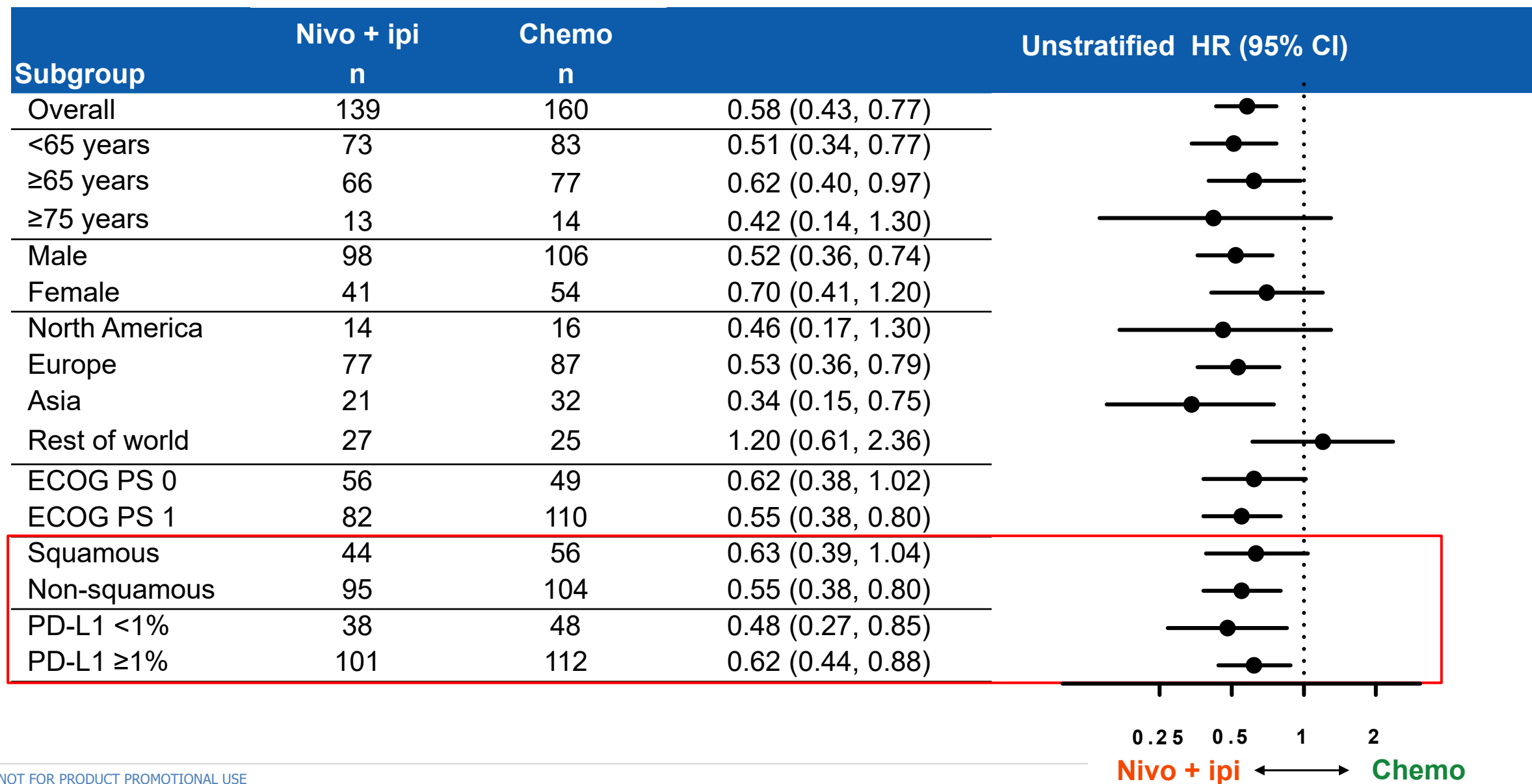
Greater Depth of Response with Opdivo/Yervoy



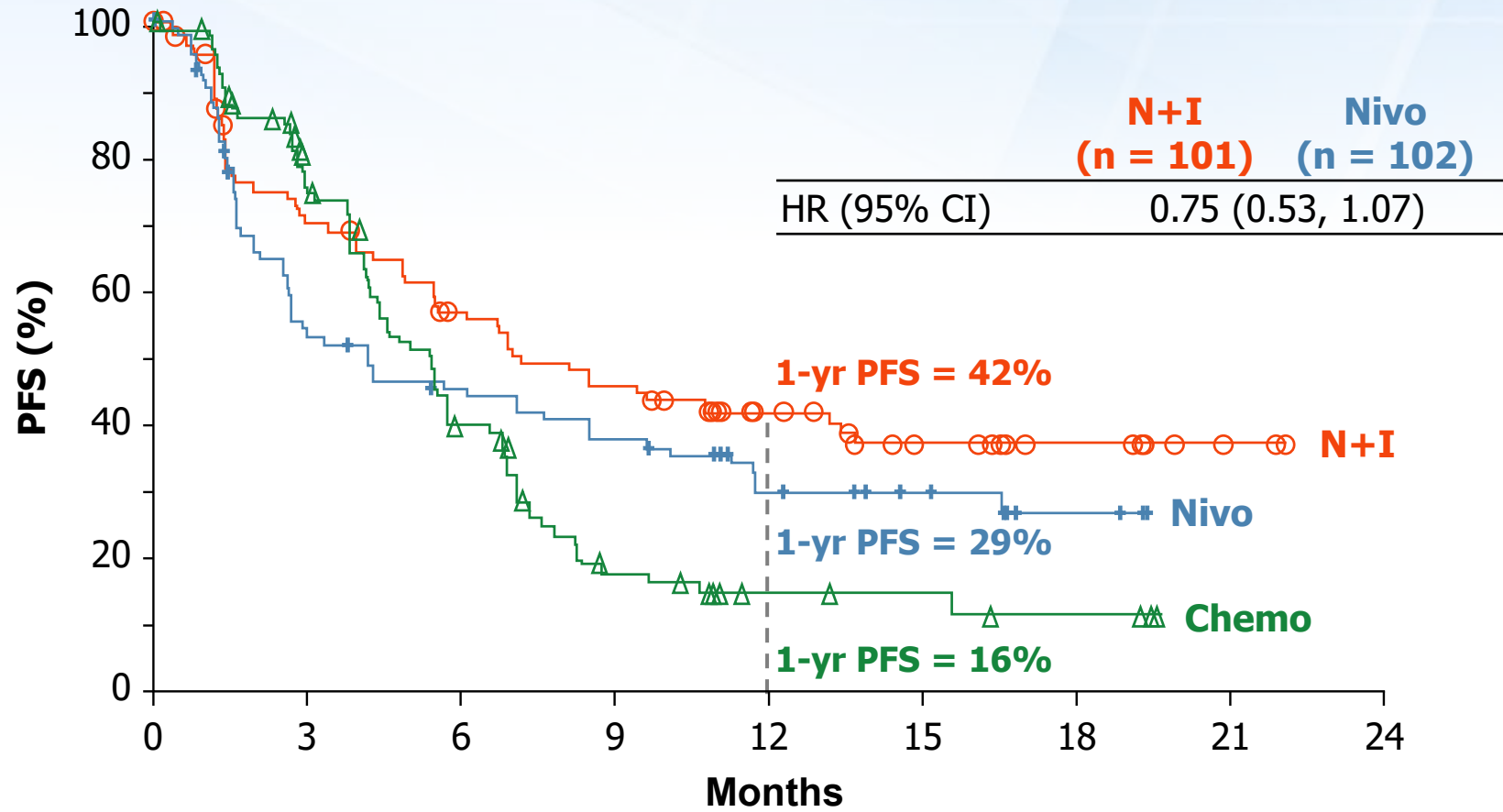
Horizontal line indicates 30% reduction consistent with a RECIST 1.1 response; Asterisk (*): Responder per RECIST1.1 criteria, confirmation of response required

^aWaterfall plots show patients with baseline and at least one on-treatment tumor assessment per BICR treated with nivolumab + ipilimumab (n = 119) or chemotherapy (n = 146). Percentages of deep response were calculated based on all randomized patients with baseline TMB ≥ 10 mut/Mb; ^bNegative/positive value means maximum tumor reduction /minimum tumor increase

Benefits Observed Regardless of PD-L1 Status and Histology

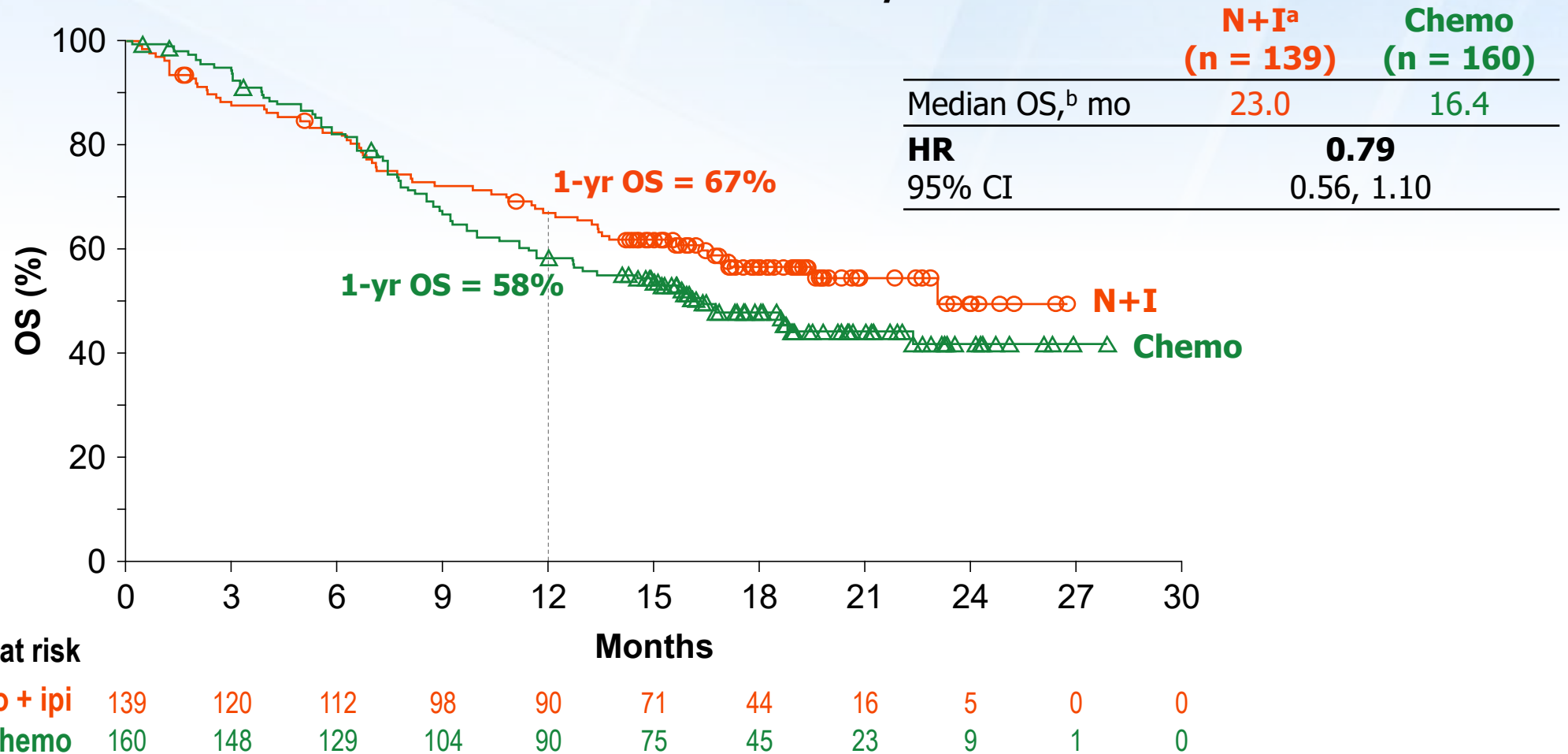


PFS: Nivolumab + Ipilimumab vs Nivolumab in Patients with High TMB (≥ 10 mut/Mb) and $\geq 1\%$ PD-L1 Expression



Preliminary OS is Encouraging

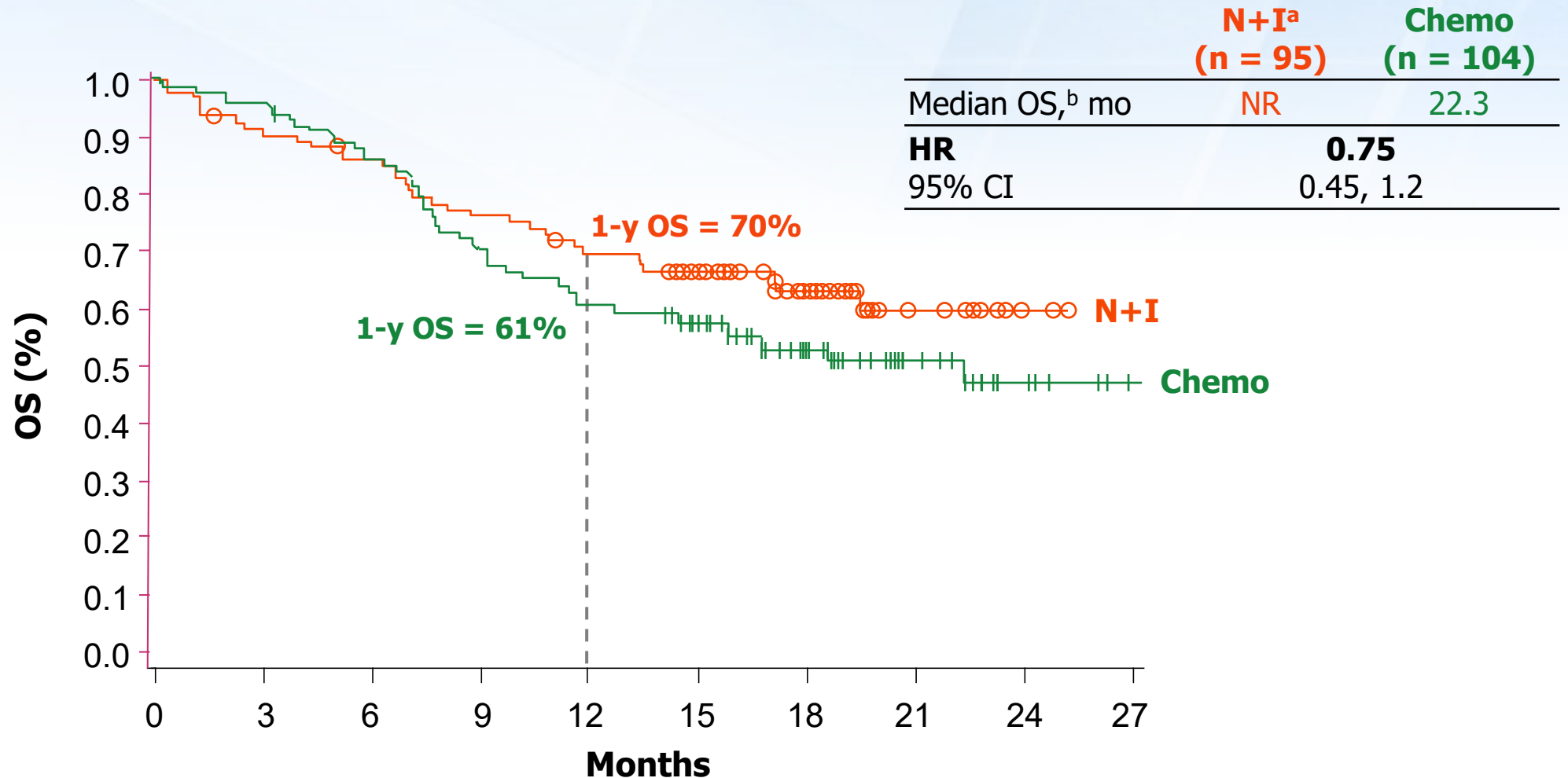
Patients with TMB ≥ 10 mut/Mb



Database lock: March 15, 2018; minimum follow-up: 14.2 months; 53% of patients were censored

Preliminary OS in Non-Squamous Patients With High TMB

Patients with TMB ≥ 10 mut/Mb



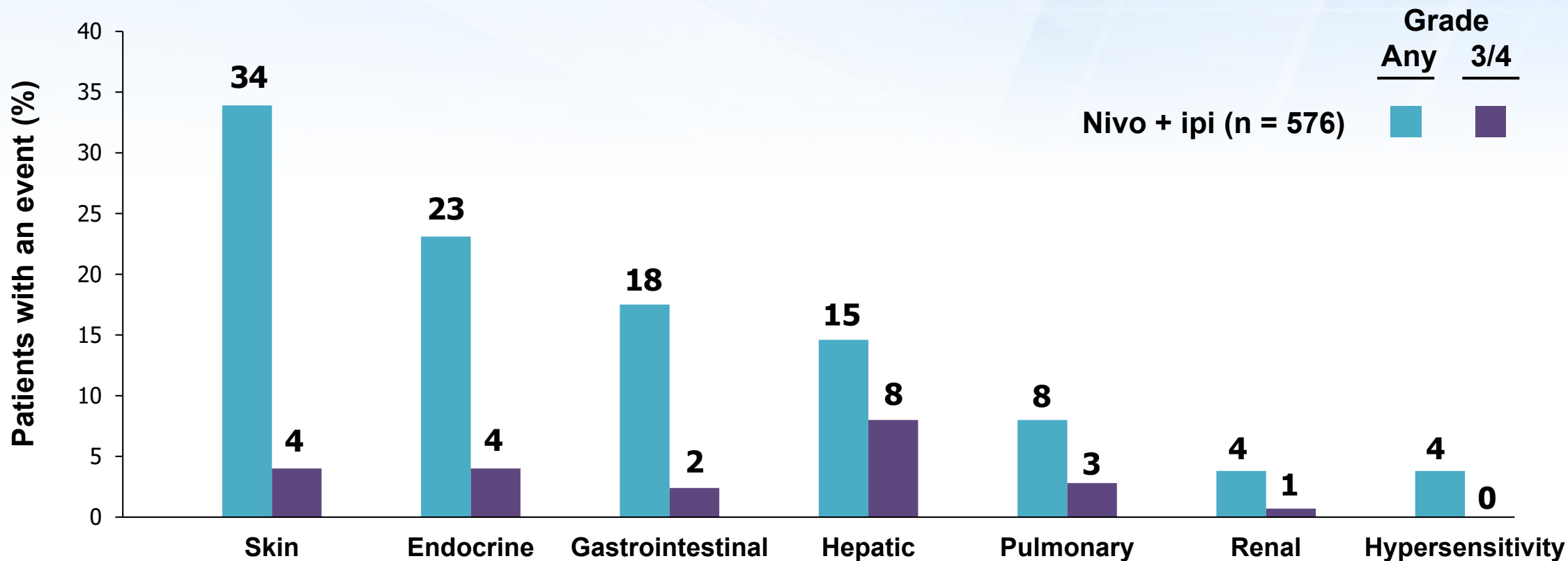
^a95% CI: nivo + ipi (19.4 mo, NR), chemo (12.7 mo, NR); ^b95% CI: nivo + ipi (6.8 mo, NR), chemo (8.5, 18.6 mo)

Safety Summary of Treatment-Related AEs

TRAE, %	Nivolumab + ipilimumab (n = 576)		Chemotherapy (n = 570)	
	Any grade	Grade 3–4	Any grade	Grade 3–4
Any TRAE	75	31	81	36
TRAE leading to discontinuation	17	12	9	5
Most frequent TRAEs (≥15%)				
Rash	17	2	5	0
Diarrhea	16	2	10	1
Fatigue	13	1	18	1
Decreased appetite	13	<1	19	1
Nausea	10	<1	36	2
Constipation	4	0	15	<1
Anemia	4	2	32	11
Neutropenia	<1	0	17	9
Treatment-related deaths	1		1	

- Median duration (range) of therapy was 4.2 months (0.03–24.0+) with nivolumab + ipilimumab and 2.6 months (0.03–22.1+) with chemotherapy
- Median number of doses of nivolumab (Q2W) and ipilimumab (Q6W) received were 9 and 3, respectively

Treatment-Related Select AEs in Patients Treated With Nivolumab + Ipilimumab^{a,b}



^a Select AEs are those with potential immunologic etiology that require frequent monitoring/intervention; ^b Includes events reported between first dose and 30 days after last dose of study drug



The NEW ENGLAND
JOURNAL of MEDICINE

ORIGINAL ARTICLE

Nivolumab plus Ipilimumab in Lung Cancer with a High Tumor Mutational Burden

Matthew D. Hellmann, M.D., Tudor-Eliade Ciuleanu, M.D.,
Adam Pluzanski, M.D., Jong-Seok Lee, M.D., Gregory A. Otterson, M.D.,
Clarisse Audigier-Valette, M.D., Elisa Minenza, M.D., Helena Linardou, M.D.,
Sjaak Burgers, M.D., Pamela Salman, M.D., Hossein Borghaei, D.O.,
Suresh S. Ramalingam, M.D., Julie Brahmer, M.D., Martin Reck, M.D.,
Kenneth J. O'Byrne, M.D., William J. Geese, Ph.D., George Green, Ph.D.,
Han Chang, Ph.D., Joseph Szustakowski, Ph.D.,
Prabhu Bhagavatheeswaran, Ph.D., Diane Healey, M.S., Yali Fu, M.D.,
Faith Nathan, M.D., and Luis Paz-Ares, M.D.



Tom Lynch

Chief Scientific Officer

AACR Summary

- Significant innovation and advancing the science in NSCLC

- TMB may help physicians, payors, and patients guide optimal treatment

- Increasing market segmentation and potential role for Opdivo and low-dose Yervoy as a chemo-sparing regimen in a selected patient population

- Reinforces need for new biomarkers, ongoing translational work, and continued development of combination therapies

ORIGINAL ARTICLE

Neoadjuvant PD-1 Blockade in Resectable Lung Cancer

P.M. Forde, J.E. Chaft, K.N. Smith, V. Anagnostou, T.R. Cottrell, M.D. Hellmann, M. Zahurak, S.C. Yang, D.R. Jones, S. Broderick, R.J. Battafarano, M.J. Velez, N. Rekhtman, Z. Olah, J. Naidoo, K.A. Marrone, F. Verde, H. Guo, J. Zhang, J.X. Caushi, H.Y. Chan, J.-W. Sidhom, R.B. Scharpf, J. White, E. Gabrielson, H. Wang, G.L. Rosner, V. Rusch, J.D. Wolchok, T. Merghoub, J.M. Taube, V.E. Velculescu, S.L. Topalian, J.R. Brahmer, and D.M. Pardoll

Significant Opportunities to Address Unmet Need

- ▶ Multiple data readouts upcoming from Opdivo including:
 - Lung
 - RCC
 - HCC
 - Gastric
 - SCLC
 - SCCHN
- ▶ Broaden use of Opdivo in earlier lines of therapy and new tumors
- ▶ Advancing next wave of Opdivo-based combination therapies
- ▶ Leveraging Translational Capabilities, Biomarkers, and Cancer Biology



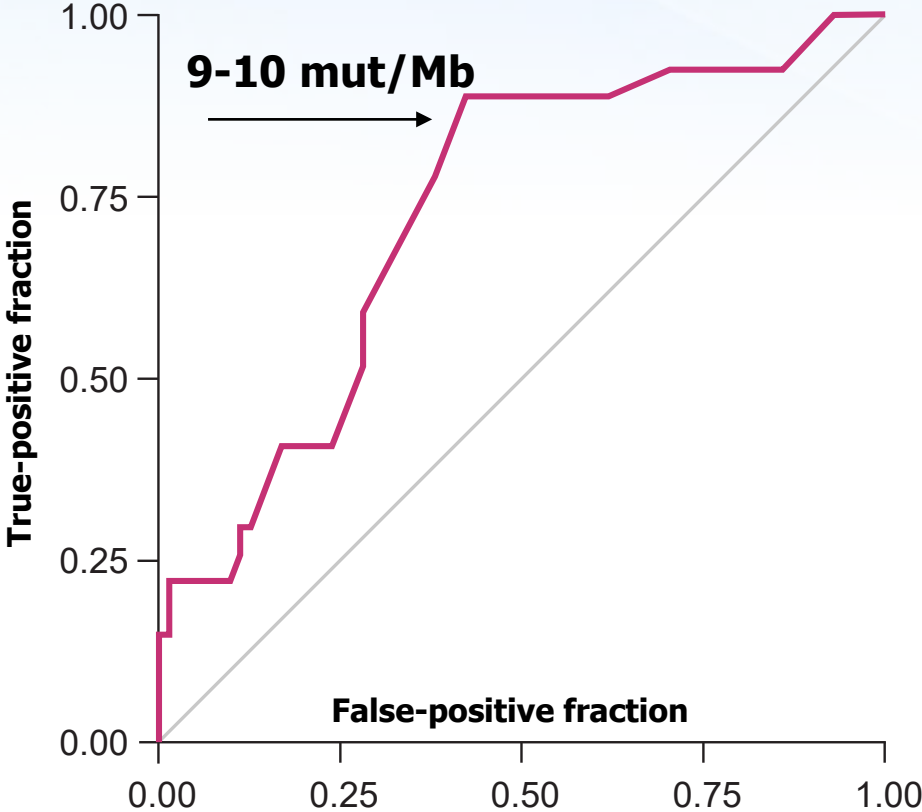
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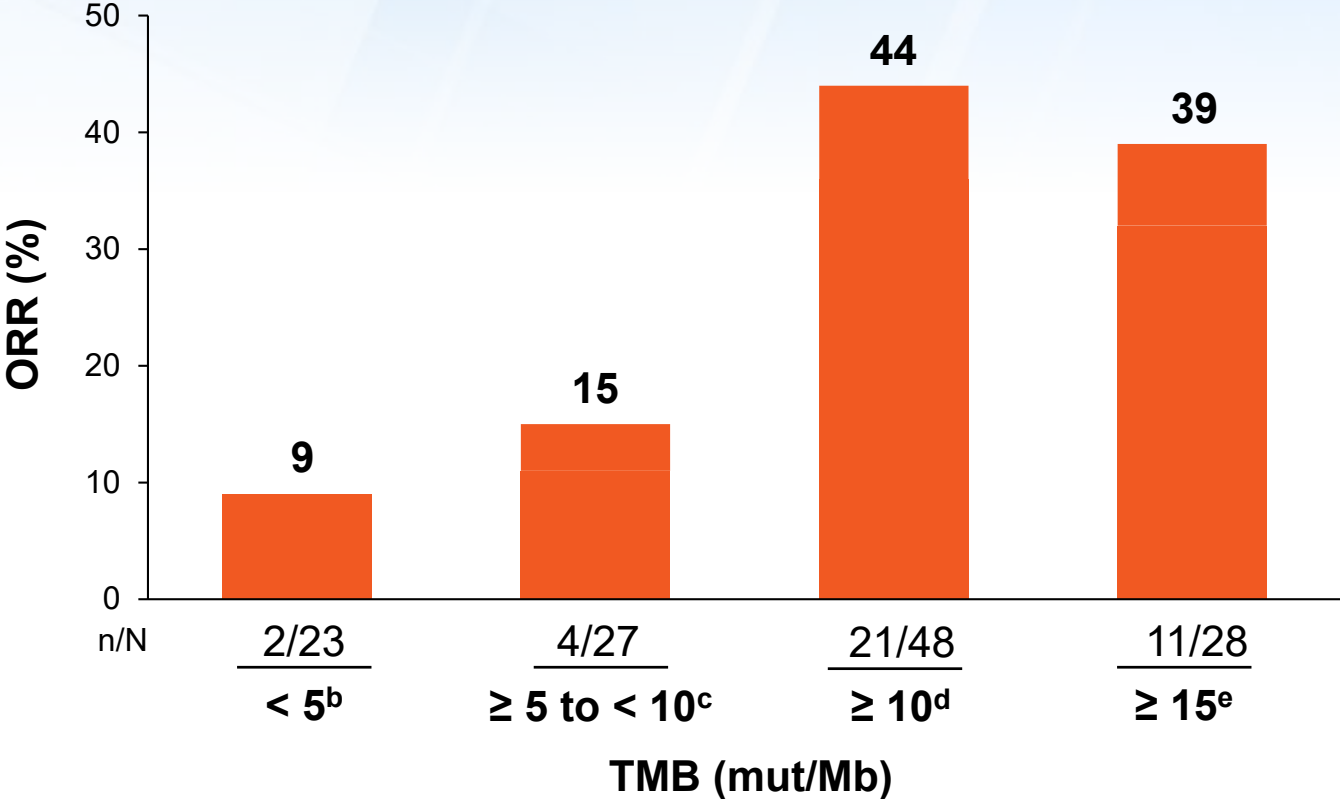
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CM-568: Rationale for ≥ 10 mut/mb Cutpoint with FoundationOne CDx

ROC for TMB by ORR irrespective of tumor PD-L1 expression (n=98)



ORR by TMB^a

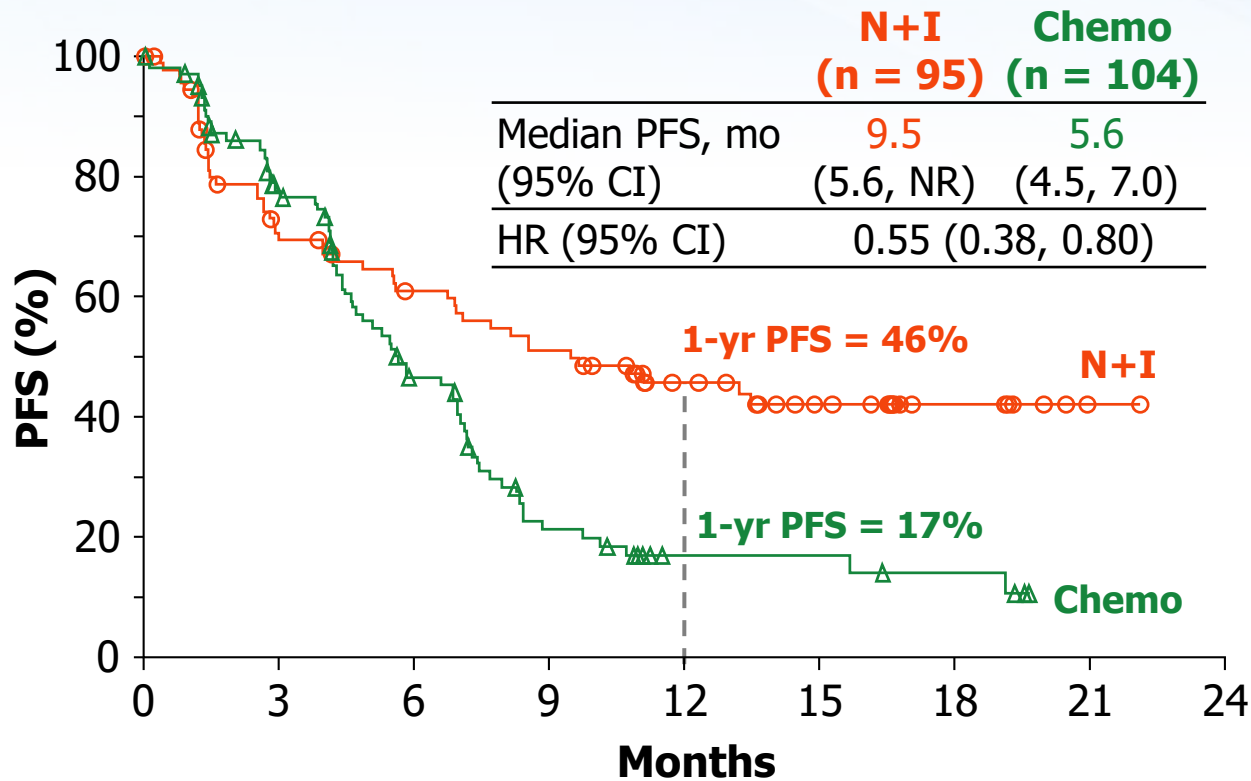


1. Carbone DP, et al. *N Engl J Med* 2017;376:2415–2426.
 2. Ramalingam S, et al. Presented at AACR Annual Meeting; April 14–18, 2018; Chicago, IL, USA. CT078.
 3. Hellmann MD, et al. *Cancer Cell* (accepted) 2018.

^aIrrespective of PD-L1 expression; ^bCR = 0; ^cCR = 4%; ^dCR = 8%; ^eCR = 7%
 12% ORR for <10 mut/Mb; 50% ORR for ≥10 to <15 mut/Mb

PFS in Patients With High TMB (≥ 10 mut/Mb) by Tumor Histology

Non-squamous



Squamous

