Optimal Integration of Immune Checkpoint Inhibitors into the Management of Metastatic Triple-Negative Breast Cancer

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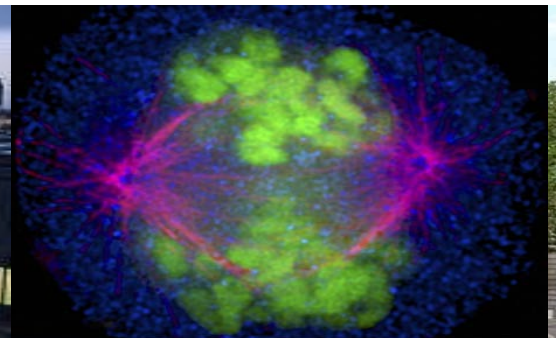
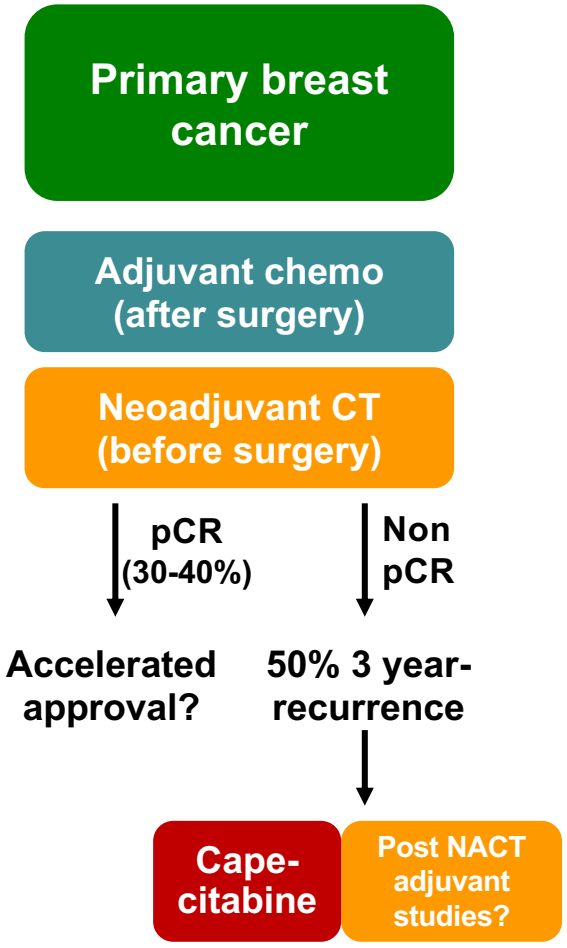



Queen Mary University of London

Barts Health NHS Trust

Triple Negative Breast Cancer – Management in 2017

Median OS for met. TNBC 12-18 months!

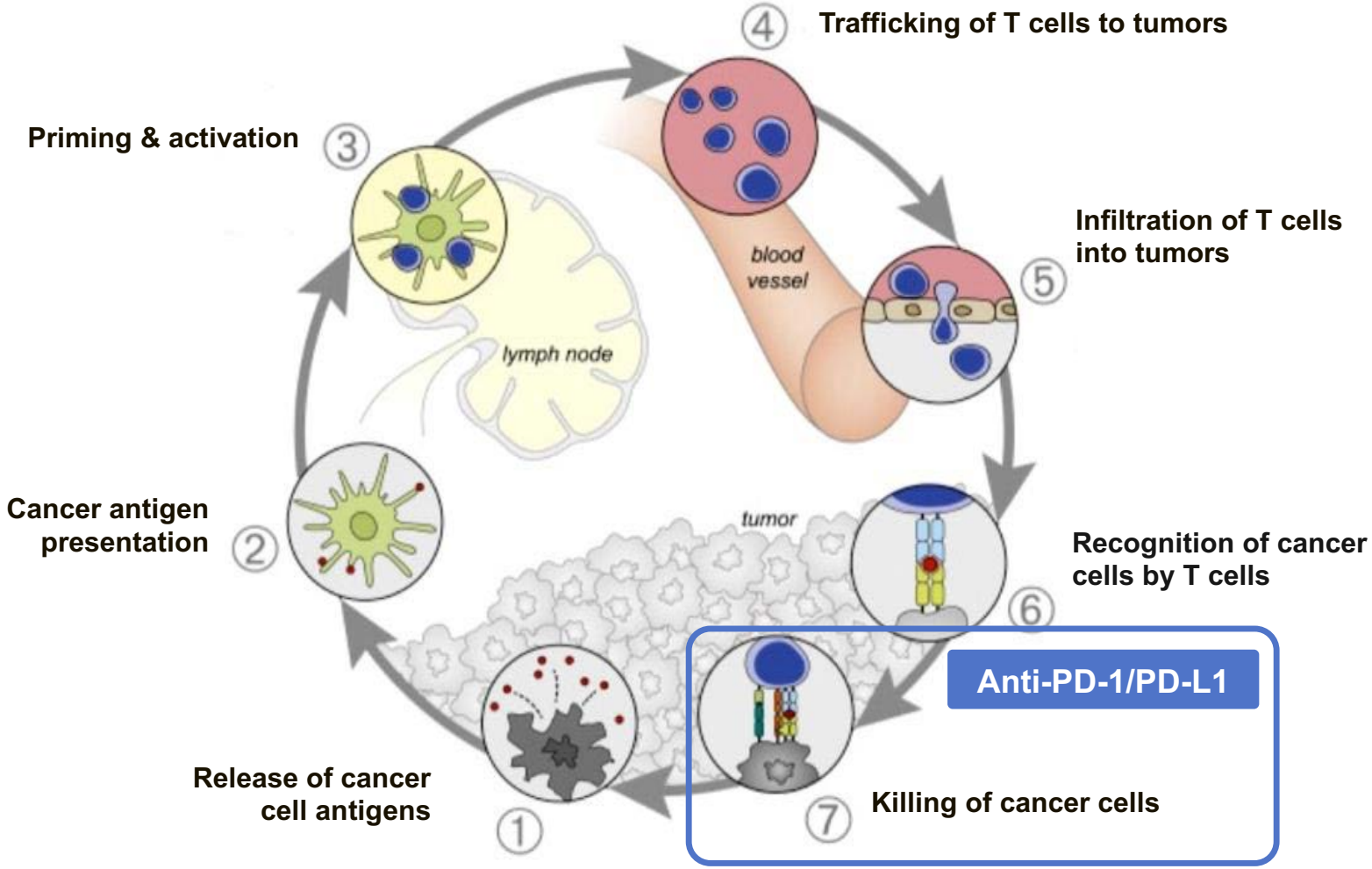


MBC 1st line	MBC 2nd line	MBC >2nd line
Taxanes (if DFI >1a)	Capecitabine	Eribulin
Platinum Combinations (CarboTax, GC)	Platinum Combinations (CarboTax, GC)	BSC
Taxanes + Bevacizumab	Eribulin	

Schmid P, et al. Personal Communication

Courtesy of Professor Peter Schmid, MD, PhD

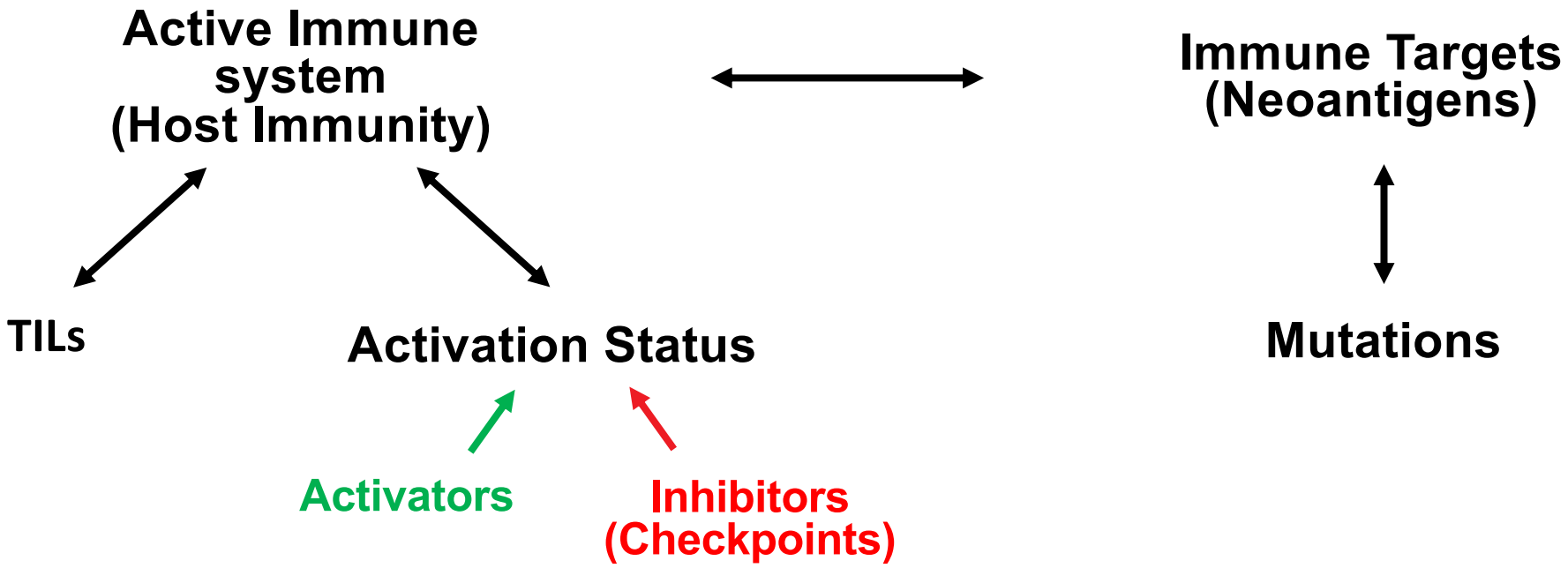
Antitumor Immunity is a Dynamic Process



Courtesy of Professor Peter Schmid, MD, PhD

1. Chen and Mellman 2013; 2. Liakou et al. 2008; 3. Herr and Morales 2008; 4. Bajorin et al. 2014

Cancer and Immunity



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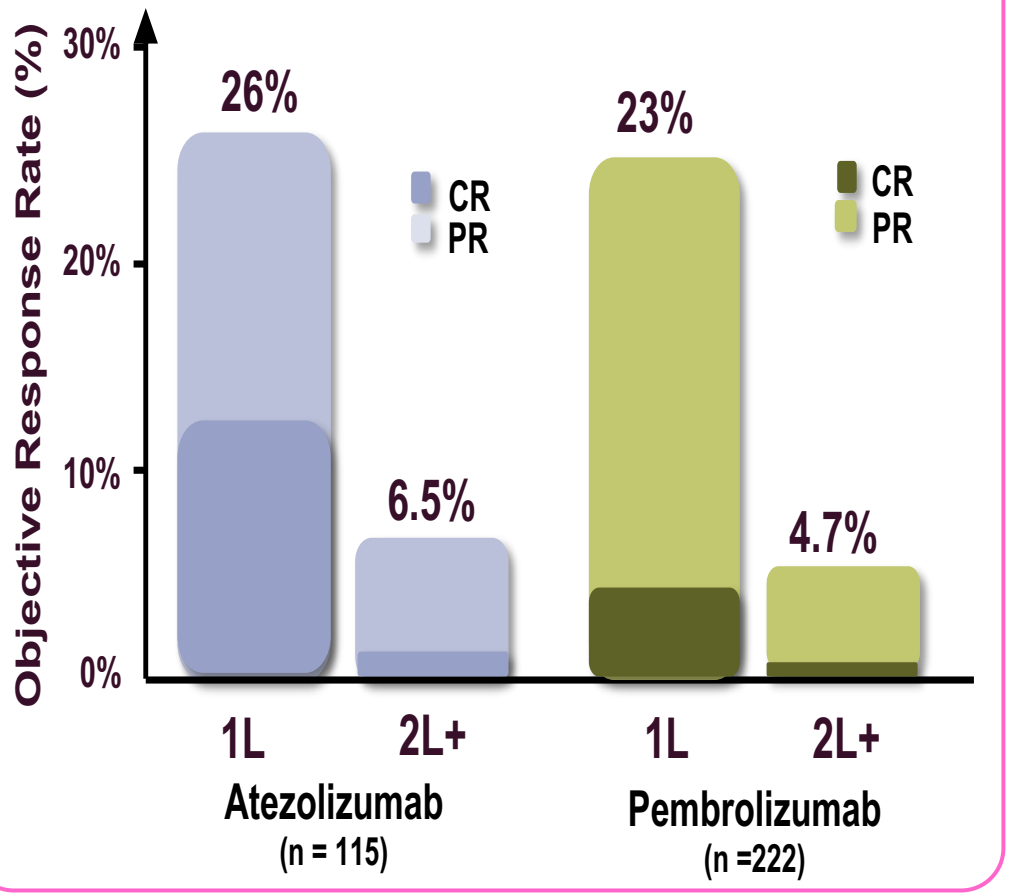
Schmid P, et al. Personal Communication

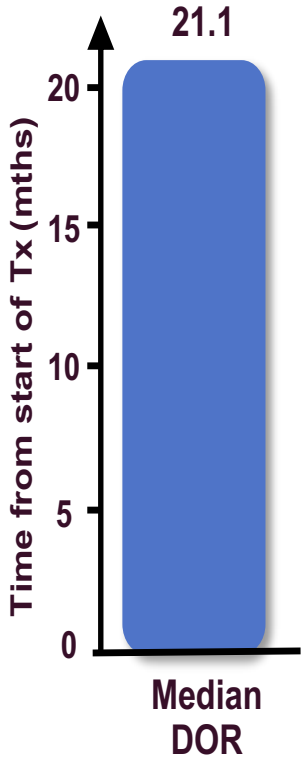
Single agent activity of anti-PD-1/PD-L1 in Triple-negative breast cancer

Response to single agent anti-PD-L1/PD-1

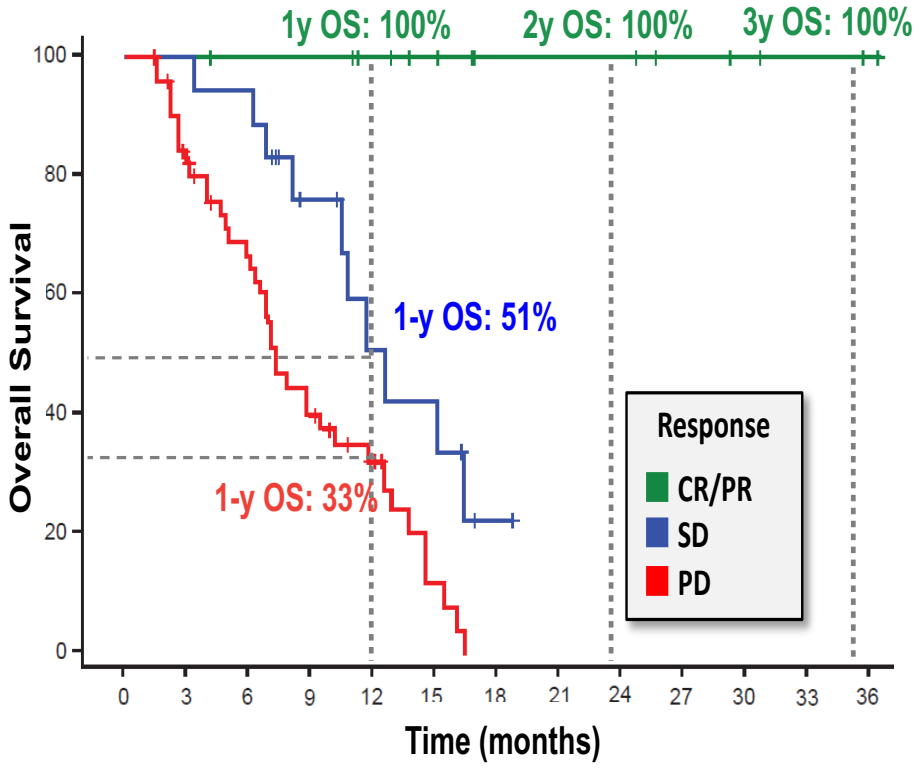
Response in mTNBC ≥1L (PDL1+/-)



Duration of Response



Overall Survival

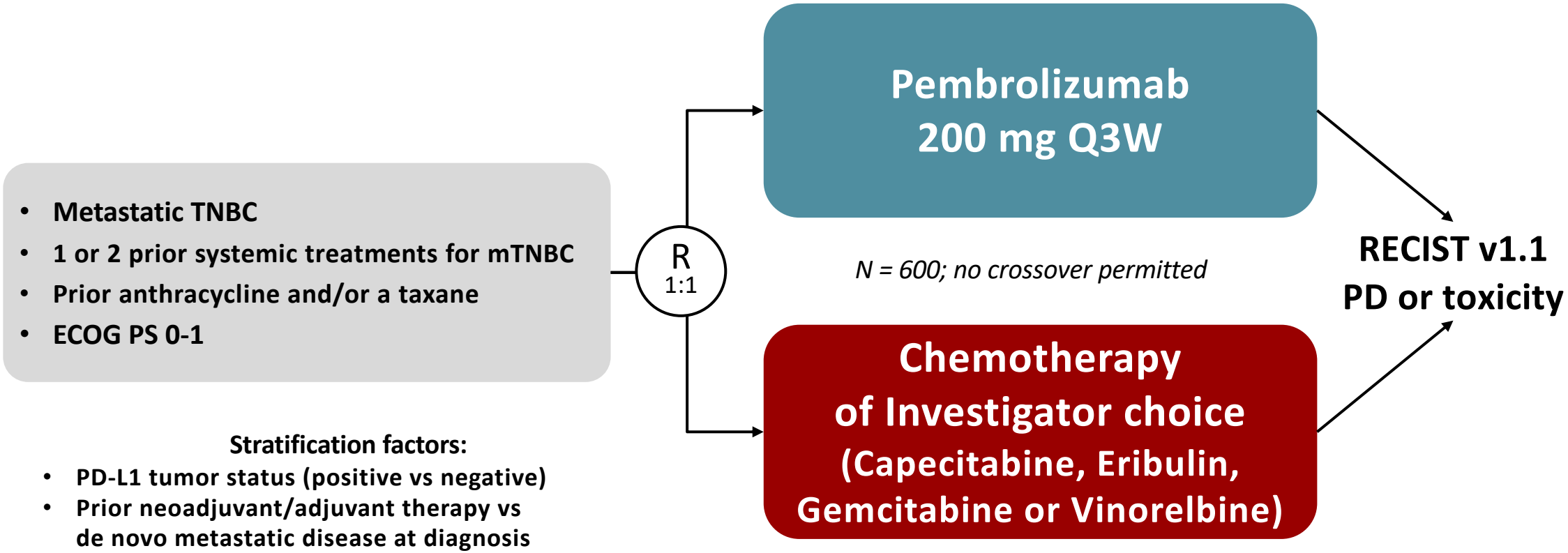


Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. AACR 2017; Adams S, et al ASCO 2017

Pembrolizumab versus chemotherapy in 2L/3L TNBC

KEYNOTE-119 study design



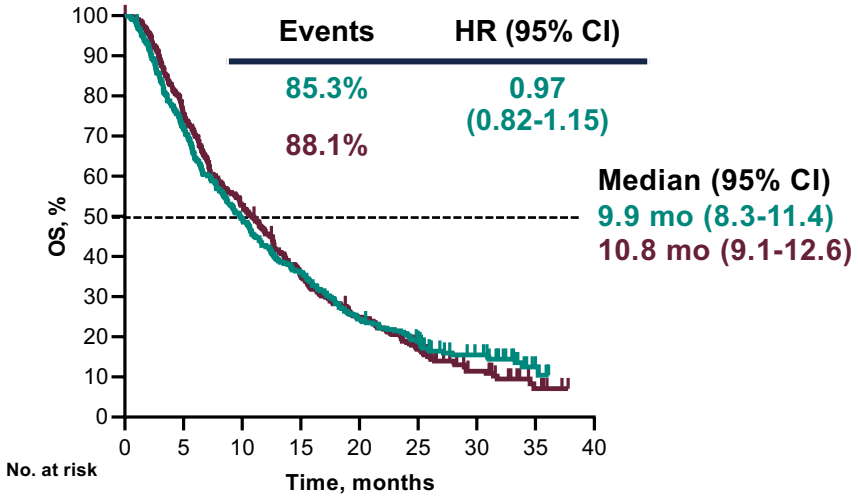
- **Co-primary endpoints were OS in the CPS ≥10, in the CPS ≥1, and in the ITT populations**

Courtesy of Professor Peter Schmid, MD, PhD

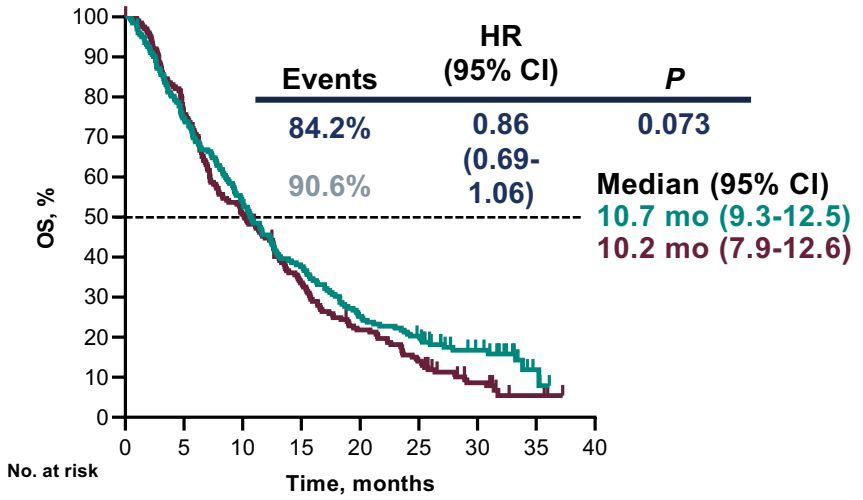
Cortes, et al. ESMO 2019

Pembrolizumab vs chemo in 2L/3L TNBC: OS by PD-L1 CPS (KN119)

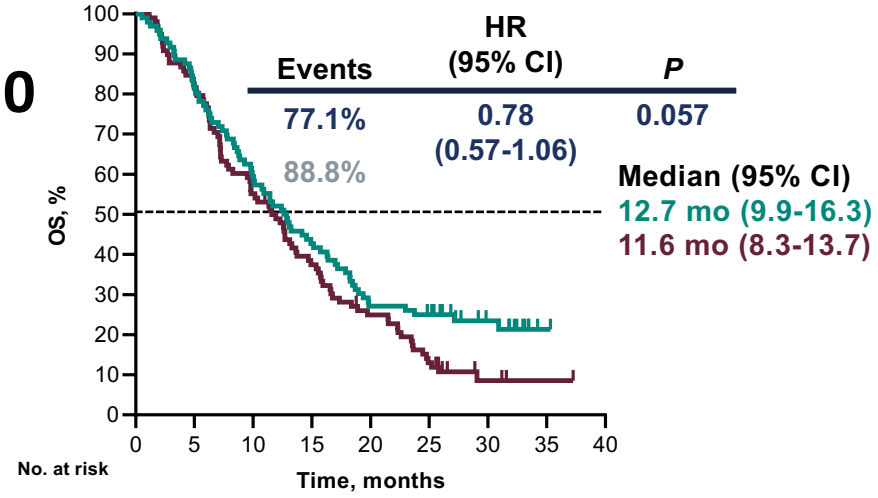
ITT



CPS ≥1

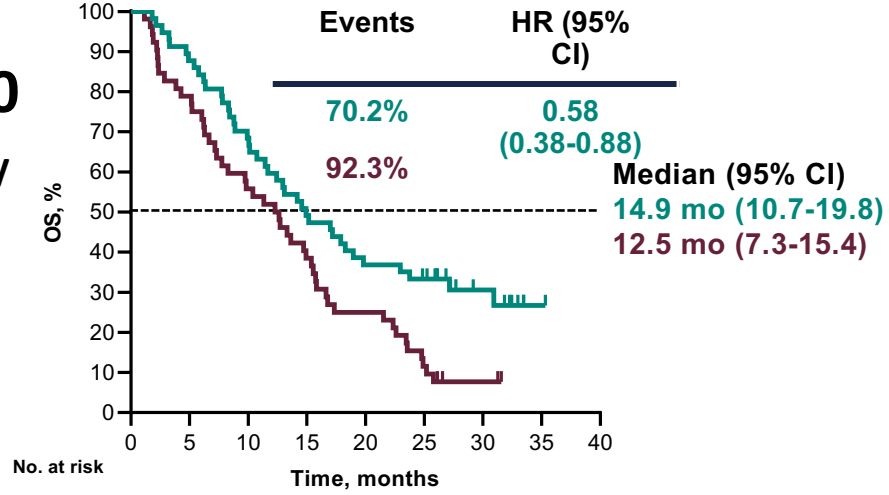


CPS ≥10



CPS ≥20

Exploratory



OS in the ITT, CPS ≥1 and CPS ≥10 populations were primary endpoints; OS in the CPS ≥20 population was an exploratory endpoint.

Courtesy of Professor Peter Schmid, MD, PhD

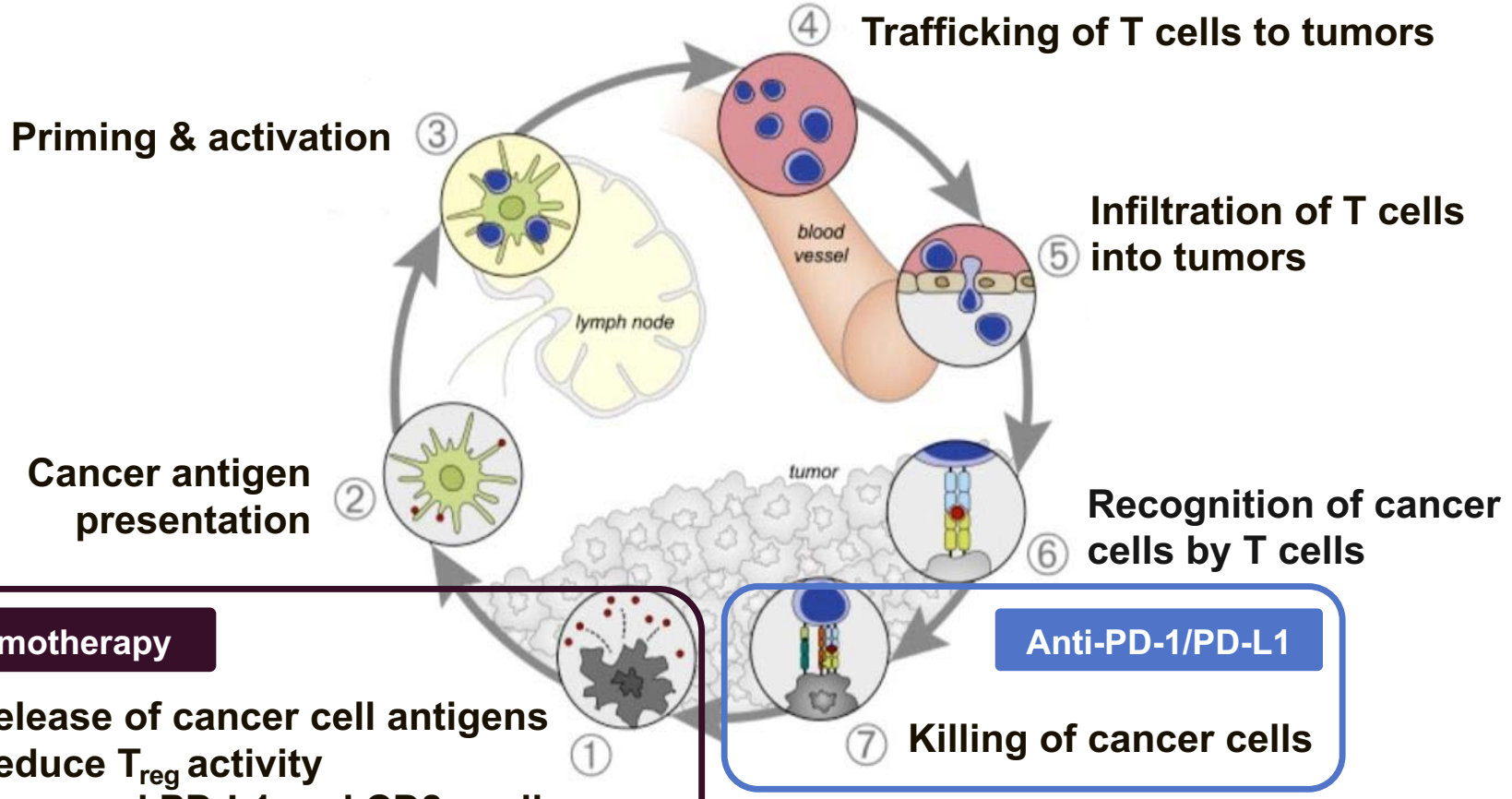
Cortes, et al. ESMO 2019

Combination therapy of anti-PD-1/PD-L1 in Triple-negative breast cancer

CIT can target several steps in the immunity cycle

Combinations to widen the target population and increase efficacy

1. Chemotherapy + CIT
2. CIT + novel targeted agents (eg PARP, MEK)?
3. CIT combination



Courtesy of Professor Peter Schmid, MD, PhD

1. Chen and Mellman 2013; 2. Liakou et al. 2008; 3. Herr and Morales 2008; 4. Bajorin et al. 2014

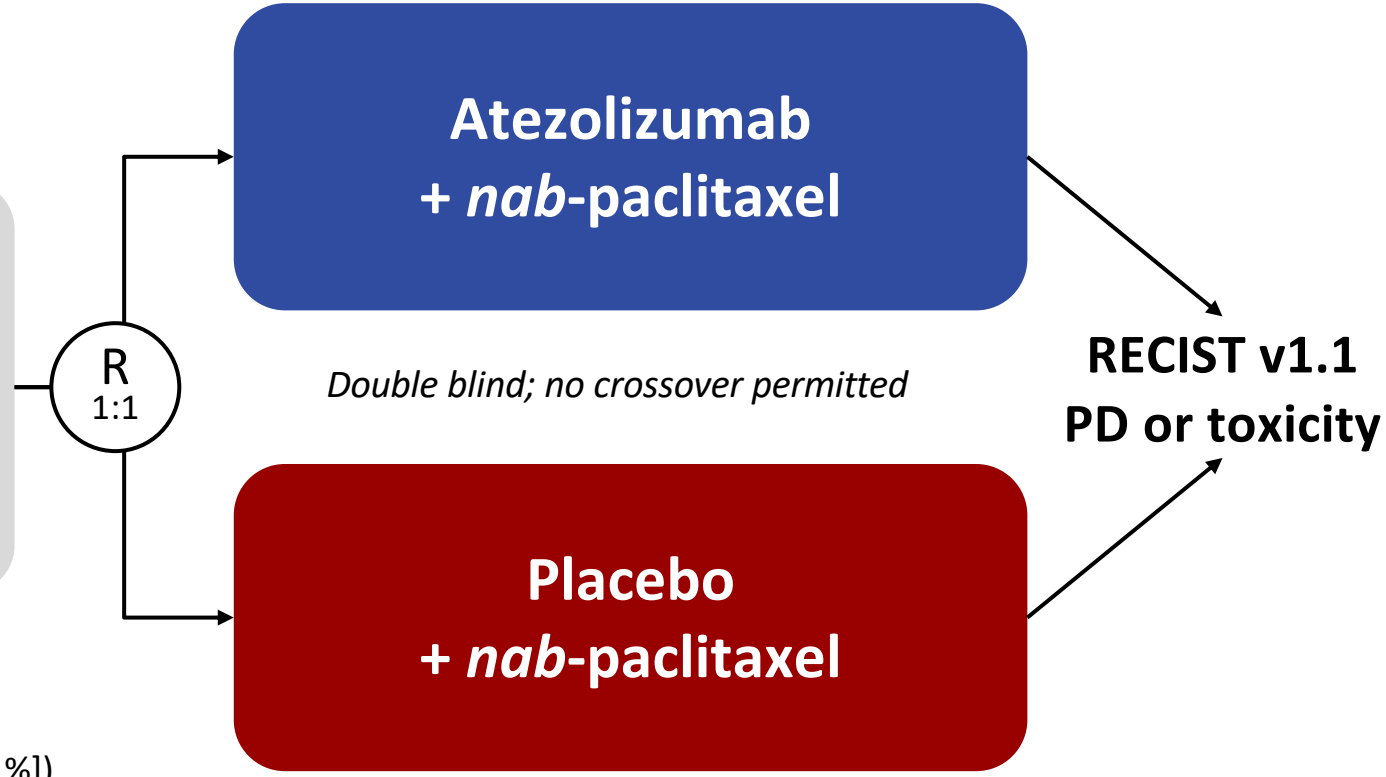
Atezolizumab (anti-PD-L1) plus chemotherapy in TNBC

IMpassion130 study design

- **Metastatic or inoperable locally advanced TNBC**
- **No prior therapy for advanced TNBC**
  - **Prior (neo)adjuvant chemo allowed if TFI ≥ 12 months**
- **ECOG PS 0-1**

Stratification factors:

- Prior taxane use (yes vs no)
- Liver metastases (yes vs no)
- PD-L1 status on IC (positive [≥ 1%] vs negative [< 1%])

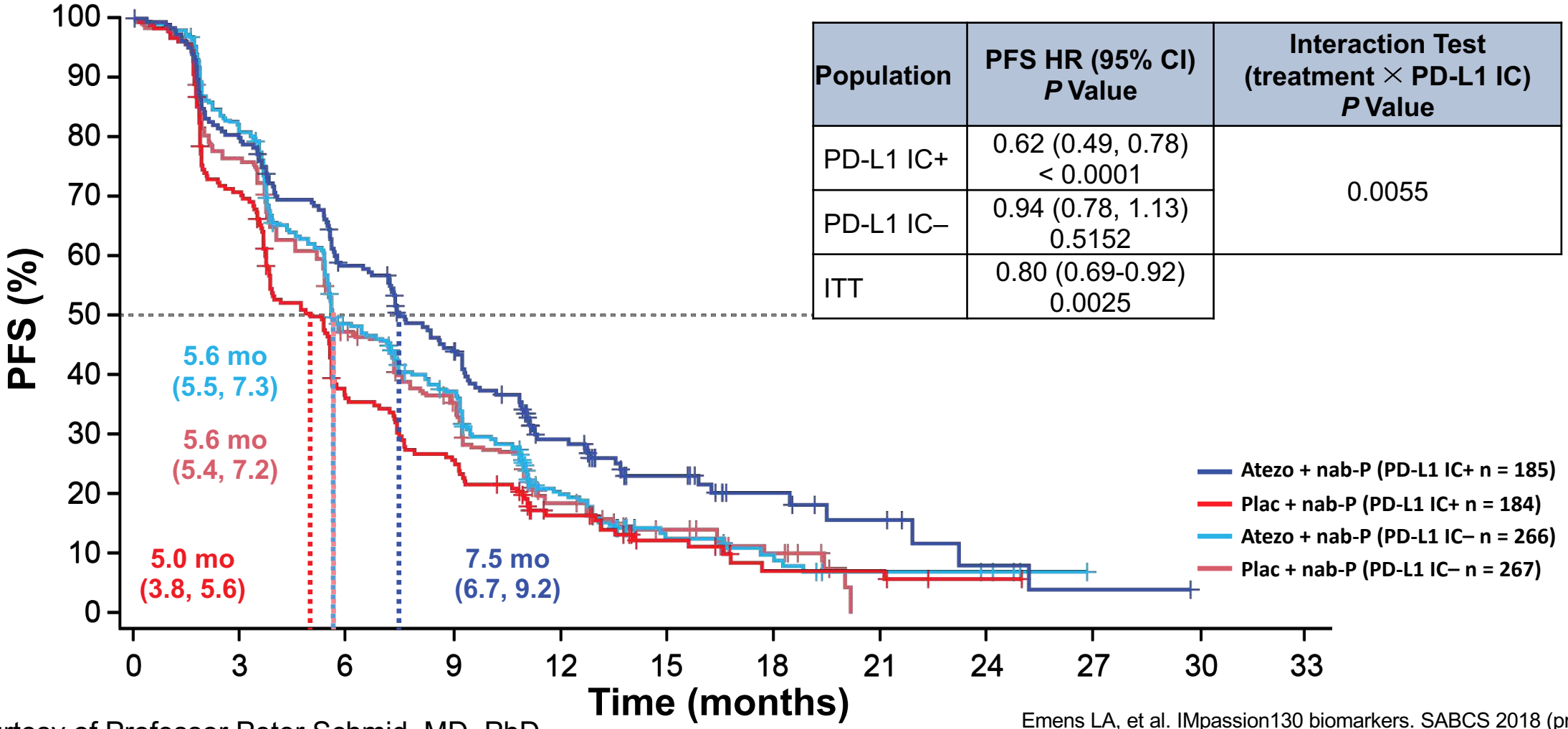


- **Co-primary endpoints were PFS and OS in the ITT and PD-L1+ populations**

Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. ESMO 2018 (LBA1); Schmid P, et al NEJM 2018

Progression-free survival: PD-L1 predicts benefit with atezolizumab



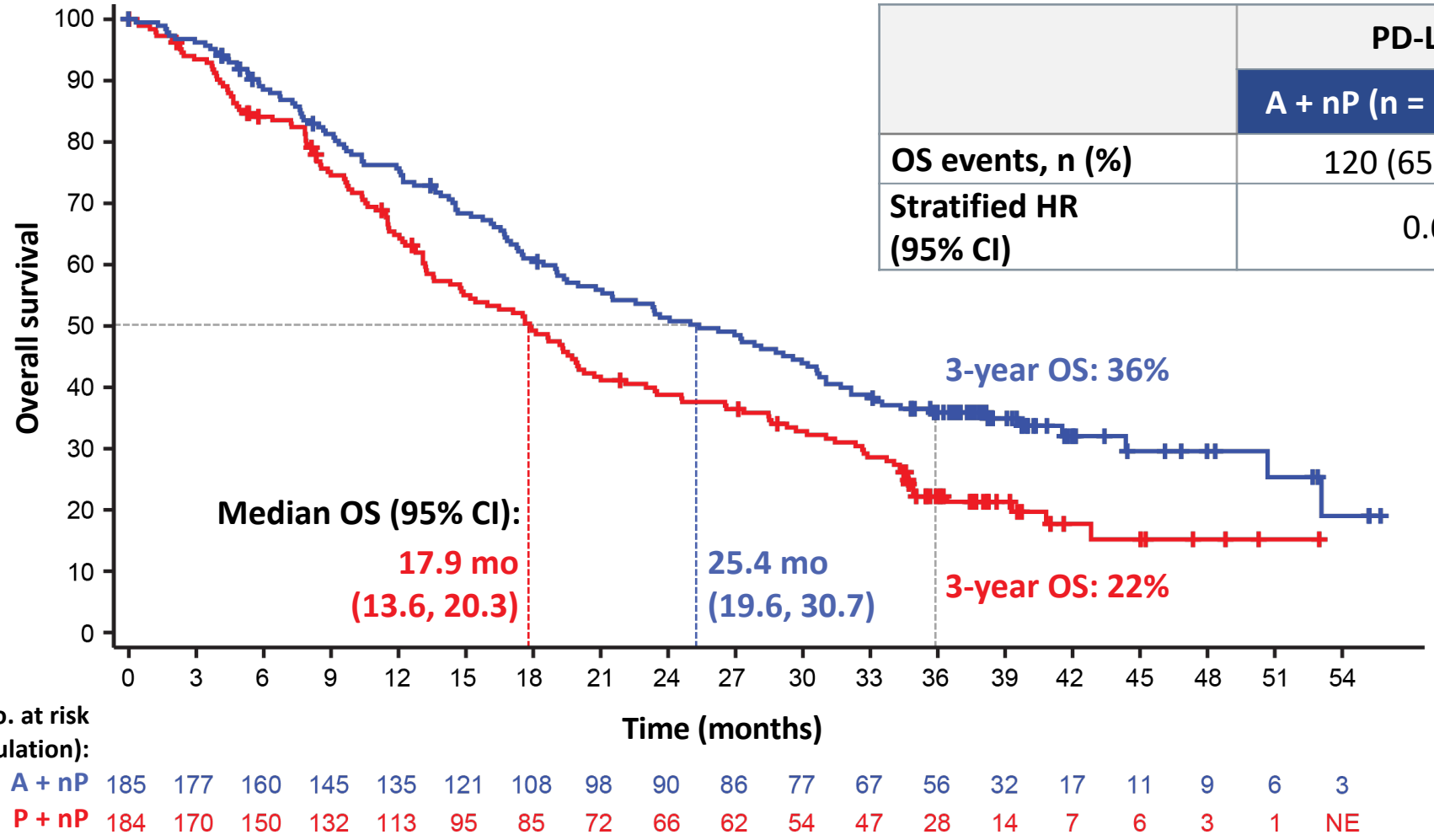
Population	PFS HR (95% CI) *P* Value	Interaction Test (treatment × PD-L1 IC) *P* Value
PD-L1 IC+	0.62 (0.49, 0.78) < 0.0001	0.0055
PD-L1 IC–	0.94 (0.78, 1.13) 0.5152	
ITT	0.80 (0.69-0.92) 0.0025	

Courtesy of Professor Peter Schmid, MD, PhD

Emens LA, et al. IMpassion130 biomarkers. SABCS 2018 (program #GS1-04); Schmid P, et al. ESMO 2018 (LBA1); Schmid P, et al NEJM 2018

Overall survival: PD-L1 status predicts benefit with atezolizumab

	PD-L1 IC+ population	
	A + nP (n = 185)	P + nP (n = 184)
OS events, n (%)	120 (65)	139 (76)
Stratified HR (95% CI)	0.67 (0.53, 0.86)[a]	

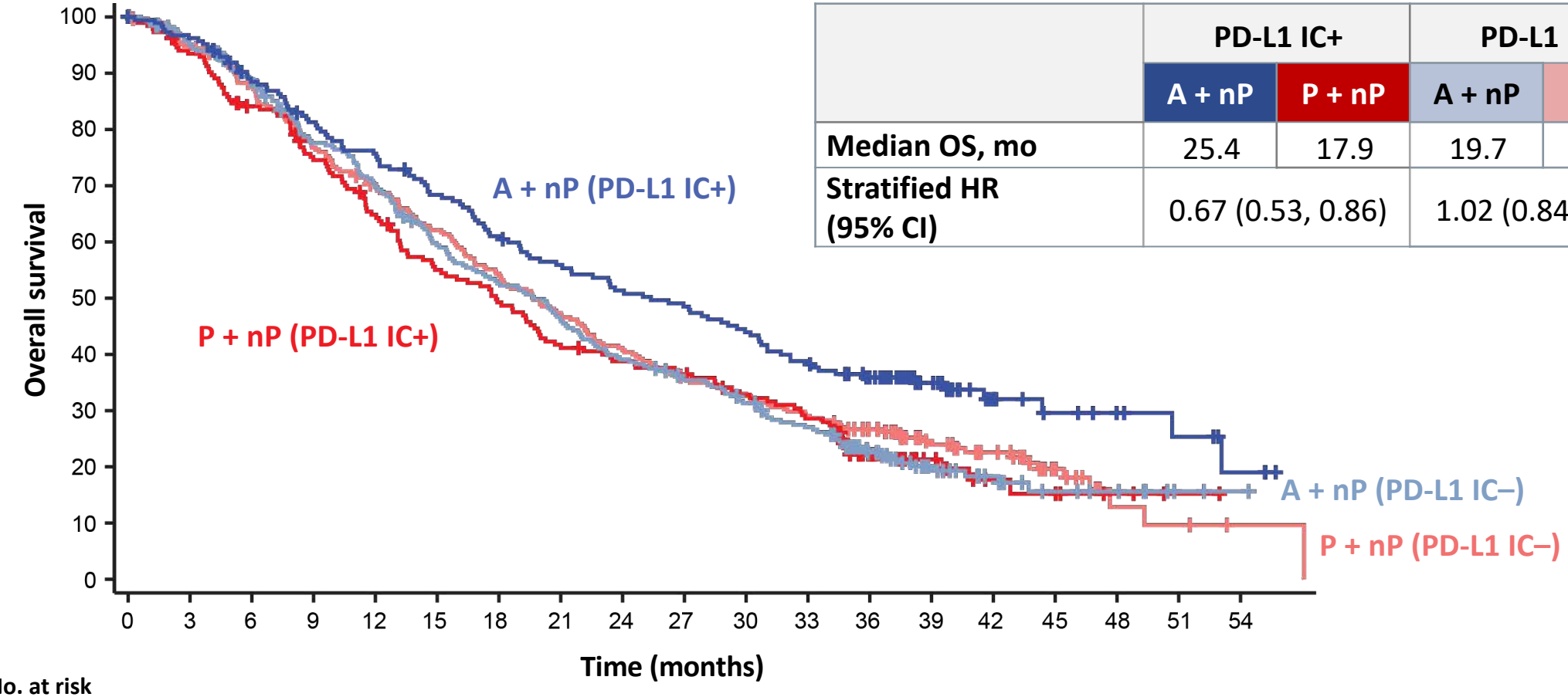


Courtesy of Professor Peter Schmid, MD, PhD

Data cutoff, 14 April 2020. NE, not estimable. [a] *P* value not formally tested per hierarchical study design.

Emens LA. ESMO 2020

Overall survival: PD-L1 status predicts benefit with atezolizumab



	PD-L1 IC+		PD-L1 IC–	
	A + nP	P + nP	A + nP	P + nP
Median OS, mo	25.4	17.9	19.7	19.7
Stratified HR (95% CI)	0.67 (0.53, 0.86)		1.02 (0.84, 1.24)	

No. at risk

A + nP (PD-L1 IC+)	185	177	160	145	135	121	108	98	90	86	77	67	56	32	17	11	9	6	3
A + nP (PD-L1 IC–)	266	249	229	197	177	149	132	116	98	86	75	63	43	26	16	9	7	2	1
P + nP (PD-L1 IC+)	184	170	150	132	113	95	85	72	66	62	54	47	28	14	7	6	3	1	NE
P + nP (PD-L1 IC–)	267	250	229	200	181	160	140	122	106	91	84	74	61	38	28	14	4	3	1

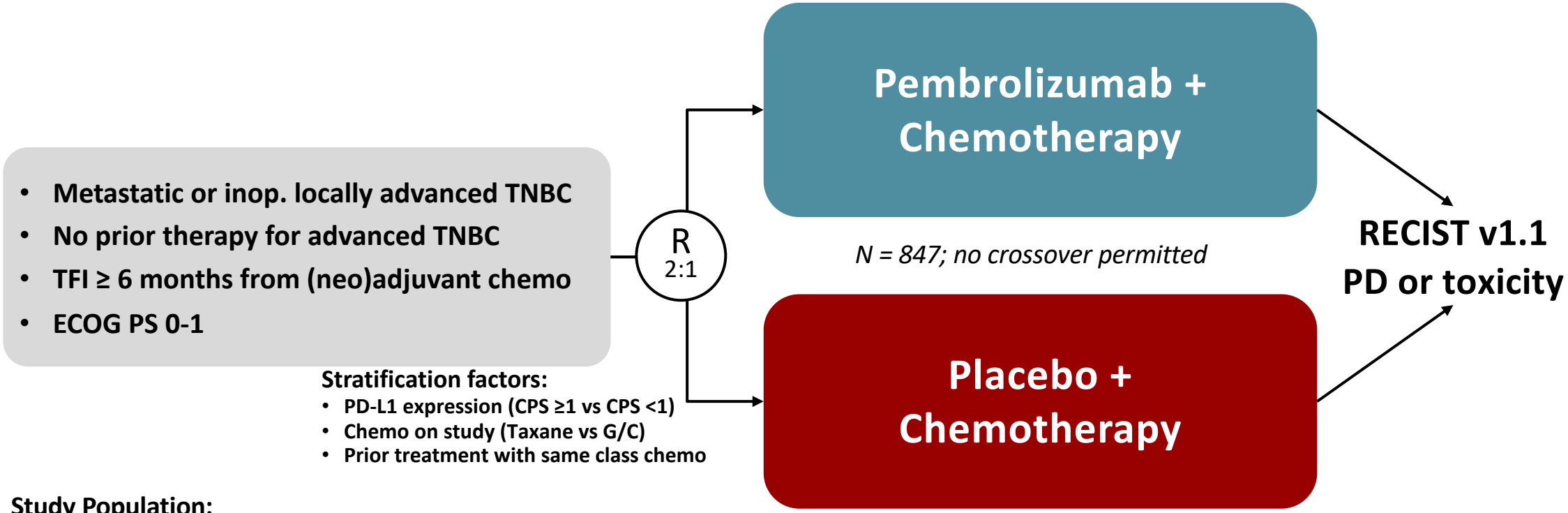
Data cutoff, 14 April 2020.

Courtesy of Professor Peter Schmid, MD, PhD

Emens LA. ESMO 2020

Pembrolizumab (anti-PD-1) plus chemotherapy in TNBC

KEYNOTE-355 study design



- Metastatic or inop. locally advanced TNBC
- No prior therapy for advanced TNBC
- TFI ≥ 6 months from (neo)adjuvant chemo
- ECOG PS 0-1

Stratification factors:
- PD-L1 expression (CPS ≥1 vs CPS <1)
- Chemo on study (Taxane vs G/C)
- Prior treatment with same class chemo

Study Population:
- CPS≥10, 75%; CPS≥1, 38%; CPS <1, 25%
- Taxane, 45%; Gem/carboplatin, 55%
- Prior treatment with same class chemo, 22%
- De novo MBC, 30%; DFI 6-12, 21%; DFI >12, 49%

Nab-paclitaxel, 100 mg/m^2 IV on days 1, 8, and 15 every 28 days
Paclitaxel, 90 mg/m^2 IV on days 1, 8, and 15 every 28 days
Gemcitabine, 1000 mg/m^2/carboplatin AUC 2 on days 1 and 8 every 21 days

- **Co-primary endpoints were PFS and OS in the CPS ≥10, CPS ≥1, and ITT populations**

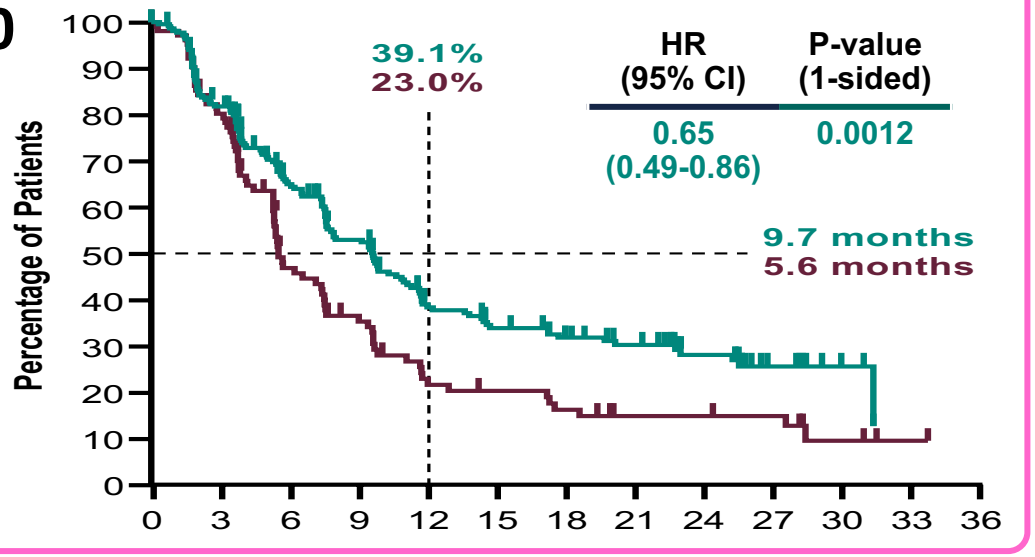
Statistical design: Overall alpha controlled at one-sided 0.025, split among PFS (0.005),OS (0.018), and ORR (0.002); hierarchical testing PFS (CSP10>CP1>ITT)

Courtesy of Professor Peter Schmid, MD, PhD

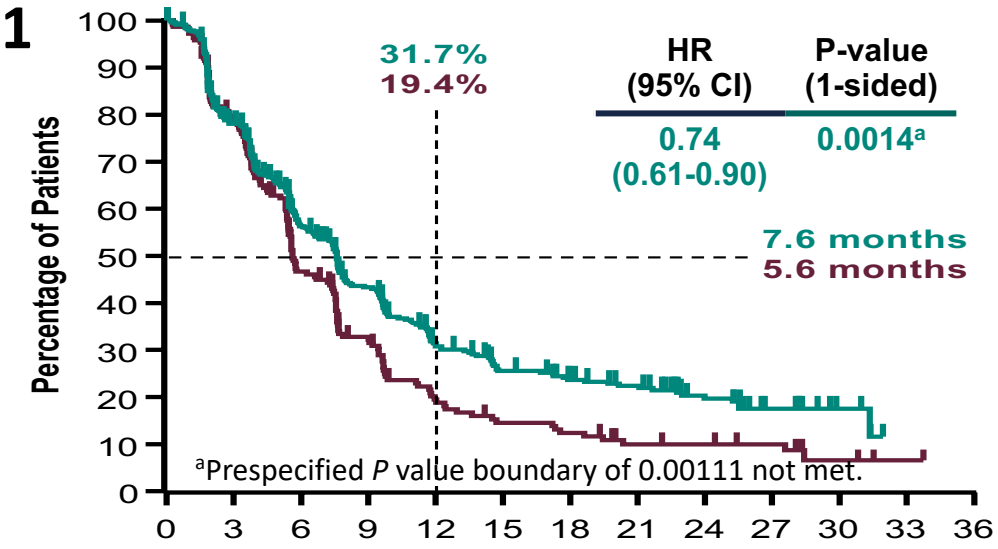
Cortes, et al. ASCO 2020

Pembrolizumab (anti-PD-1) plus chemo: Progression-free Survival

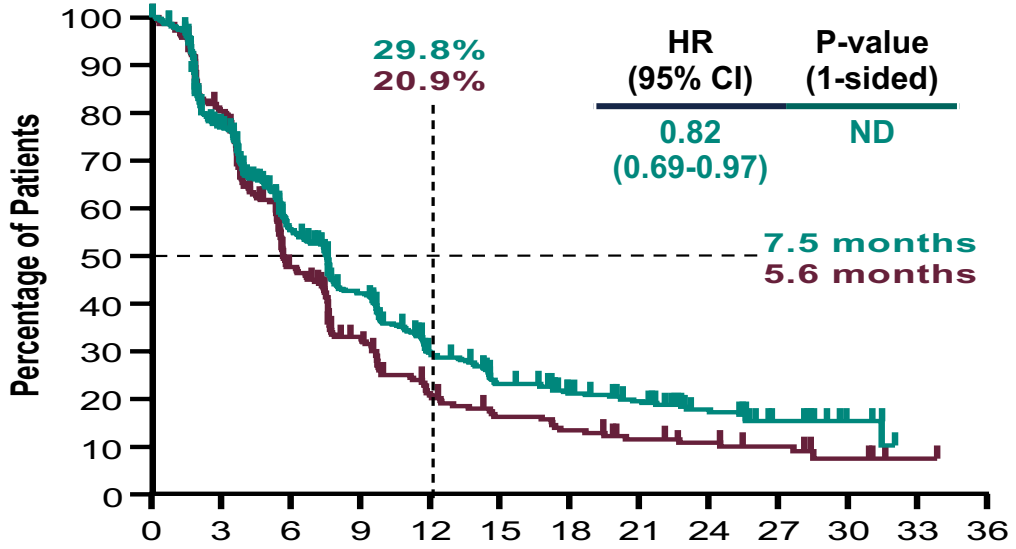
CPS ≥10



CPS ≥1



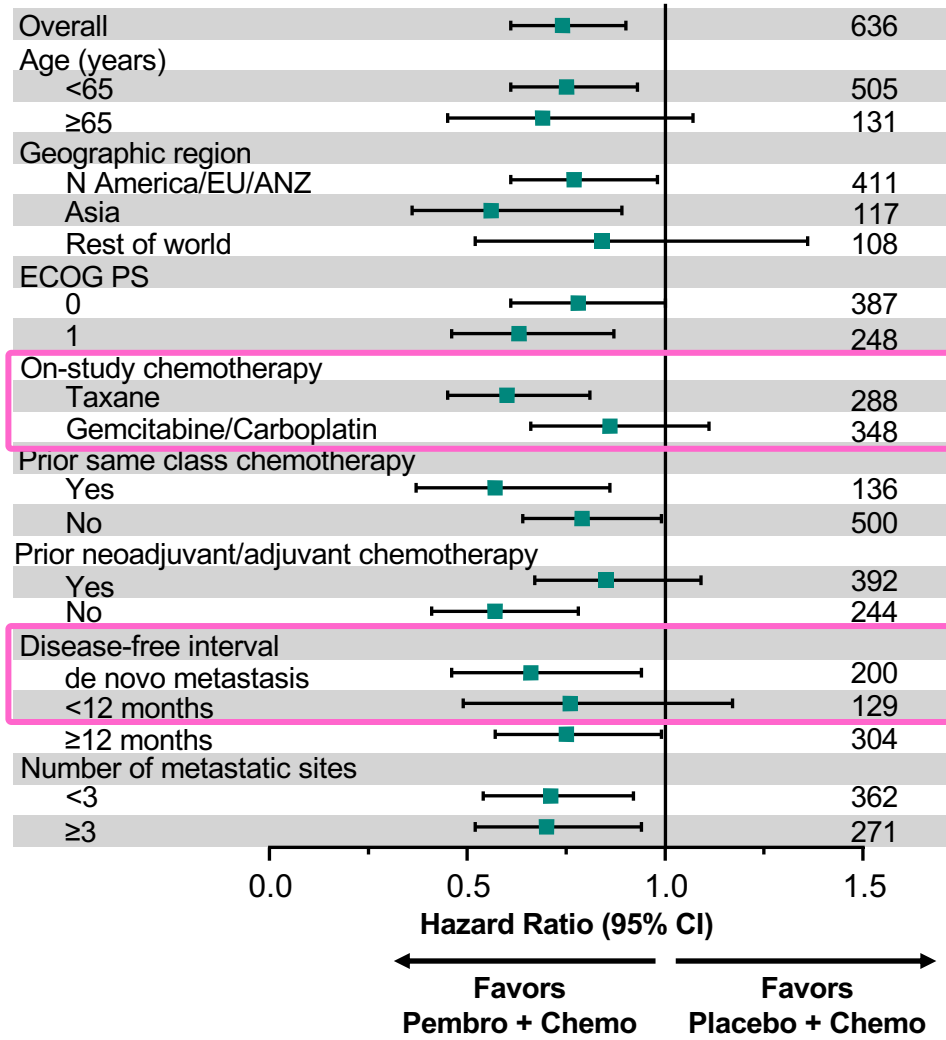
ITT



Courtesy of Professor Peter Schmid, MD, PhD

Cortes, et al. ASCO 2020

Progression-Free Survival in Subgroups: PD-L1 CPS ≥1



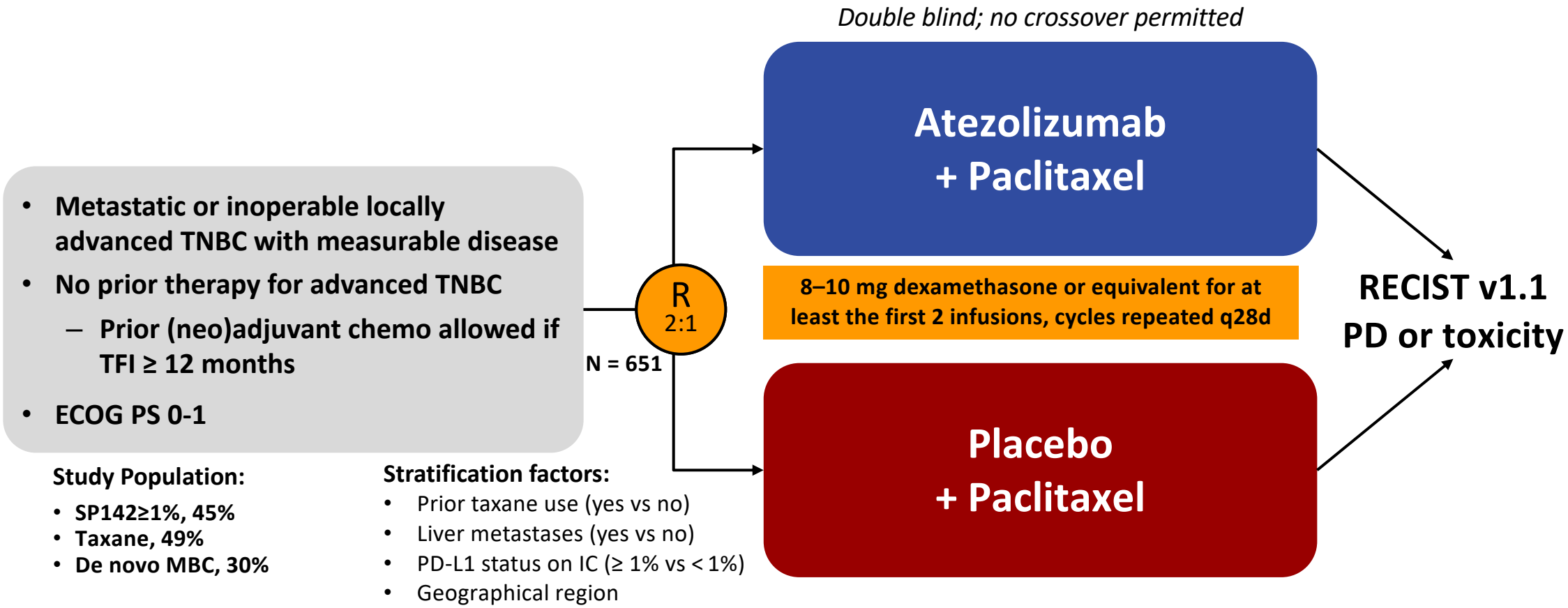
Subgroup	N	Median PFS (mo)		Hazard Ratio for Progression or Death (95% CI)
		Pembro + Chemo	Placebo + Chemo	
Overall	636	7.6	5.6	0.74 (0.61 to 0.90)
Age (years)				
<65	505	7.5	5.6	0.75 (0.61 to 0.93)
≥65	131	8.2	6.6	0.69 (0.45 to 1.07)
Geographic region				
N America/EU/ANZ	411	7.6	5.7	0.77 (0.61 to 0.98)
Asia	117	7.7	5.6	0.56 (0.36 to 0.89)
Rest of world	108	6.6	5.4	0.84 (0.52 to 1.36)
ECOG PS				
0	387	7.7	6.7	0.78 (0.61 to 1.00)
1	248	6.6	5.4	0.63 (0.46 to 0.87)
On-study chemotherapy				
Taxane	288	7.6	5.1	0.60 (0.45 to 0.81)
Gemcitabine/Carboplatin	348	7.5	7.5	0.86 (0.66 to 1.11)
Prior same class chemotherapy				
Yes	136	7.5	5.4	0.57 (0.37 to 0.86)
No	500	7.6	6.6	0.79 (0.64 to 0.99)
Prior neoadjuvant/adjuvant chemotherapy				
Yes	392	6.8	5.7	0.85 (0.67 to 1.09)
No	244	8.0	5.5	0.57 (0.41 to 0.78)
Disease-free interval				
de novo metastasis	200	7.6	5.6	0.66 (0.46 to 0.94)
<12 months	129	5.8	5.4	0.76 (0.49 to 1.17)
≥12 months	304	7.7	6.6	0.75 (0.57 to 0.99)
Number of metastatic sites				
<3	362	9.2	6.7	0.71 (0.54 to 0.92)
≥3	271	6.2	5.3	0.70 (0.52 to 0.94)

Courtesy of Professor Peter Schmid, MD, PhD

Cortes, et al. ASCO 2020

Atezolizumab (anti-PD-L1) plus Paclitaxel in TNBC

IMpassion131 study design

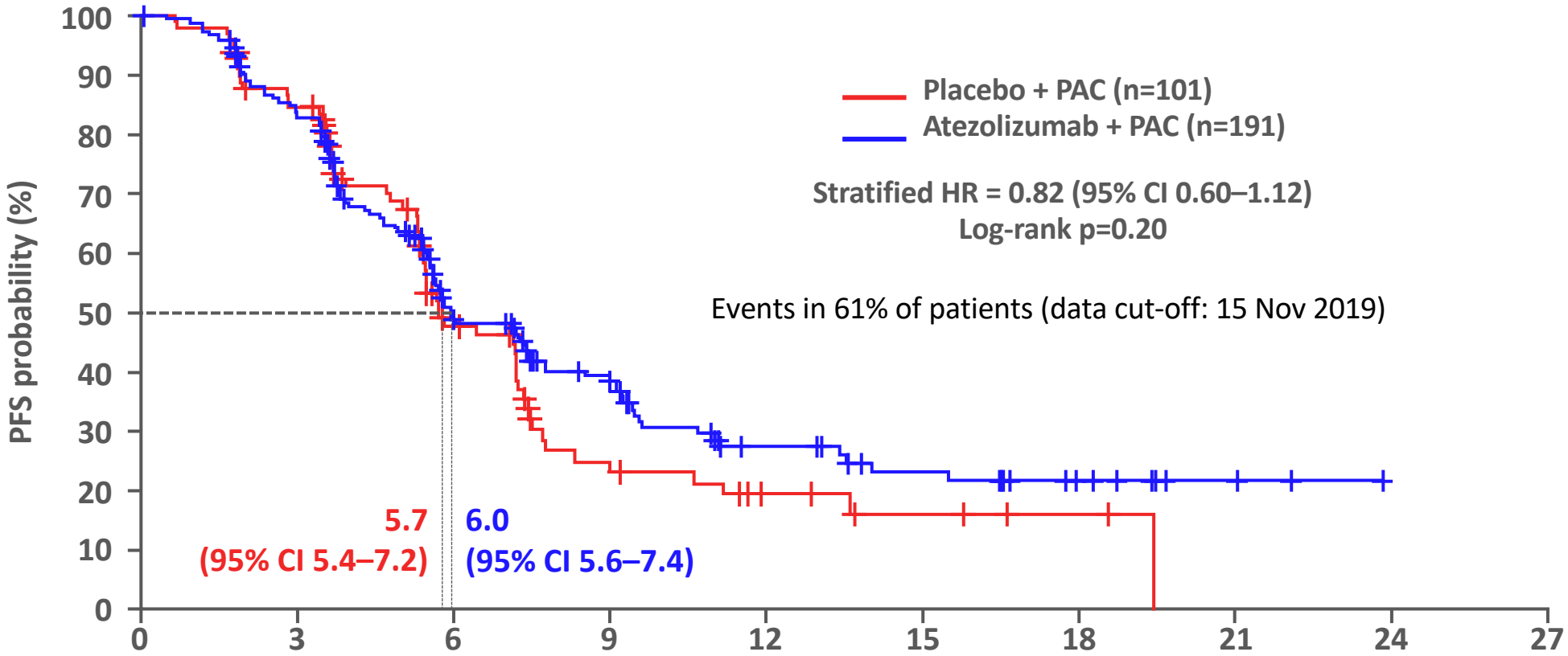


- **Co-primary endpoints were PFS (investigator assessed) in the PD-L1+ and ITT populations**

Courtesy of Professor Peter Schmid, MD, PhD

Miles D, et al. ESMO 2020

Atezolizumab plus Paclitaxel: Progression-free Survival in PD-L1+



Number at risk										
Placebo + PAC	101	81	33	14	7	4	2	0	0	0
Atezolizumab + PAC	191	152	69	44	22	15	8	3	0	0

Courtesy of Professor Peter Schmid, MD, PhD

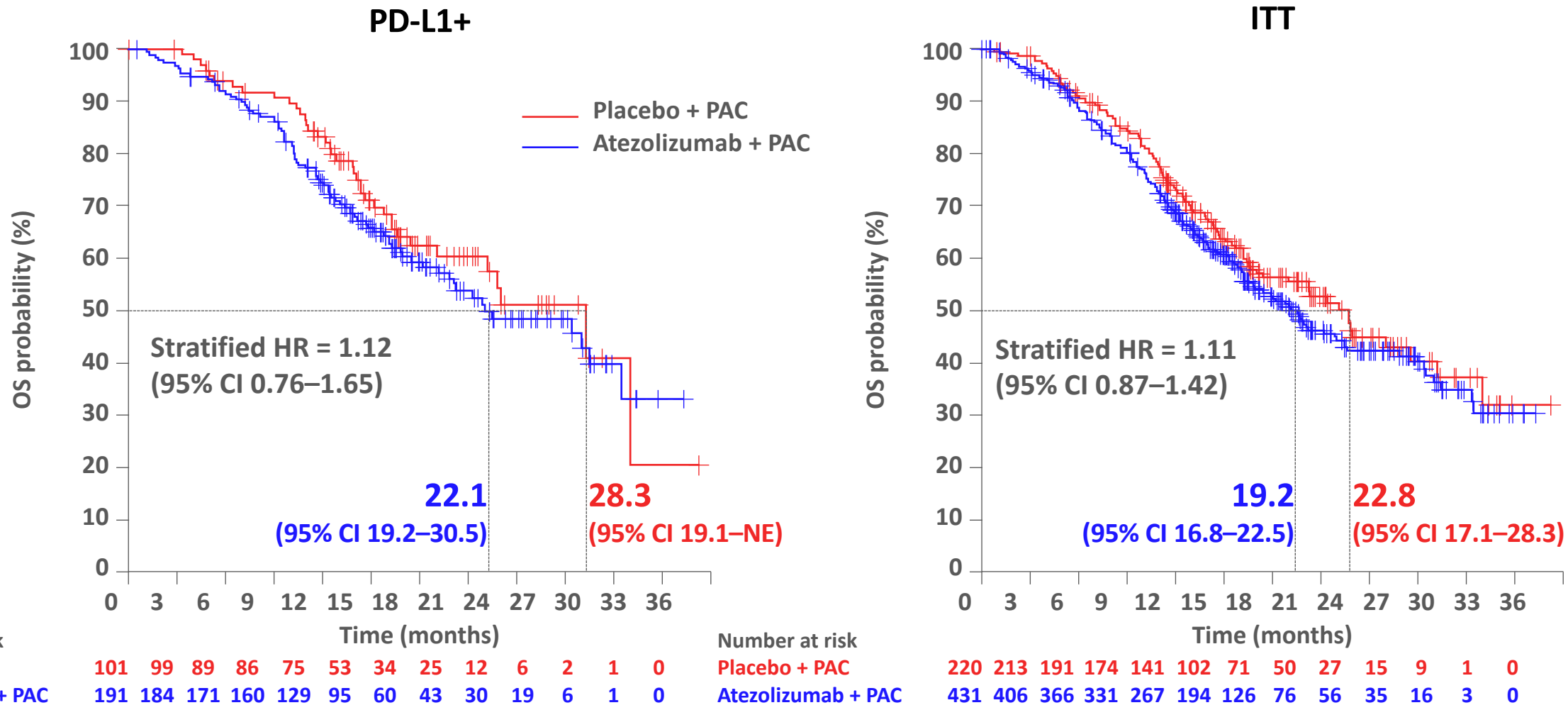
Median duration of follow-up: 8.6 months (placebo + PAC) vs 9.0 months (atezolizumab + PAC). CI = confidence interval

Miles D, et al. ESMO 2020

Atezolizumab plus Paclitaxel: Interim Survival Analysis

Updated interim OS analysis (data cut-off: 19 Aug 2020), events in 47% of the ITT population

Deaths in PD-L1+ 38 (38%) vs 82 (43%)



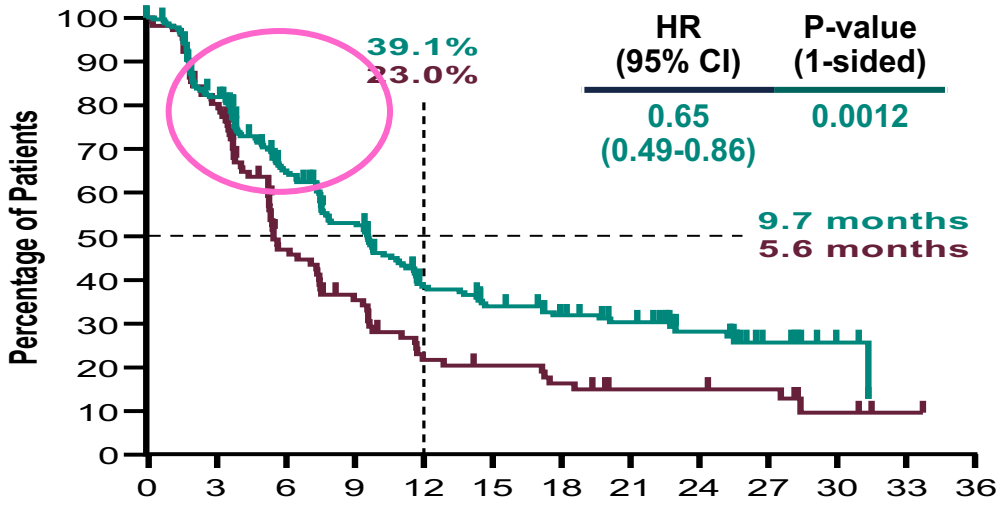
Median duration of follow-up: 14.5 months (placebo + PAC) vs 14.1 months (atezolizumab + PAC) in the ITT population

Prof. P. Schmid, Barts Cancer Institute

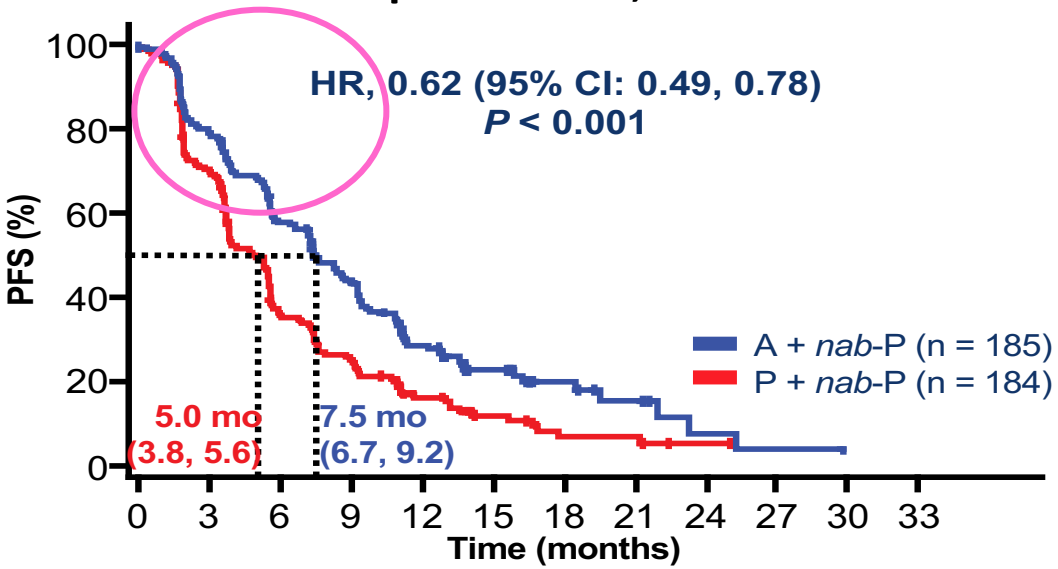
Courtesy of Professor Peter Schmid, MD, PhD

Immunotherapy plus chemo in 1L TNBC: Progression-free Survival

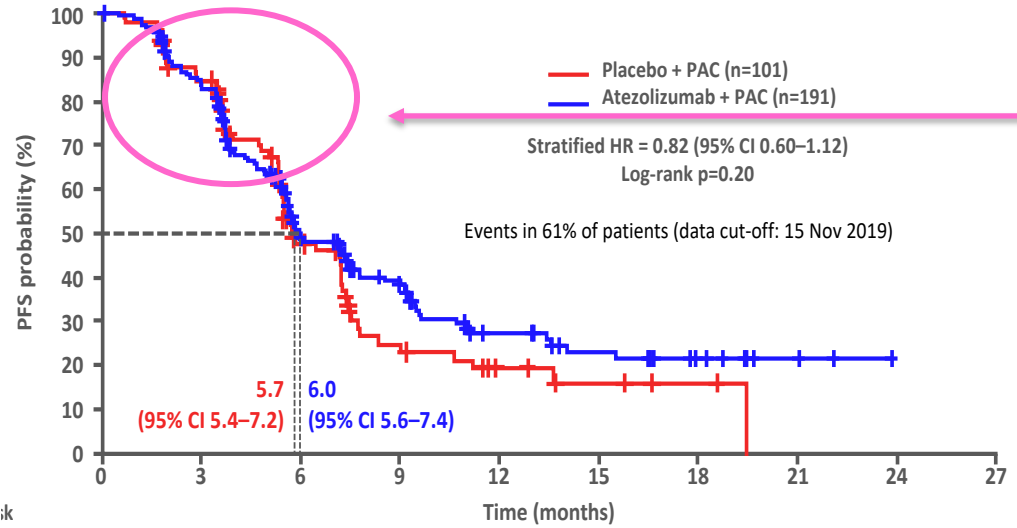
KEYNOTE-355, CPS ≥10



IMpassion130, SP142 ≥1%



IMpassion131, SP142 ≥1%

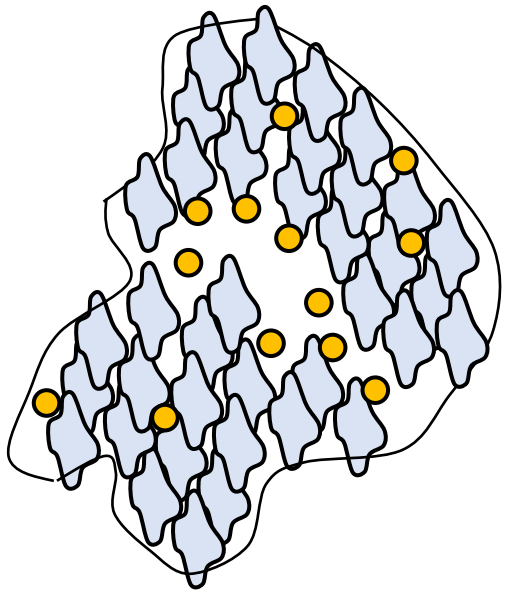


- **Investigator-assessed PFS**
- **Late separation of curves**
- **Data from IMpassion130 available in 10/2018**

Courtesy of Professor Peter Schmid, MD, PhD

How to select patients
for CIT combination therapy in metastatic TNBC

PD-L1 assessment: key variables to take into account



Tumor cells Immune cells

Type of cell to be considered

- Only tumor cells (TC)
- Only immune cells (IC)
- Both (e.g. CPS)

Modality of the scoring calculation

– Enumeration of positive cells (CPS)
– Area occupied by positive ICs (SP142)

Cut-off value

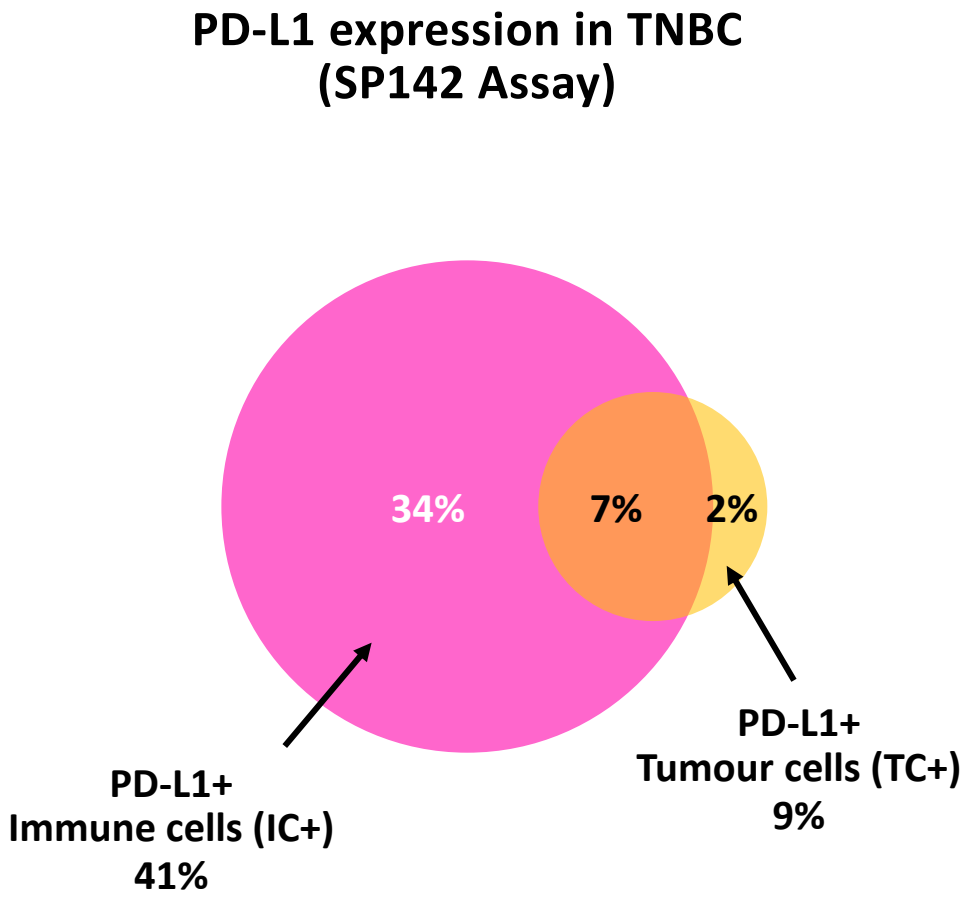
– ≥1, ≥10, ≥20, >50 …..

Primary antibody clones

– SP142, SP263 and 22C3

Courtesy of Professor Peter Schmid, MD, PhD

PD-L1-positive TNBC subpopulations



Courtesy of Professor Peter Schmid, MD, PhD

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PD-L1 status in primary vs metastatic tissues

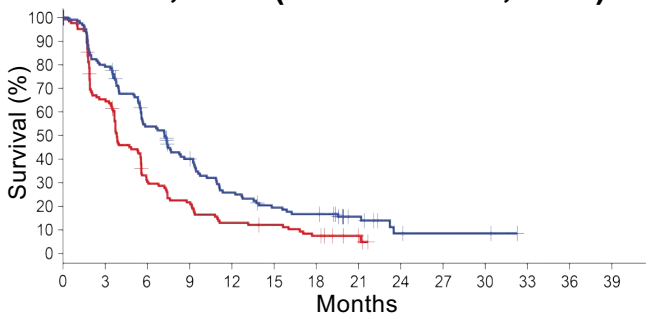
Efficacy in PD-L1 IC+

PFS

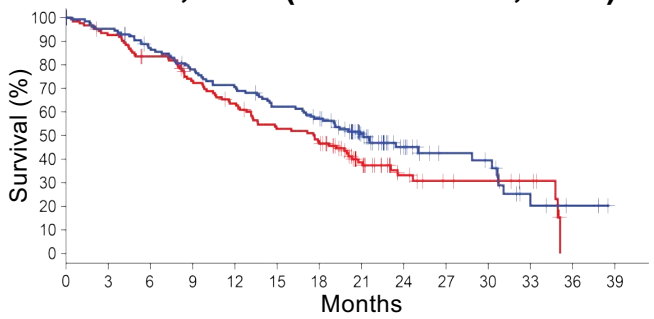
OS

Primary

HR, 0.61 (95% CI: 0.47, 0.81)

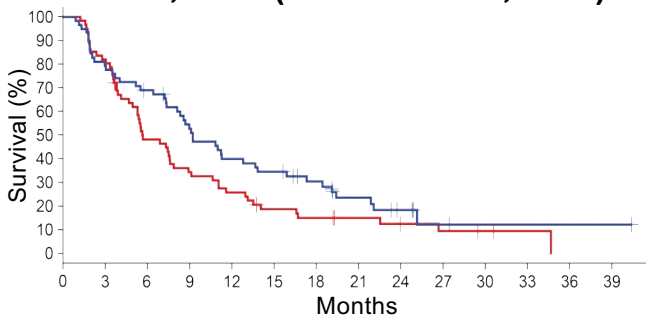


HR, 0.79 (95% CI: 0.57, 1.09)

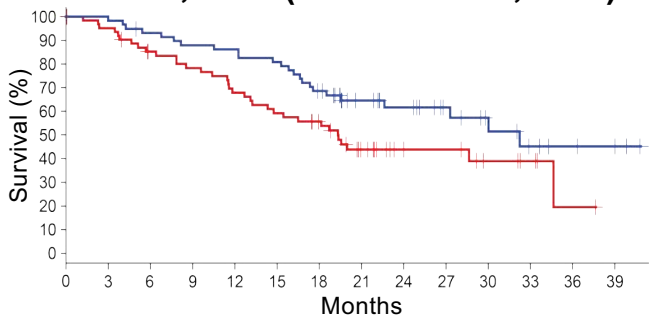


Metastatic

HR, 0.69 (95% CI: 0.46, 1.03)



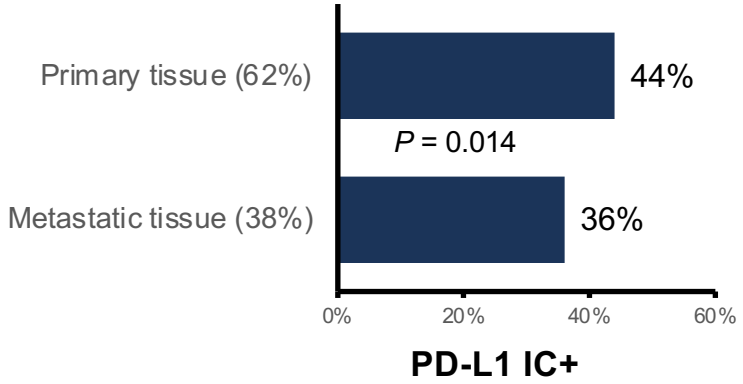
HR, 0.55 (95% CI: 0.32, 0.93)



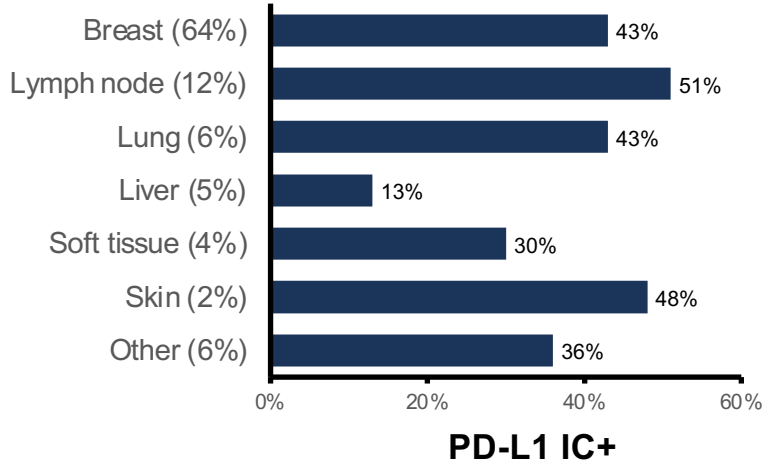
Atezolizumab + *nab*-paclitaxel

Placebo + *nab*-paclitaxel

PD-L1 status by primary vs metastatic tissue[a]



PD-L1 status by anatomical location[a]

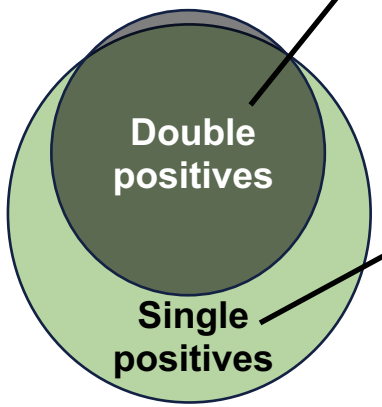


[a] Evaluable population (n = 901). PD-L1 IC+: PD-L1 in ≥ 1% of IC as percentage of tumour area assessed with the SP142 assay.
HRs adjusted for prior taxanes, presence of liver metastases, age and ECOG PS. Median time of sample collection to randomization: 61 days. No major differences were observed for clinical benefit in samples collected within 61 days of randomization or beyond that period (Emens, et al, manuscript in preparation).

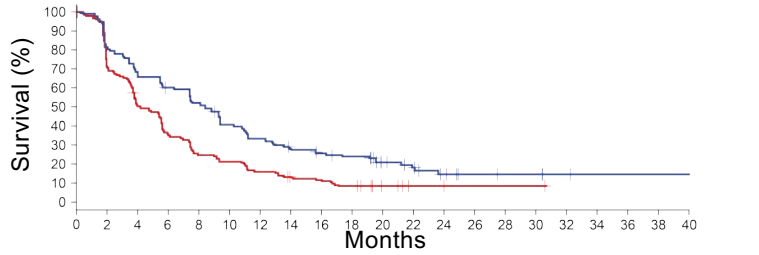
Courtesy of Professor Peter Schmid, MD, PhD

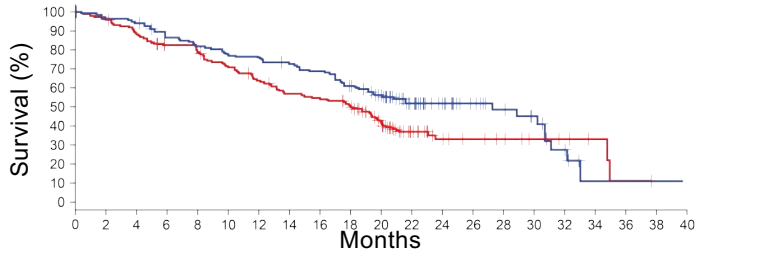
Rugo, ESMO 2019

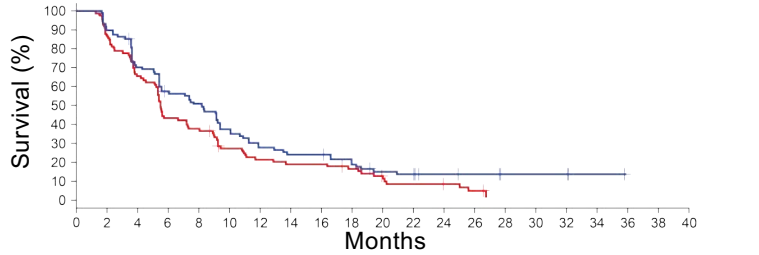
PFS and OS by different PD-L1 Assay: SP142 (IC 1%) and 22C3 (CPS 1)

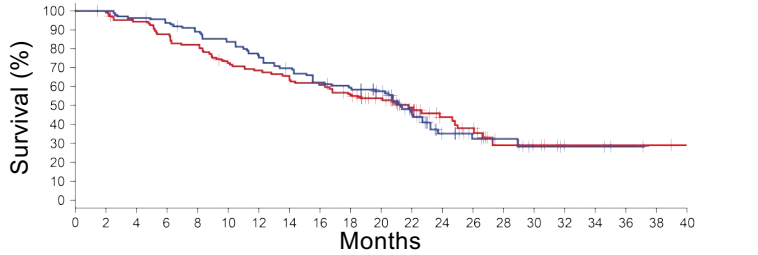


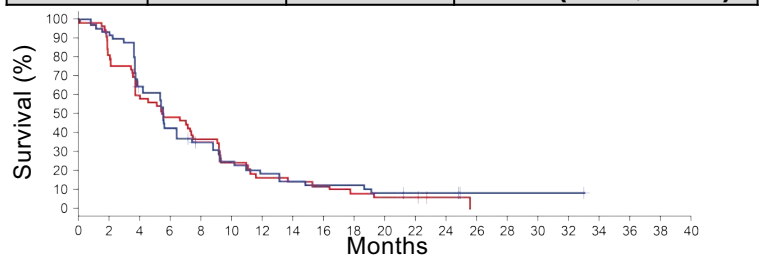
Population	Median PFS, mo			HR (95% CI)	Median OS, mo			HR (95% CI)
	A + nP	P + nP	Δ		A + nP	P + nP	Δ	
SP142+ 22C3+ (45%; 279/614)	8.3	3.9	4.4	0.60 (0.46, 0.78)	27.3	18.0	9.3	0.71 (0.52, 0.98)
SP142− 22C3+ (36%; 218/614)	7.3	5.6	1.7	0.81 (0.61, 1.09)	21.3	21.8	−0.5	0.92 (0.64, 1.31)
Double negatives SP142− 22C3− (18%, 111/614)	5.5	5.6	−0.1	1.00 (0.66, 1.51)	14.7	19.6	−4.9	1.08 (0.67, 1.76)

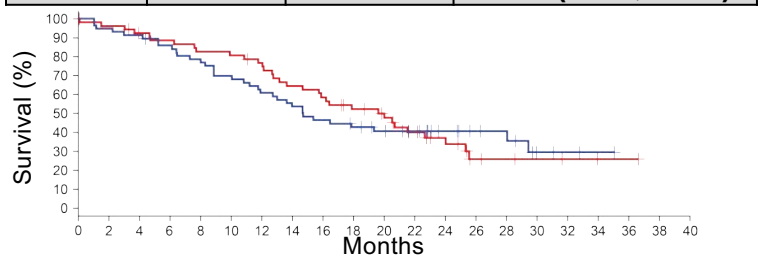












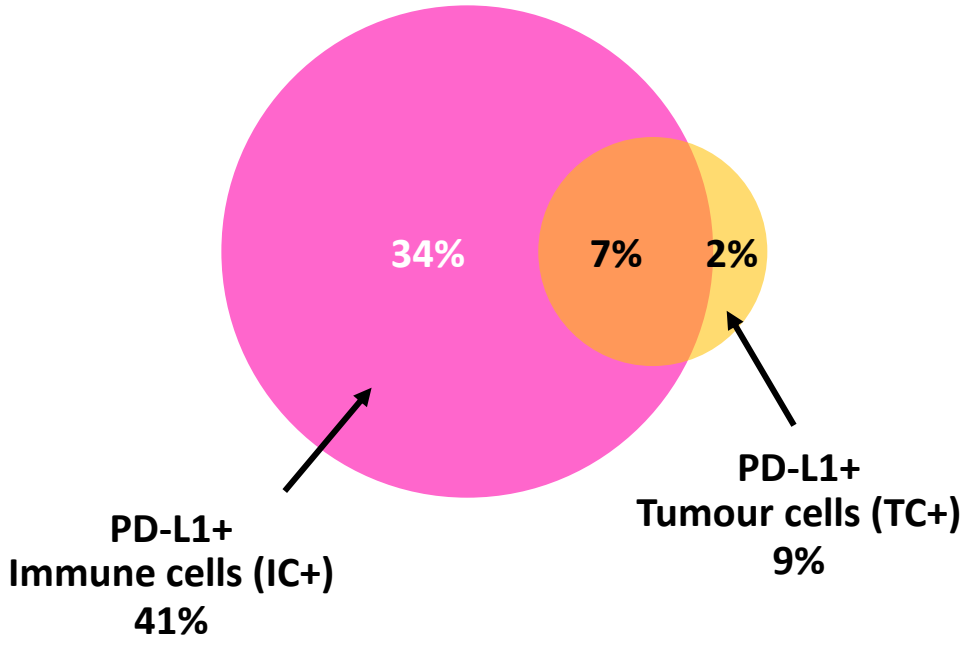
Double positive: SP142 IC ≥ 1%, 22C3 CPS ≥ 1; single positive: SP142 IC < 1%, 22C3 CPS ≥ 1; double negative: SP142 IC < 1%, 22C3 CPS < 1.
HR adjusted for prior taxanes, presence of liver metastases, age and ECOG PS.

Courtesy of Professor Peter Schmid, MD, PhD

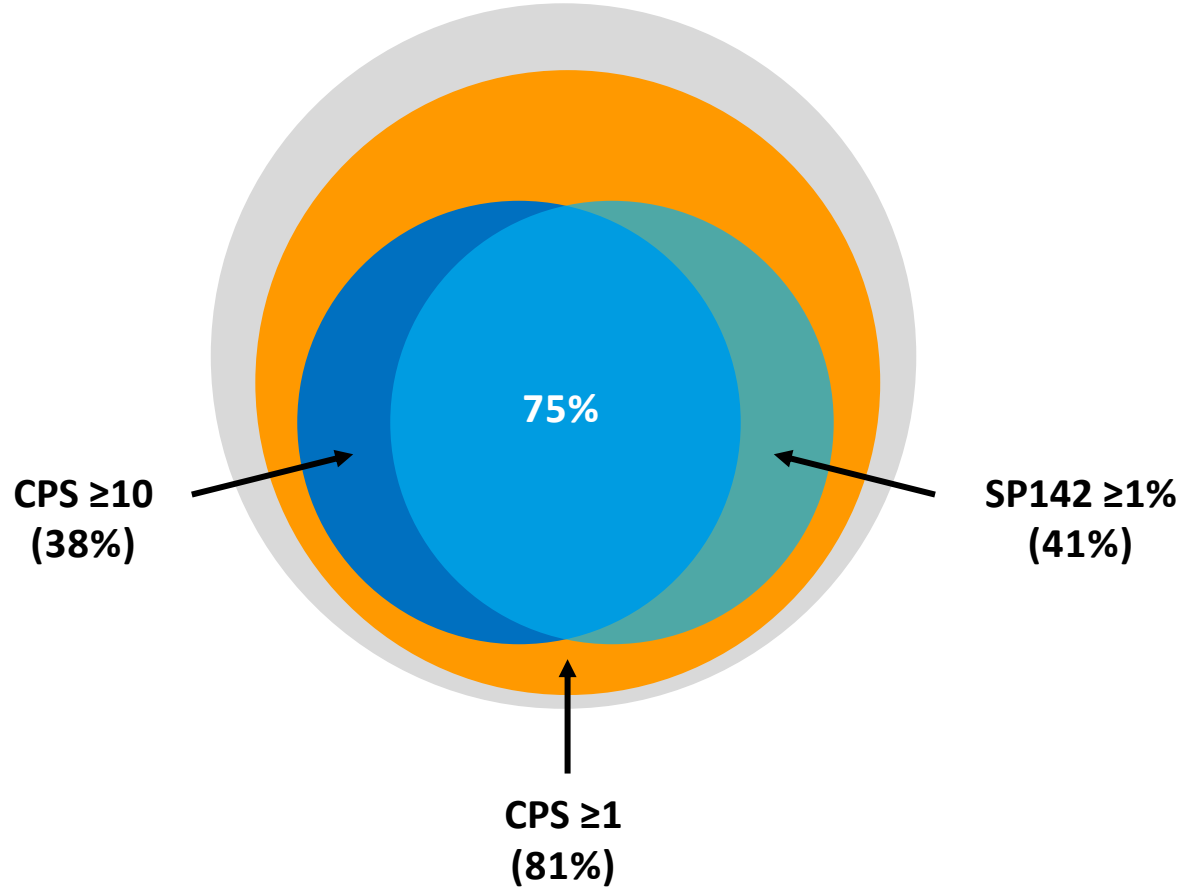
Rugo, et al ESMO 2019

PD-L1-positive TNBC subpopulations

PD-L1 expression in TNBC (SP142 Assay)



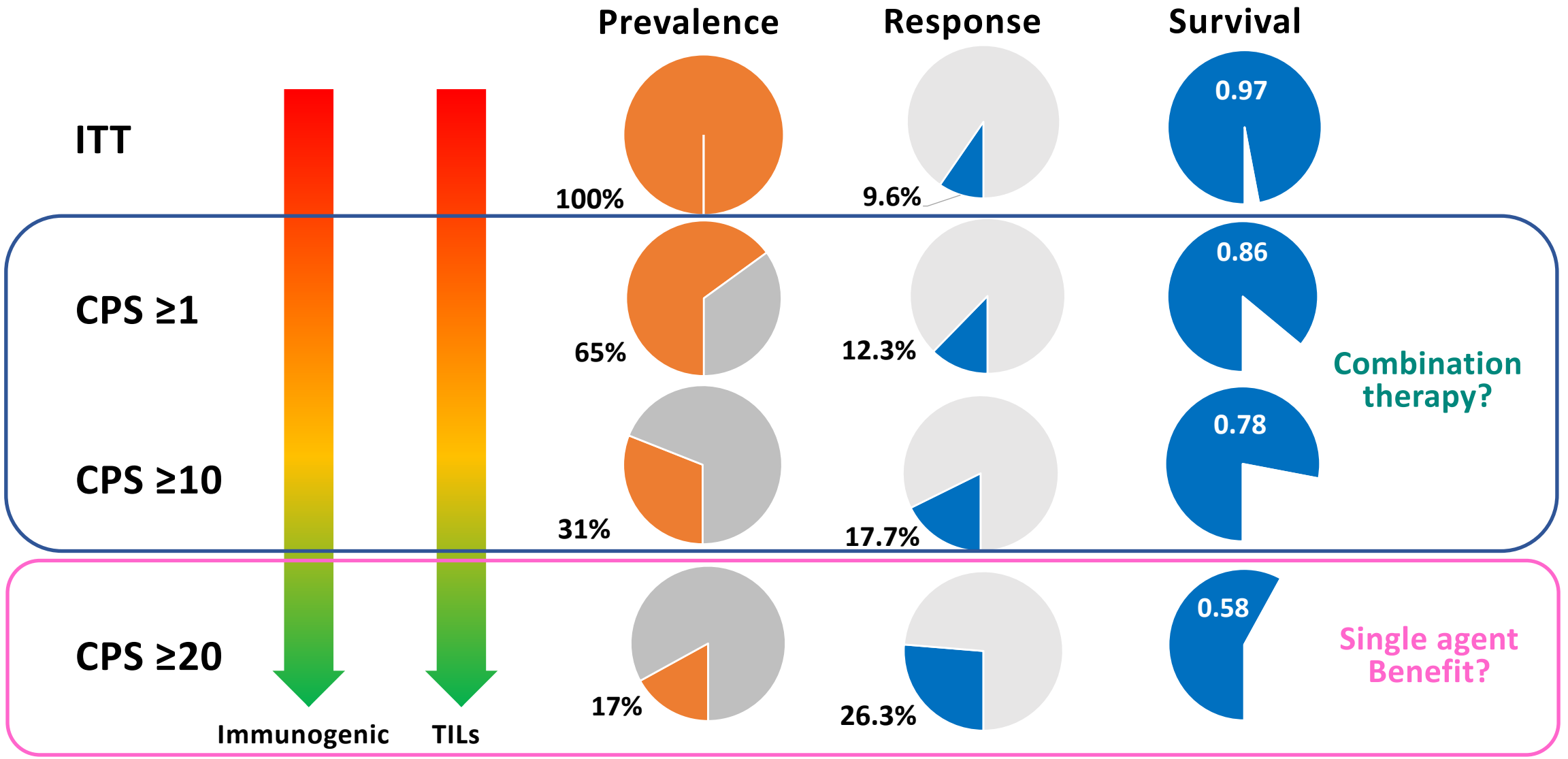
Subpopulations in TNBC defined by PD-L1 assays



Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. Personal Communication

Pembrolizumab vs chemo in 2L/3L TNBC: OR and OS by PD-L1 CPS



Courtesy of Professor Peter Schmid, MD, PhD

Cortes, et al. ESMO 2019

Safety of CPI in metastatic TNBC

Toxicities with Immune checkpoint Inhibitors

	Chemotherapy	Immunotherapy
Incidence (moderate/severe AEs)	Almost all patients	Majority without
AE profile	Well described	Variable
Affected systems/organs	Few organs affected	Any organ
Time course	Well established	Variable (even after end of Tx)
	Predictable	Relatively unpredictable

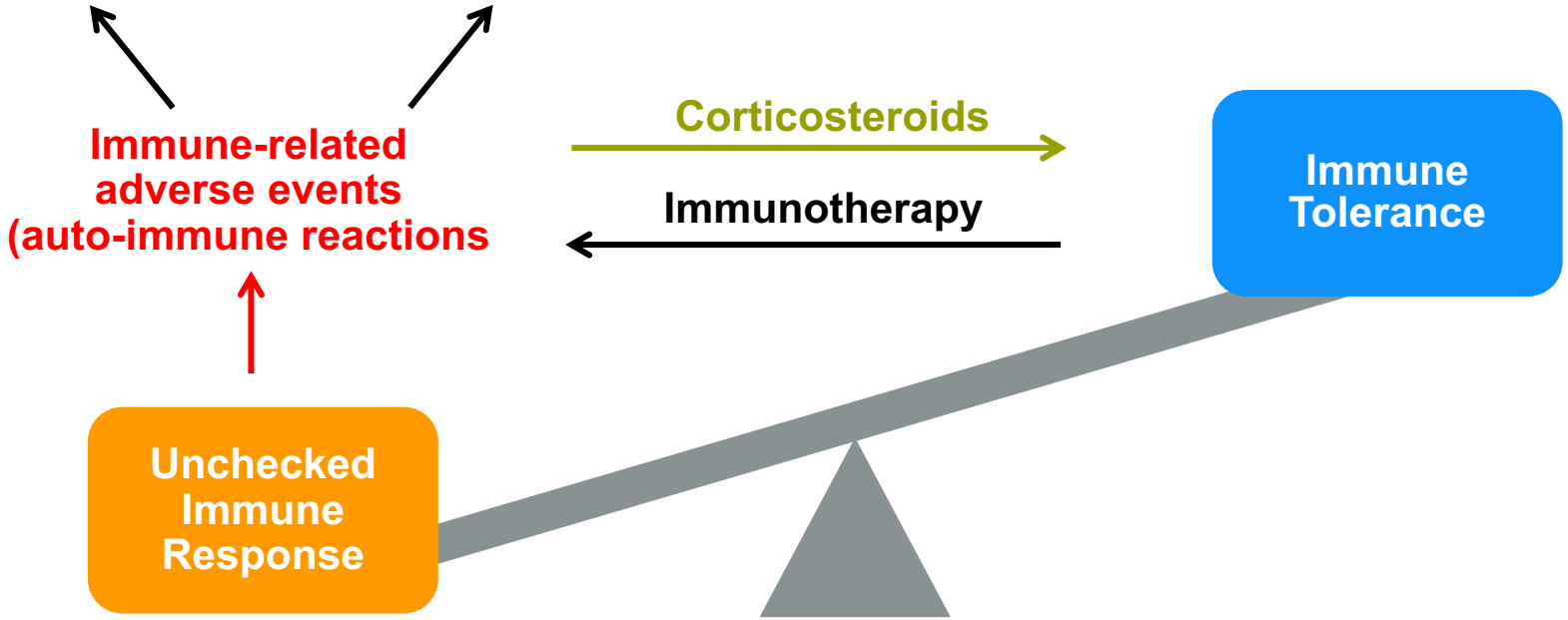
Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. Personal Communication

Toxicities with Immune checkpoint Inhibitors

Organ-specific events
- Endocrine system
- Skin
- Gastrointestinal
- Liver
- Pulmonary

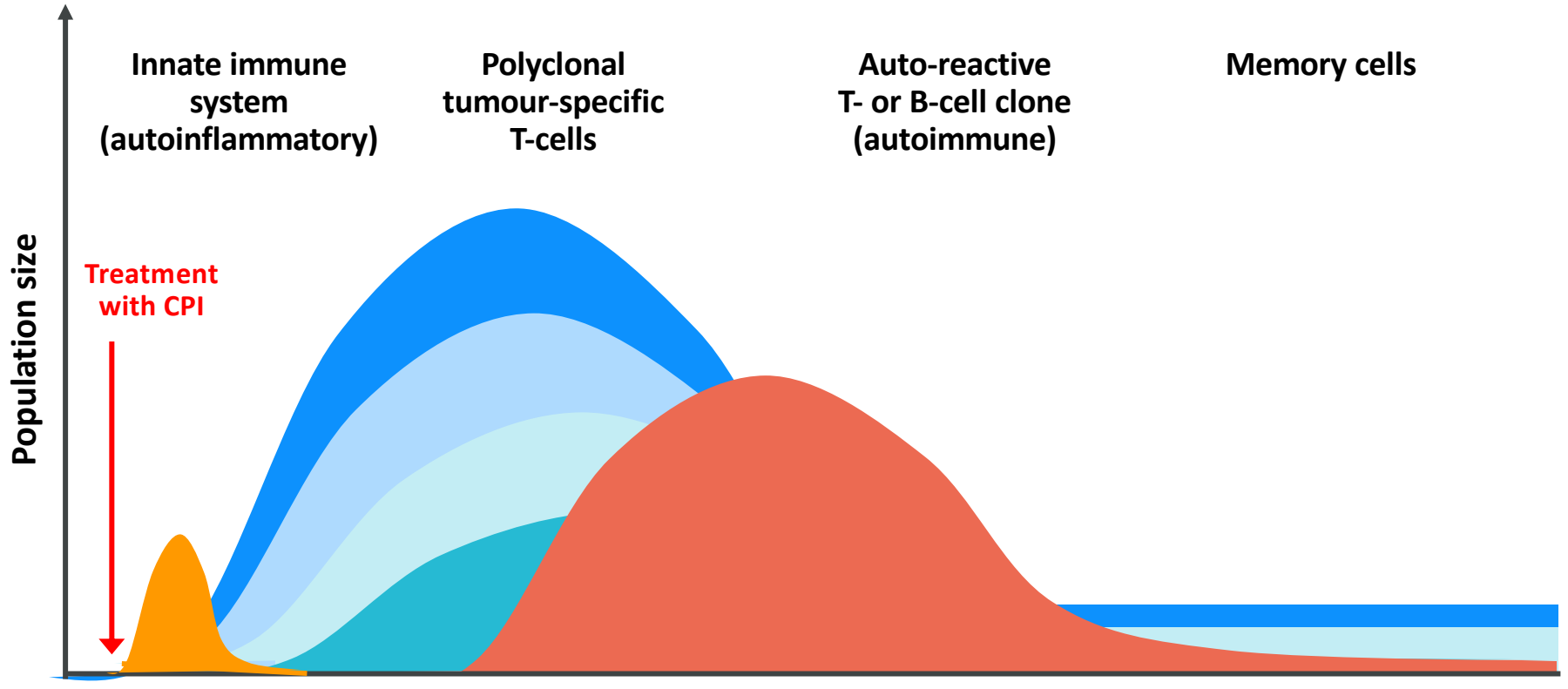
General events
- Fatigue
- Pyrexia, Chills
- Infusion reactions



Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. Personal Communication

Kinetic of anti-tumour and auto-immune response

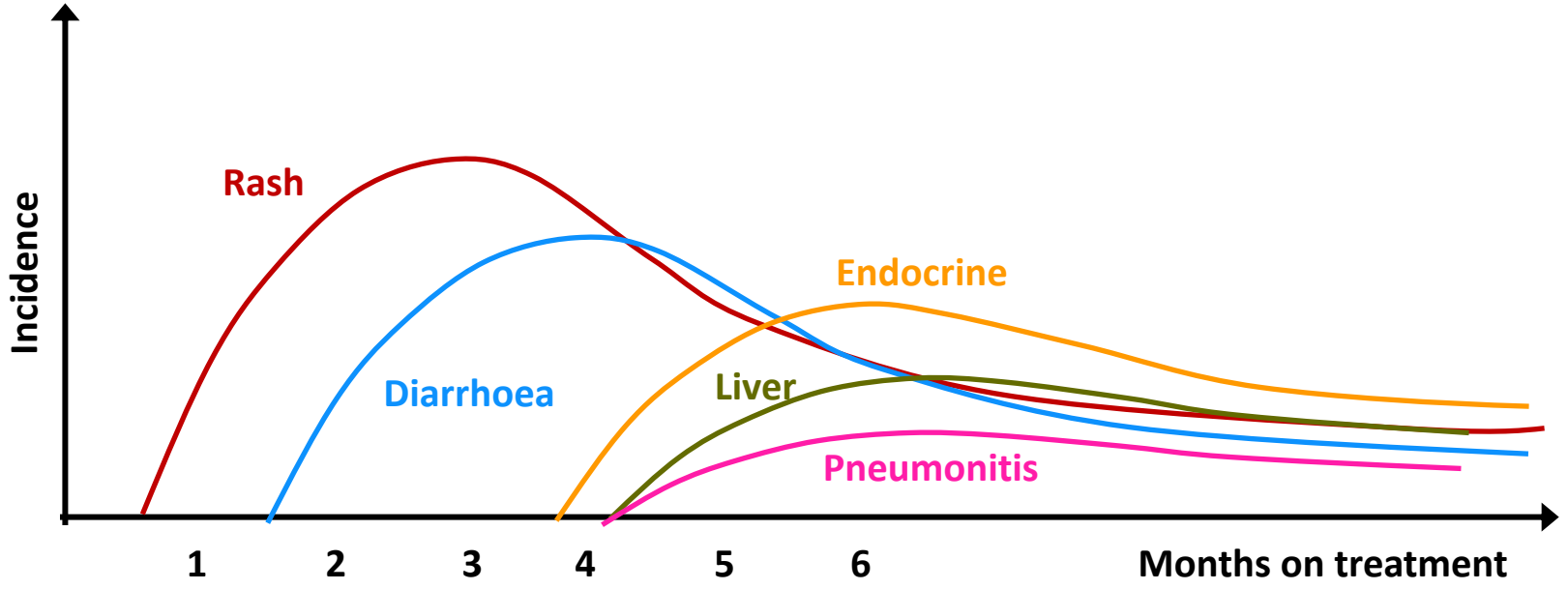


Courtesy of Professor Peter Schmid, MD, PhD

Adapted from Michot, JM. Cancer world 2019

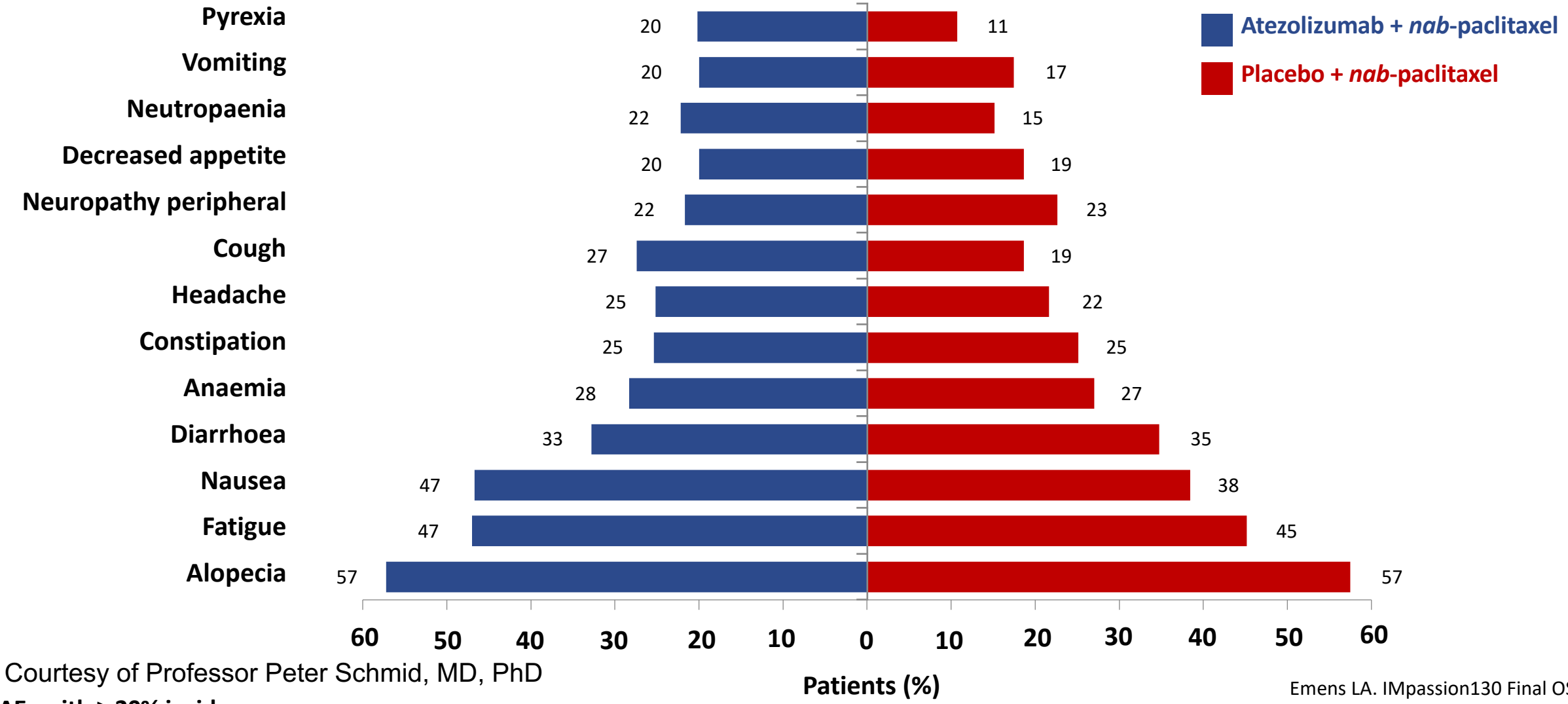
Toxicities with Immune checkpoint Inhibitors

- Timing can be highly variable
- irAE can occur even months after the end of treatment
- Time course might be even more variable with novel combinations



Courtesy of Professor Peter Schmid, MD, PhD

IMpassion130: Most common AEs regardless of attribution



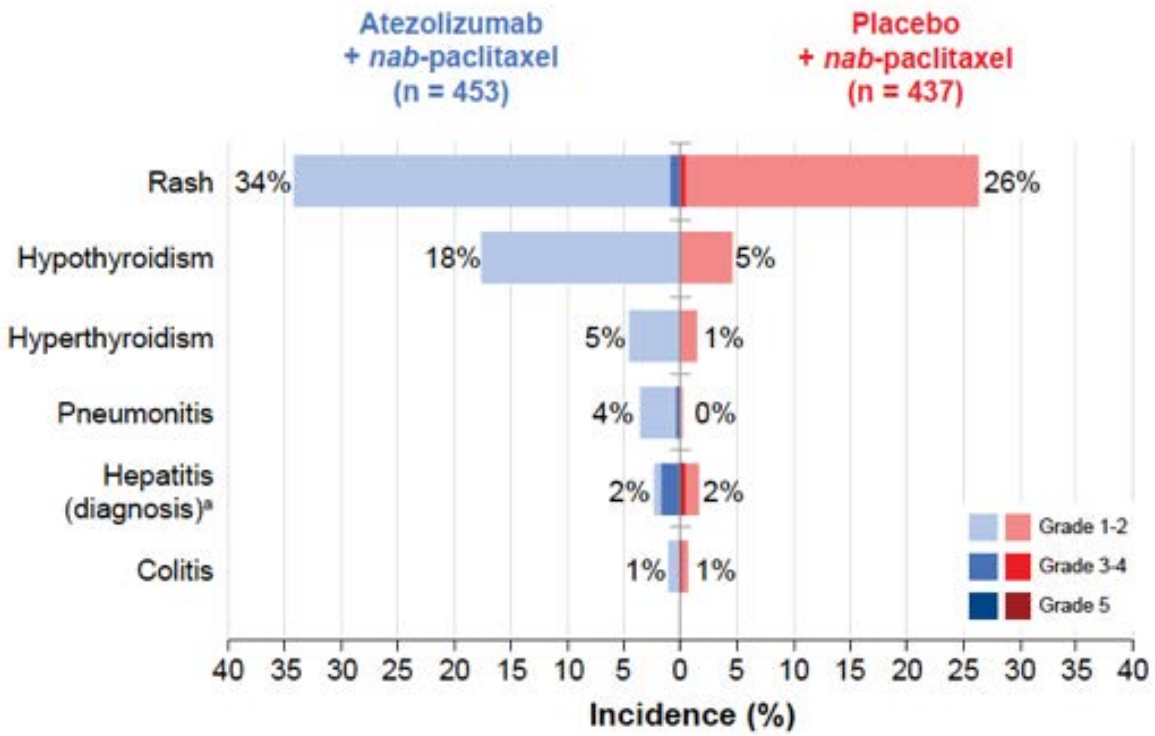
Courtesy of Professor Peter Schmid, MD, PhD

AEs with ≥ 20% incidence

Emens LA. IMpassion130 Final OS. ESMO 2020. https://bit.ly/34BtGfV

IMpassion130: Immune-Related Adverse Events

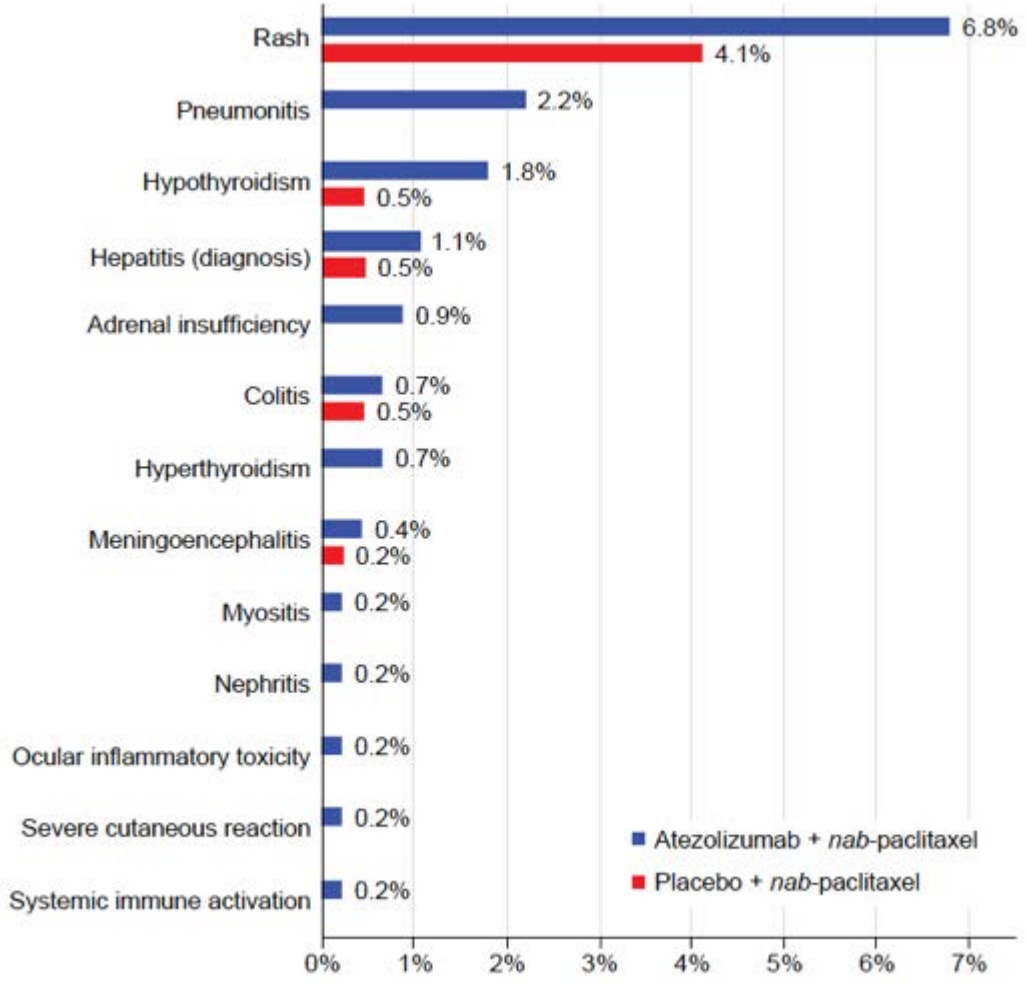
Most Clinically Relevant AESI by Grade



AESI = adverse event of special interest

Courtesy of Professor Peter Schmid, MD, PhD

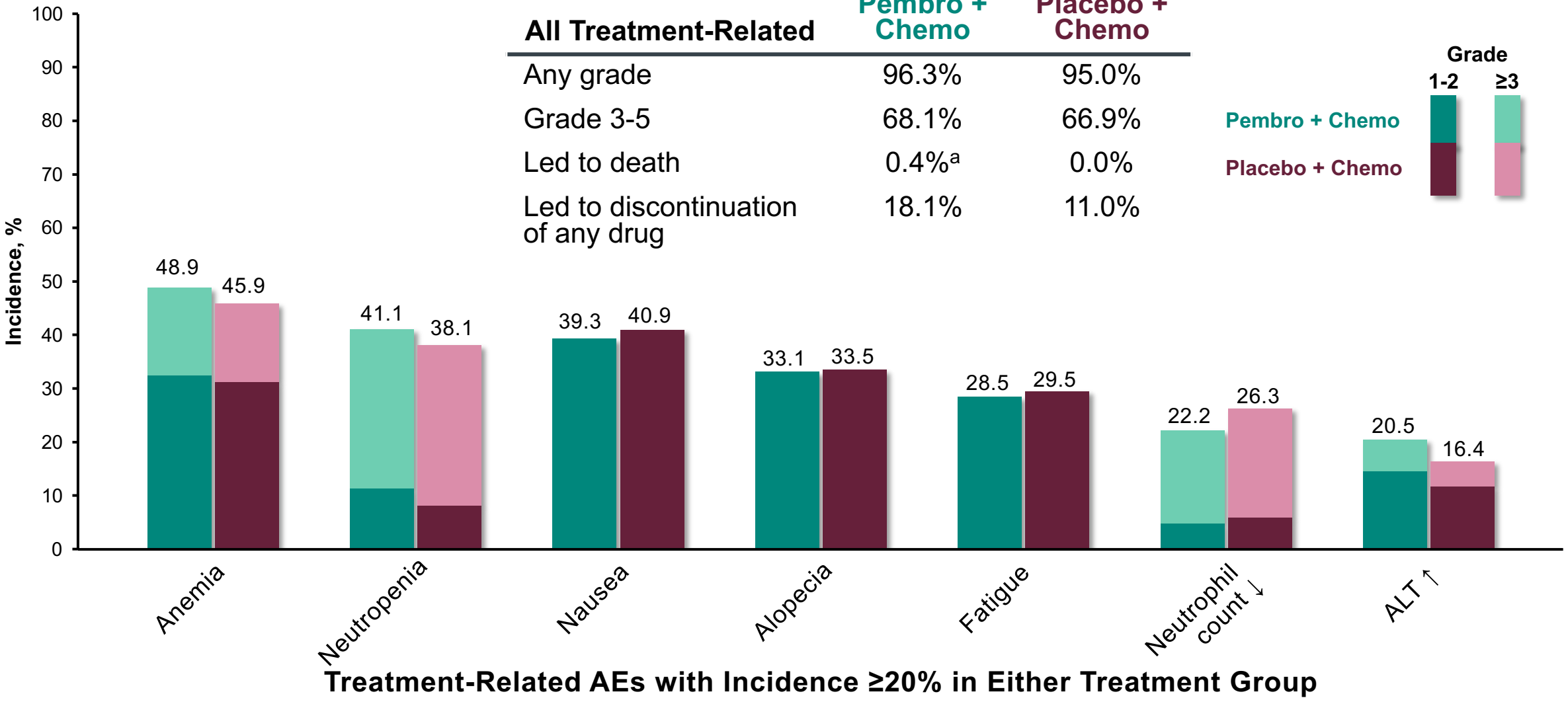
Immune-Mediated AESI Requiring Systemic Corticosteroids



Schneeweiss, Rugo et al, ASCO 2019; Schmid et al, Lancet Oncol 2019

KEYNOTE-355: Most common AEs regardless of attribution

All Treatment-Related	Pembro + Chemo	Placebo + Chemo
Any grade	96.3%	95.0%
Grade 3-5	68.1%	66.9%
Led to death	0.4%[a]	0.0%
Led to discontinuation of any drug	18.1%	11.0%



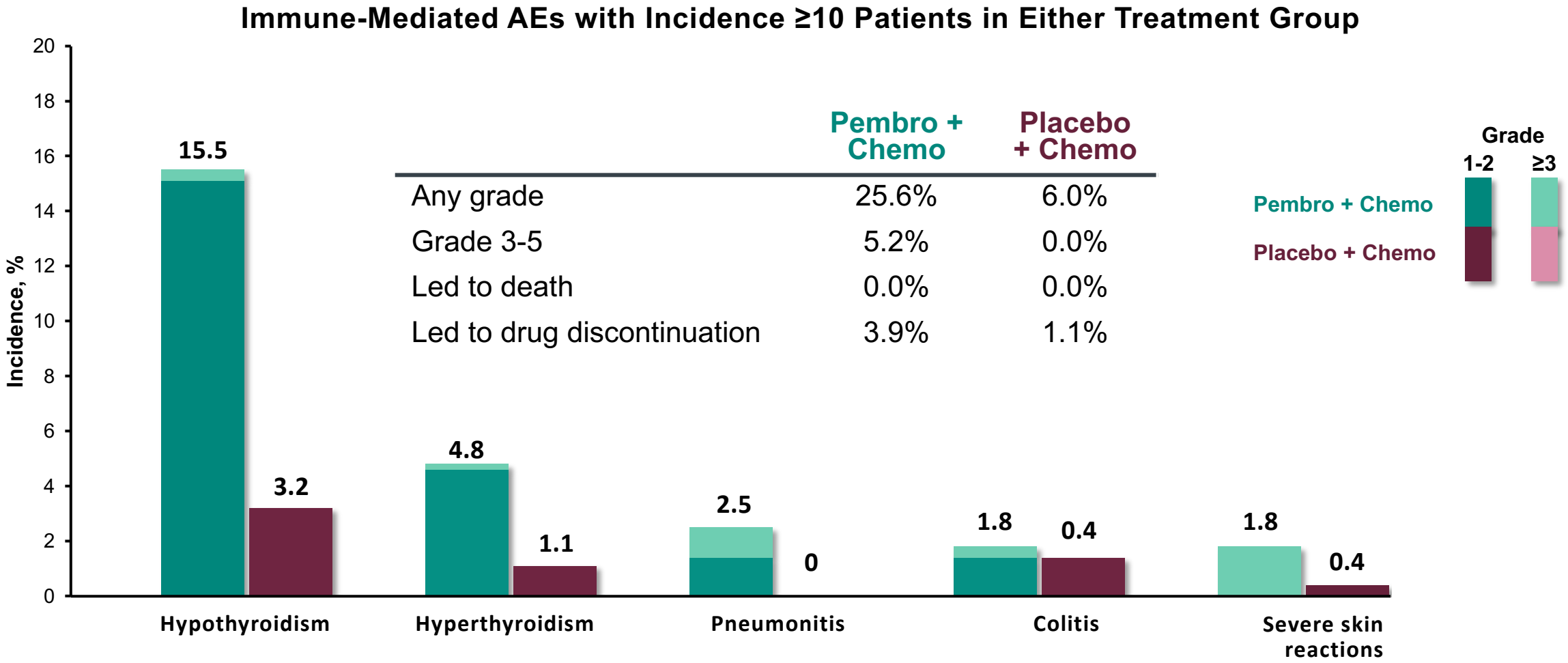
Treatment-Related AEs with Incidence ≥20% in Either Treatment Group

Courtesy of Professor Peter Schmid, MD, PhD

[a]1 patient from acute kidney injury and 1 patient from pneumonia. Data cutoff date: December 11, 2019.

Cortes, et al. ASCO 2020

KEYNOTE-355: Immune-Related Adverse Events

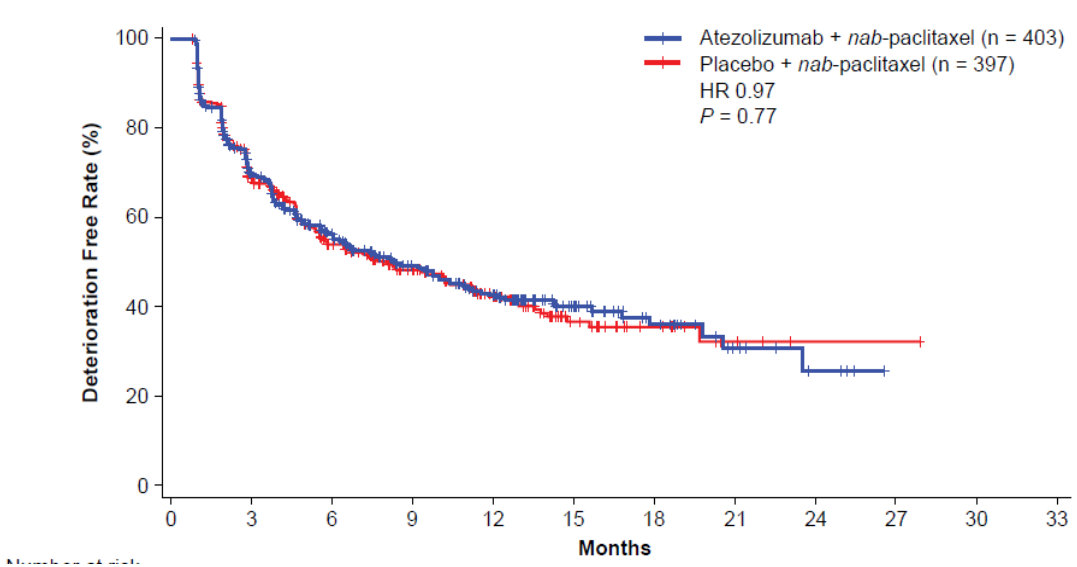


Courtesy of Professor Peter Schmid, MD, PhD

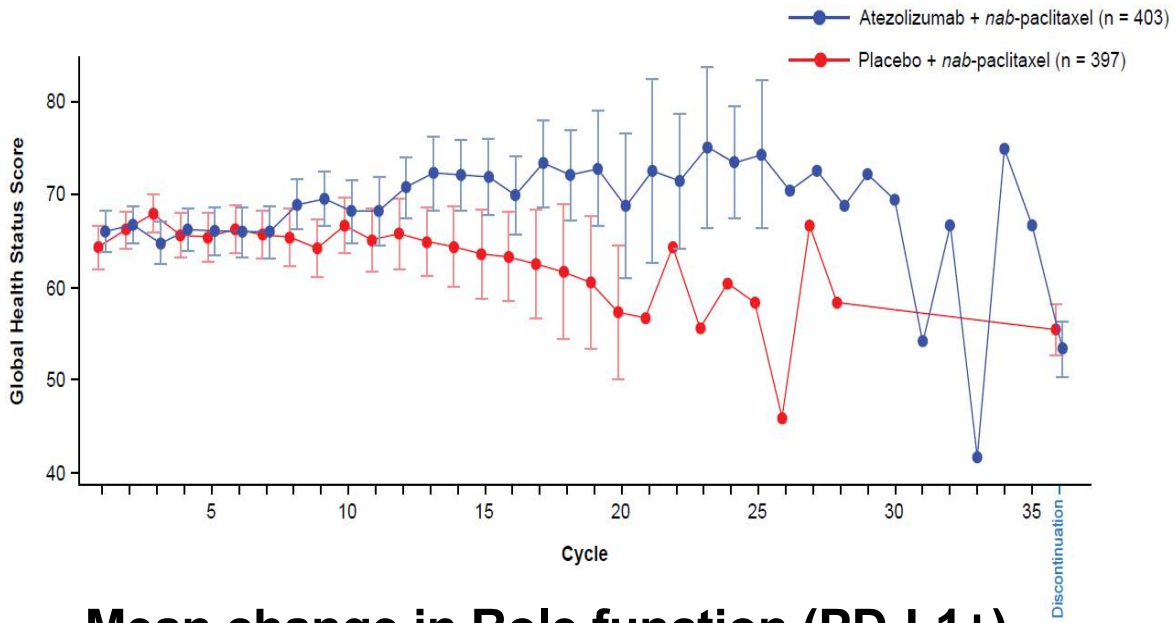
Cortes, et al. ASCO 2020

IMpassion130 PRO Analysis

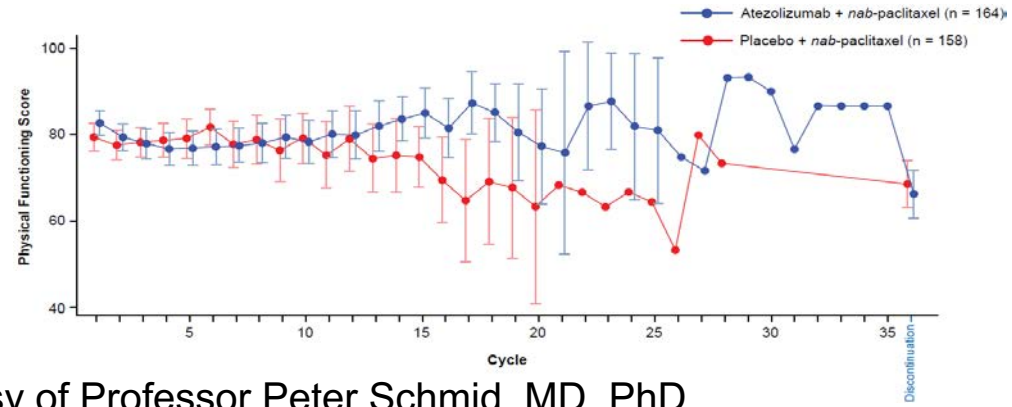
Time to deterioration of HRQoL (ITT)



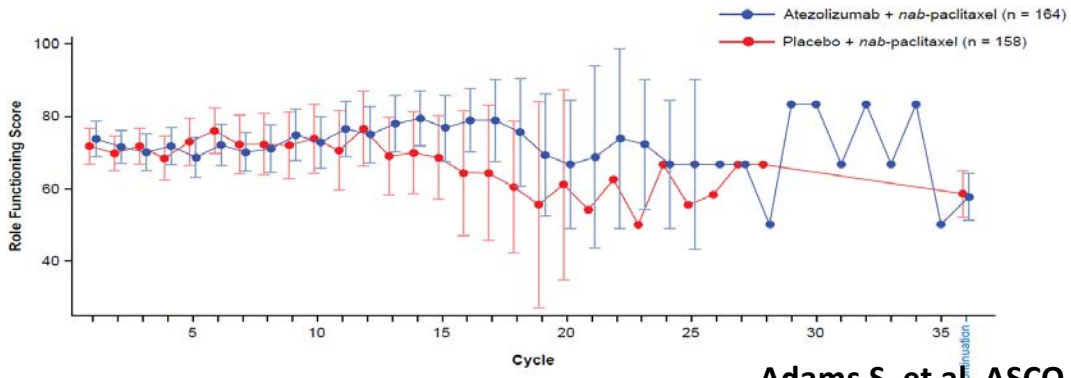
Mean HRQoL score (ITT)



Mean change in Physical function (PD-L1+)



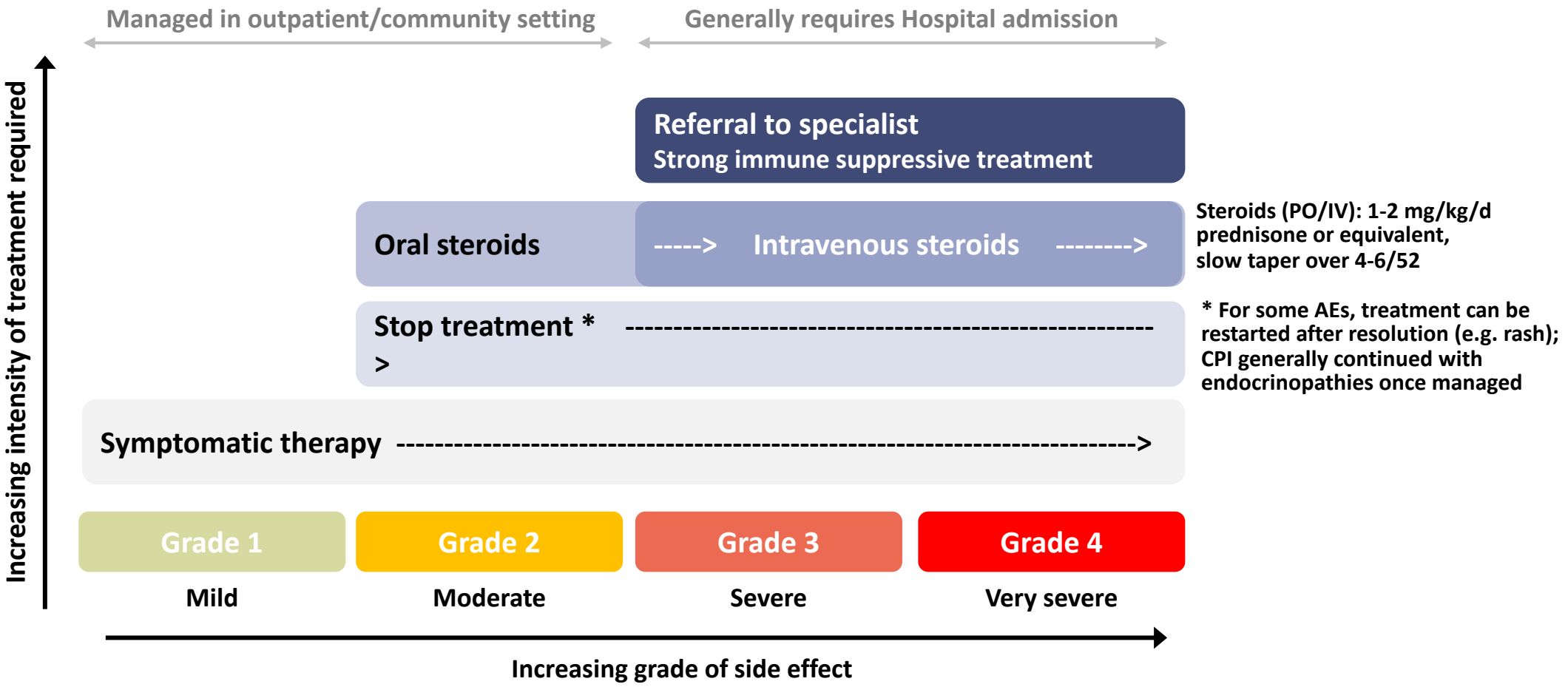
Mean change in Role function (PD-L1+)



Courtesy of Professor Peter Schmid, MD, PhD

Adams S, et al. ASCO 2019

Managing Side Effects from Immune checkpoint Inhibitors



Courtesy of Professor Peter Schmid, MD, PhD

Adapted from Champiat S. ESMO Patient Guide Series

Management of immune-related adverse events (irAE)

- Variable presentation in terms of system, combinations and timing ("anything can potentially be immune-mediated")
  - Endocrinopathies, Rash, Pneumonitis, Colitis and Hepatitis account for >90% of irAEs
  - But be aware of rare and possibly serious events
- Early recognition and treatment initiation critical
- Oncologist should lead irAE management (but consultation with subspecialty services in cases that are not straight forward)
- Steroids are highly effective therapy and don't affect efficacy of CPI ("rather once too often steroids than not giving if required")
- Long steroid taper (4-6 weeks) and multiple courses may be needed

Courtesy of Professor Peter Schmid, MD, PhD

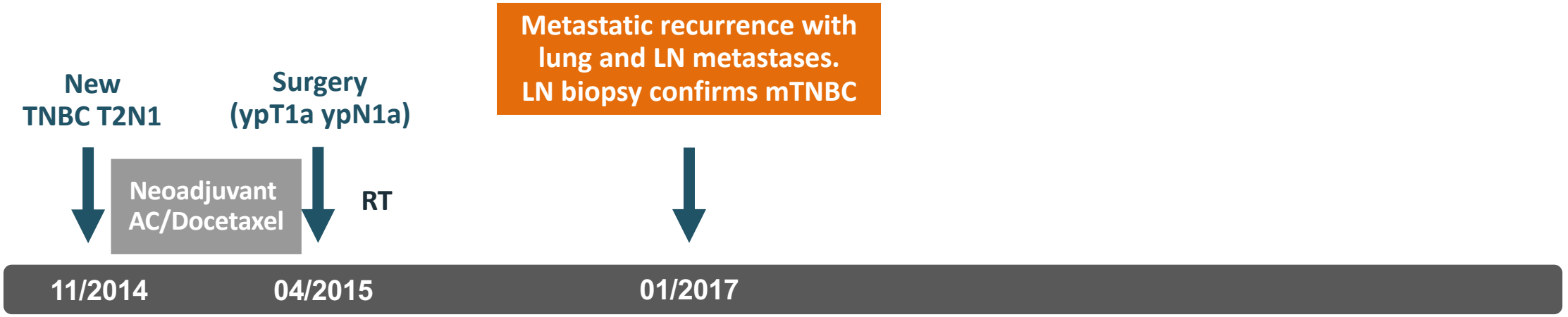
Case 1

41 y/o woman,

BRCA1 mutation carrier

What would you do at this stage?

- **Chemo**
- **Chemo + CIT**
- **PARP inhibitor**
- **Further tests**



Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. Personal Communication

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- **PARP inhibitor**
- **Further tests**

How do you test for PD-L1?

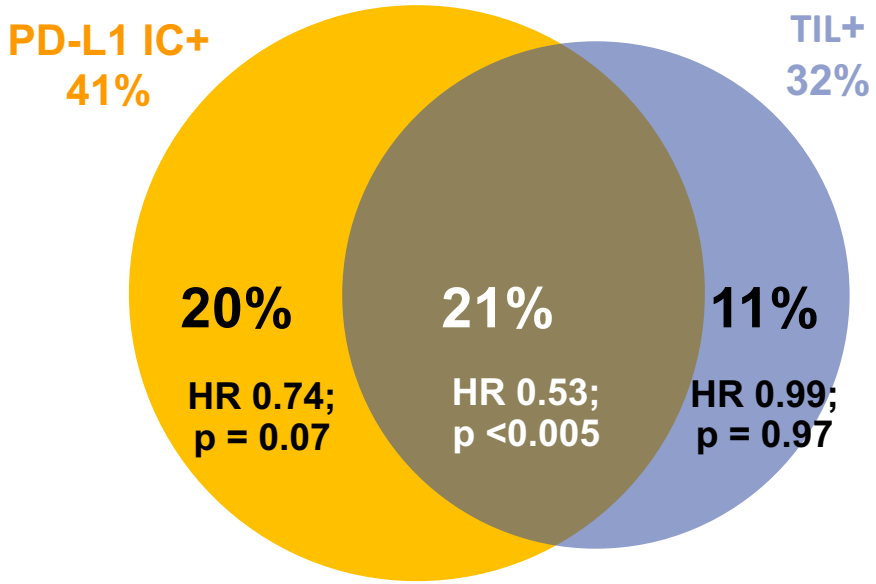
- **Which assay?**
- **Liver, lung or LN met?**
- **Primary tumour?**

Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. Personal Communication

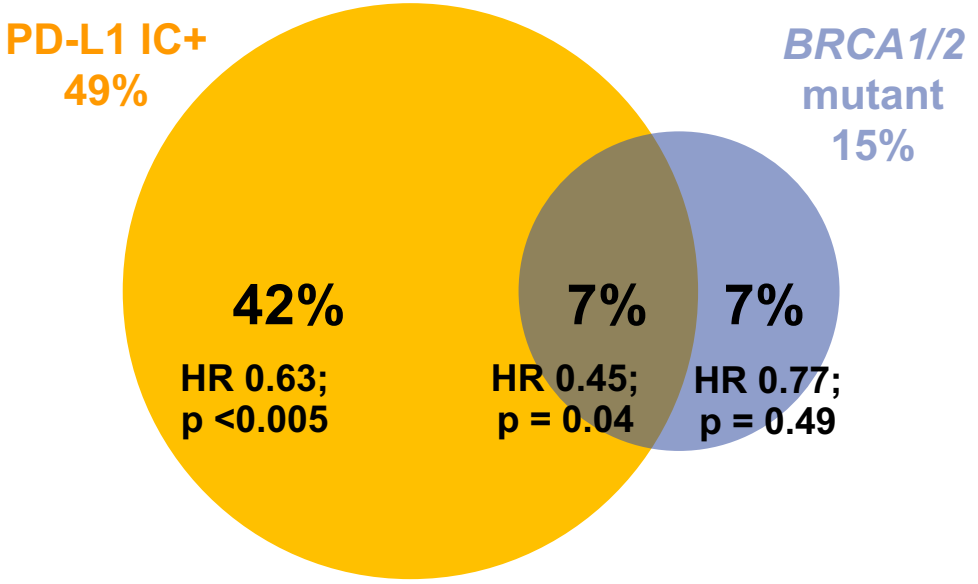
Stromal TILs & BRCA status and treatment benefit for atezolizumab

TILs



Stromal TILs have clinical benefit if co-occurring with PD-L1 IC+

BRCA1/2



The clinical benefit derived by PD-L1 IC+ patients was independent of their *BRCA1/2* mutation status

BEP (TILs): n = 893. Cutoff of 10% was used to distinguish low vs intermediate/high levels of TILs (Denkert *Lancet Oncol* 2018). All *P* values are nominal.

[a] Data derived from contingency table with Fisher exact tests.

Emens LA, et al. IMpassion130 biomarkers. SABCS 2018 (program #GS1-04)

Courtesy of Professor Peter Schmid, MD, PhD

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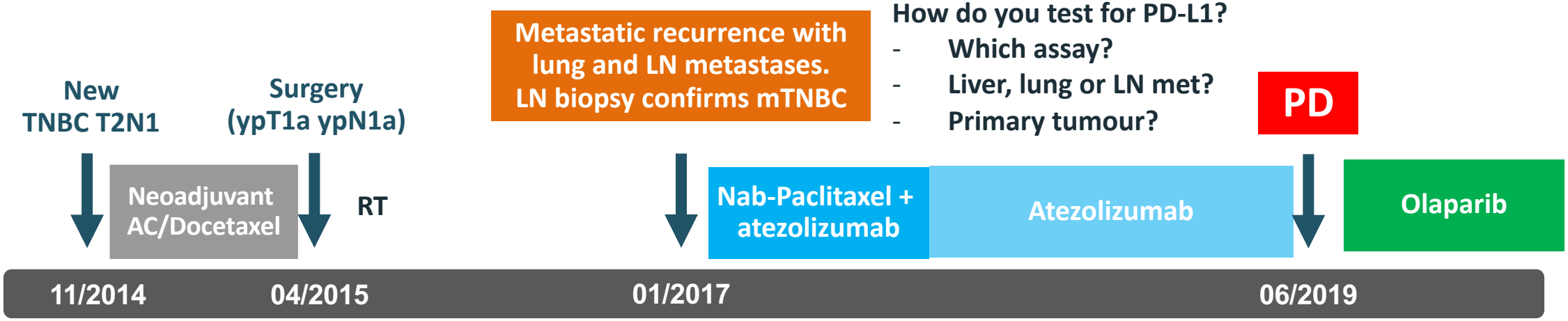
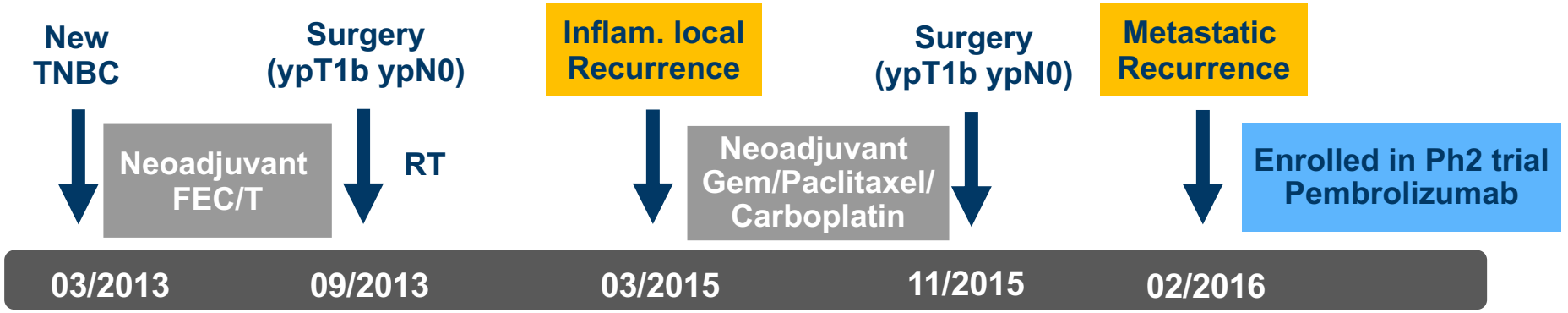


Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. Personal Communication

Case 2

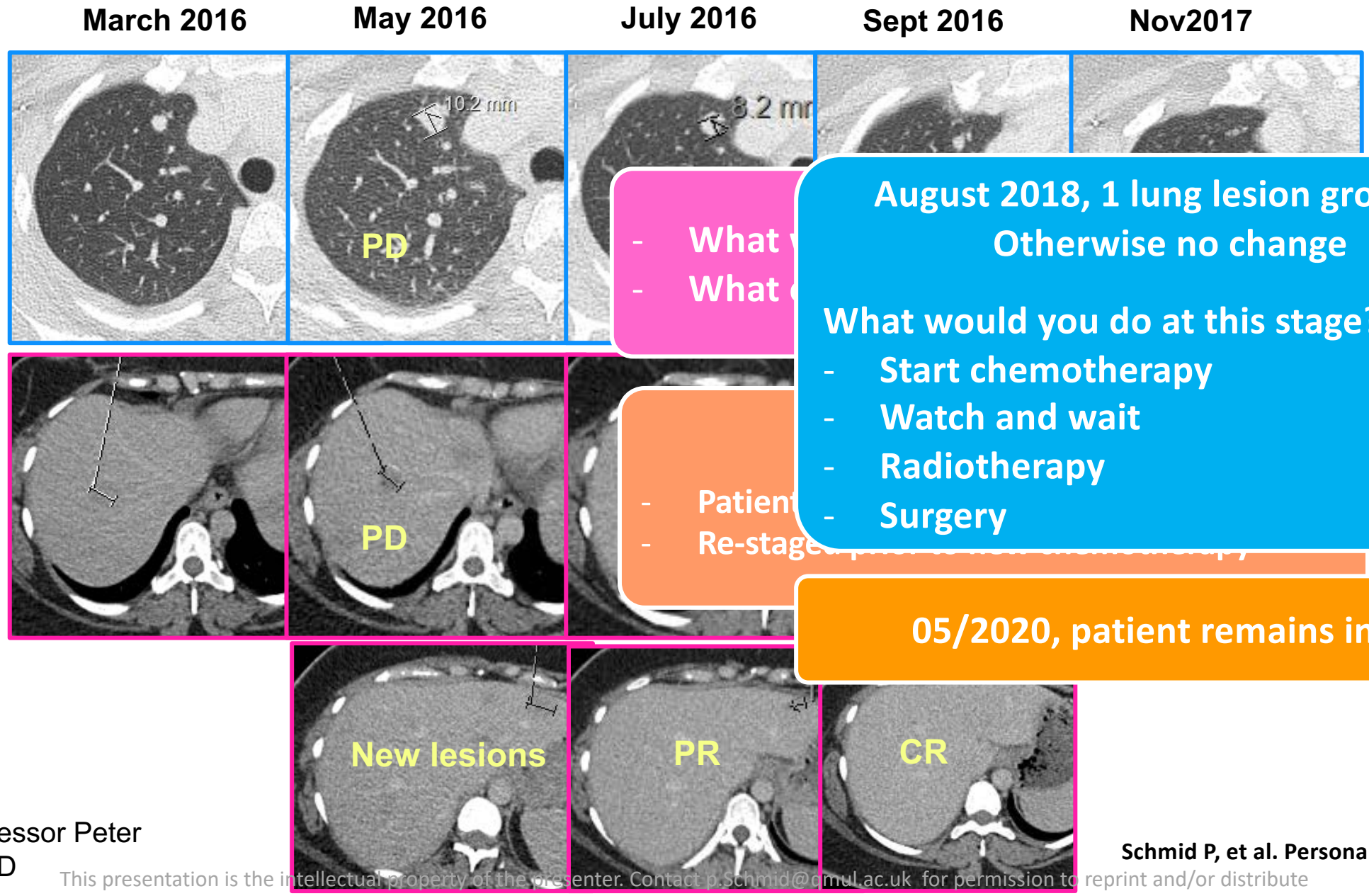
32 y/o woman



Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. Personal Communication

Case 2



Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. Personal Communication

Case 3

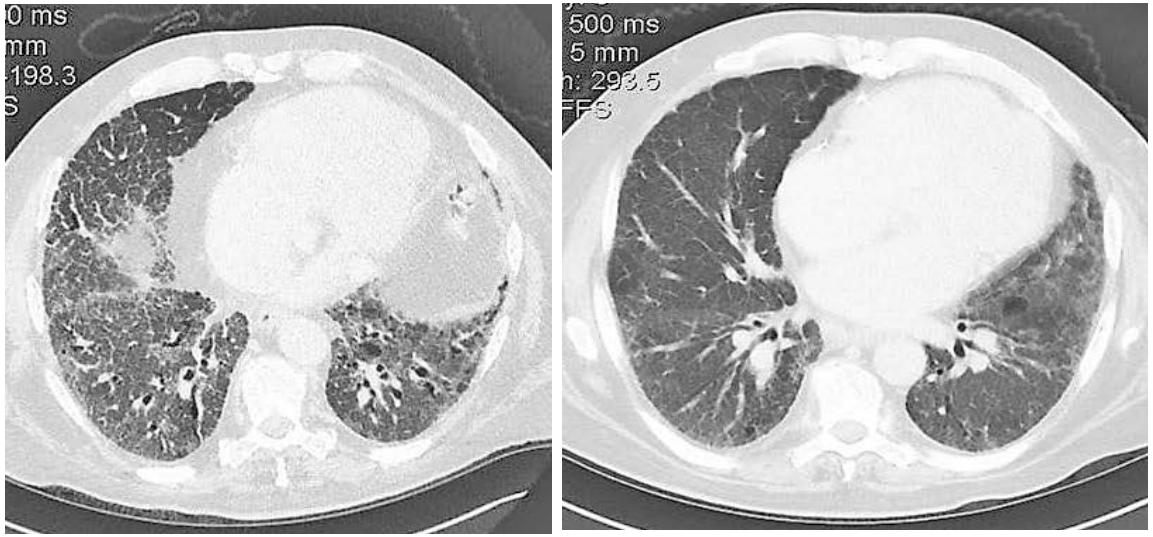
49 y/o woman

Differential Diagnosis:

1. Disease progression
2. Infection
3. Pneumonitis (Grade 2)

- Oral steroids (1-2 mg/kg)
- Hold CPI
- Empirical antibiotics
- Steroid taper 4-6 weeks

2 months later, symptoms resolved



PR

What would you do?

Patient presents with cough and dyspnoea

New TNBC cT2 cN0

Neoadjuvant EC/Paclitaxel

Surgery ypT2 ypN0

Adjuvant Capecitabine

Metastatic recurrence with lung & LN metastases.

Eribulin + anti-PD-1

11/2016 — **05/2017** — **12/2017** — **03/2018**

PR after EC
PD during Paclitaxel

Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. Personal Communication

Case 3

49 y/o woman

Differential Diagnosis:

1. Disease progression
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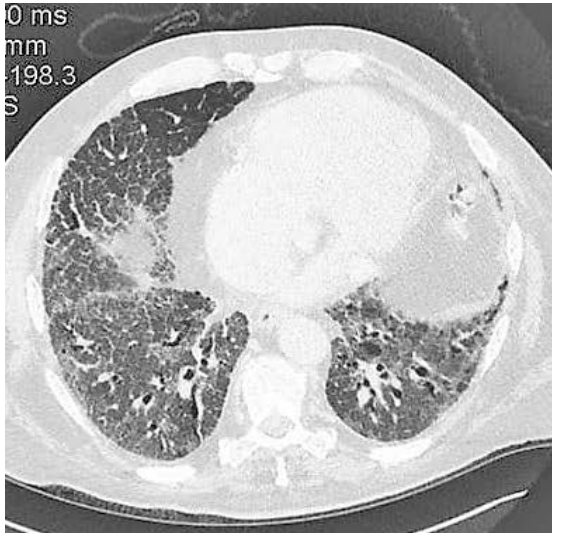

2 months later, symptoms resolved

What to do now?

1. Restart CPI
2. Change treatment
3. w/w

Pneumonitis (G2) reoccurred:

1. Oral Steroids
2. Discontinue CPI

What would you do?

PR

New TNBC cT2 cN0

Neoadjuvant EC/Paclitaxel

Surgery ypT2 ypN0

Adjuvant Capecitabine

Metastatic recurrence with lung & LN metastases.

Eribulin + anti-PD-1

Patient presents with cough and dyspnoea

Patient remains in complete response until 06/2020

11/2016 — **05/2017** — **12/2017** — **03/2018**

PR after EC
PD during Paclitaxel

Courtesy of Professor Peter Schmid, MD, PhD

Schmid P, et al. Personal Communication

Take-home messages

Single-agent anti-PD-L1/anti-PD-1 in metastatic TNBC

- Durable responses and substantial OS in metastatic TNBC
- Better response in earlier lines of therapy; phase 3 in pre-treated patients negative
- Biomarkers unable to reliably predict responders; high CPS identifies inflamed tumours

Combination of chemotherapy and anti-PD-L1/anti-PD-1 in metastatic TNBC

- Atezolizumab plus Nab-Paclitaxel improves PFS and OS in 1st line mTNBC
- Pembrolizumab plus Taxanes or Gem/Carboplatin improves PFS in 1st line mTNBC
- Effect largely limited to PD-L1+ tumours (SP142 - Atezo; CPS10 - Pembro)
- Combinations well tolerated
- Alternative strategies required for PD-L1-negative tumours (eg triplet with AKT)
- CAVEAT around use of Paclitaxel as Pac+Atezo fails to improve PFS in 1st line mTNBC

Courtesy of Professor Peter Schmid, MD, PhD