Imunoterapia – nový štandard v starostlivosti pri NSCLC

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Vyhlásenie o konflikte záujmov autora

Deklarujem nasledujúci konflikt záujmov

Forma finančného prepojenia	Spoločnosť
Participácia na klinických štúdiách/firemnom grante	
Nepeňažné plnenie (v zmysle zákona)	
Prednášajúci	Takeda, Boehringer-Ingelheim, Roche, Pfizer, Sandoz
Akcionár	
Konzultant/odborný poradca	
Ostatné príjmy (špecifikovať)	

Podľa UEMS (upravené v zmysle slovenskej legislatívy)

Táto prezentácia vznikla za podpory spoločnosti MSD

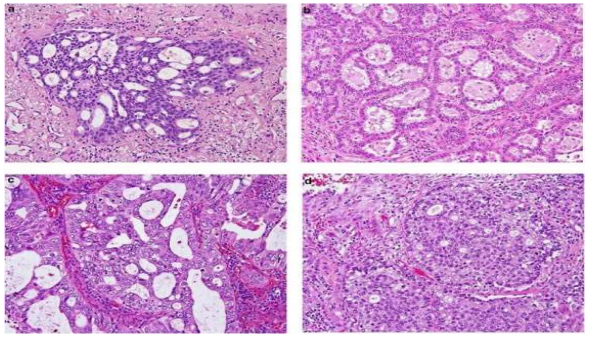
Podľa UEMS (upravené v zmysle slovenskej legislatívy)

Možnosti liečby NSCLC

Chemoterapia

Histologické podtypy

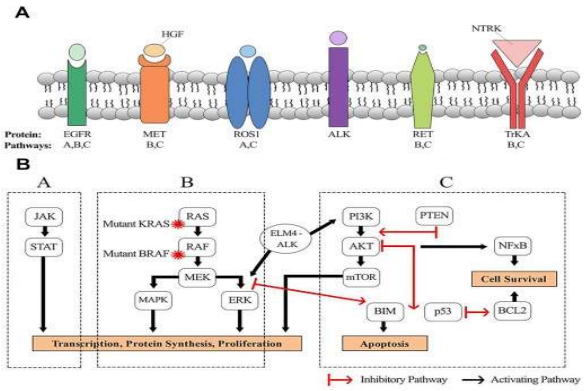
~1970 - súčasnosť



Cielená liečba

EGFR
ALK
ROS1

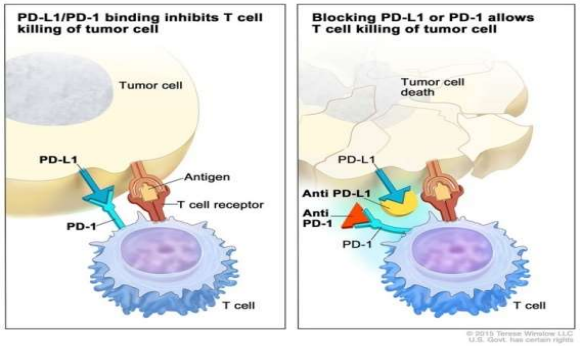
~2000 - súčasnosť



Checkpoint inhibítory

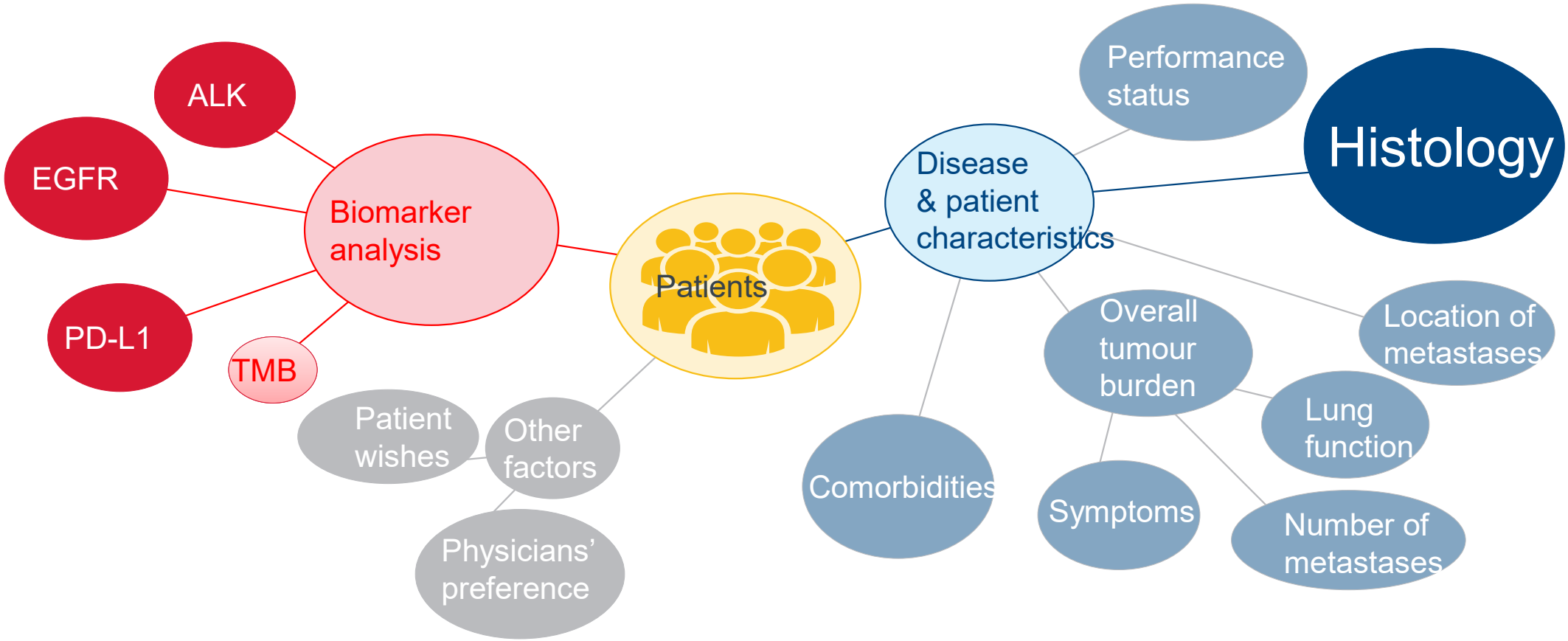
Anti–PD-1
Anti–PD-L1
Anti–CTLA-4

2015 - súčasnosť



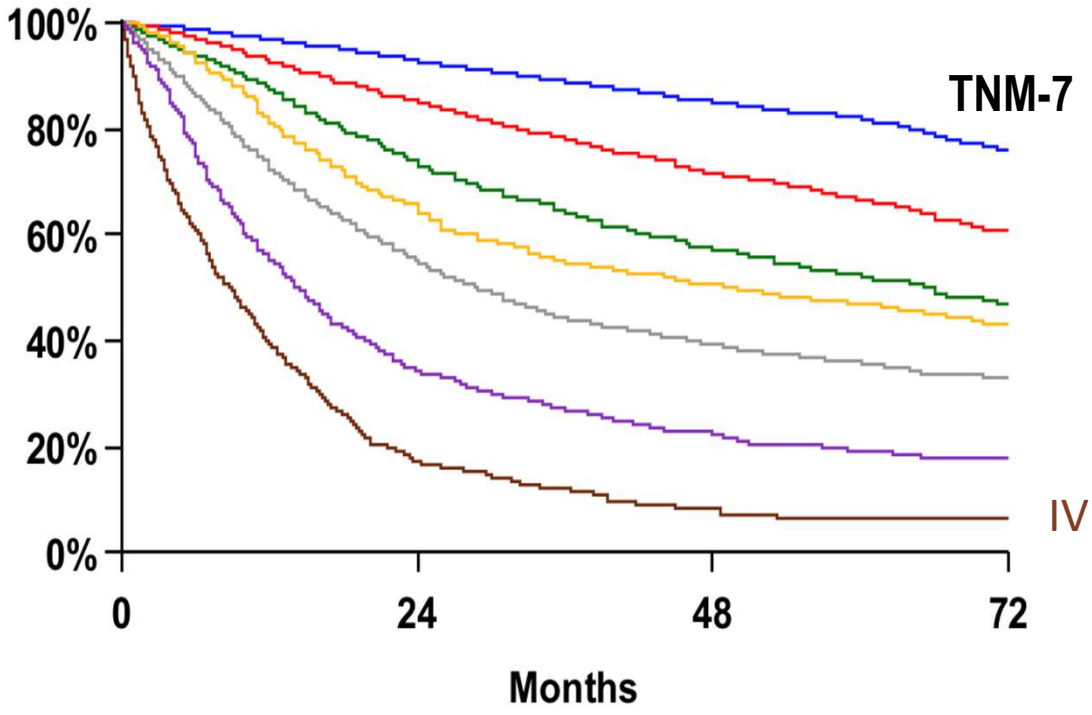
Slide credit: clinicaloptions.com

Rozhodovanie o liečbe v 1L NSCLC



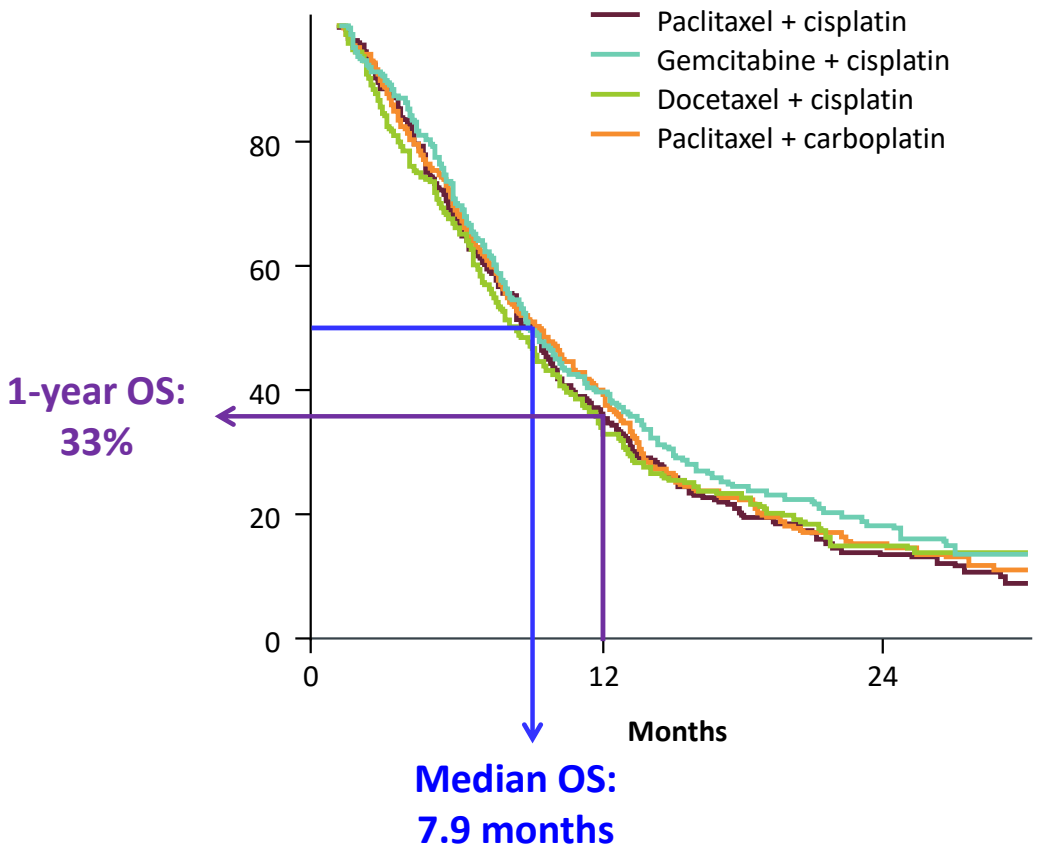
5-ročný OS v NSCLC – prežívanie podľa štádií

5-ročné OS:
klin. štádium IV 6%



Goldstraw P, et al. *J Thorac Oncol*. 2016;11(1):39–51.

Čo môžme očakávať od chemoterapie?

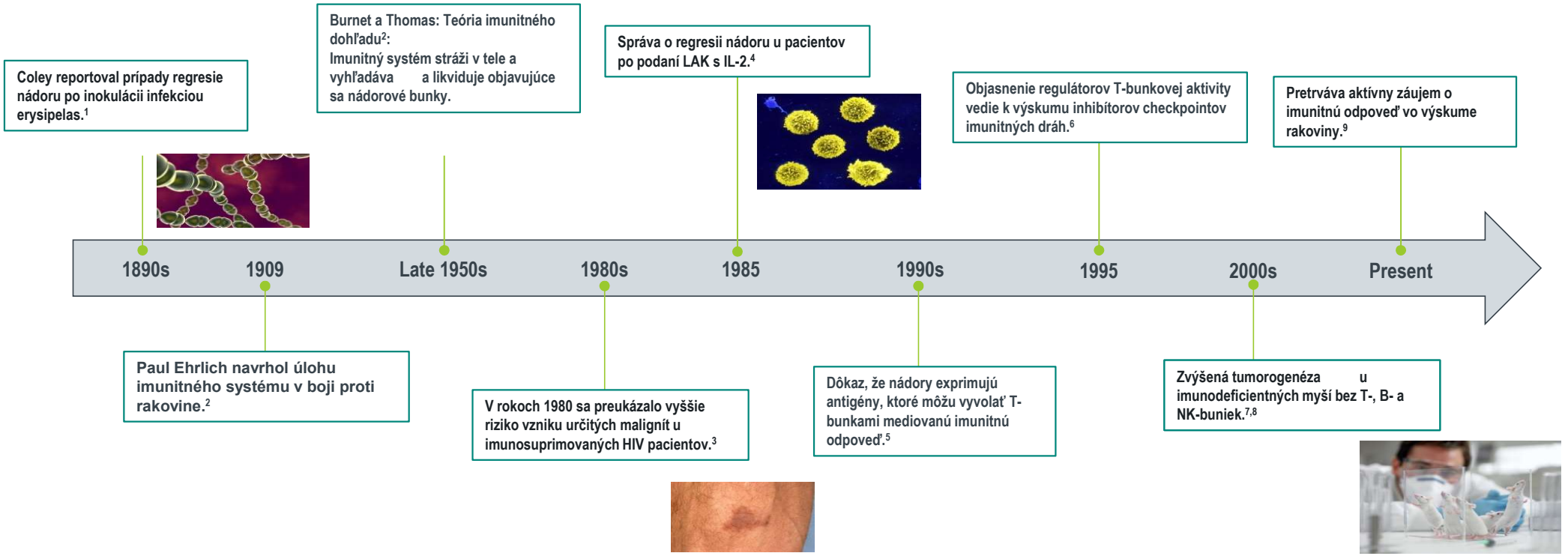


- Efficacy of platinum-based chemotherapy
- Comparable efficacy
- No selection factors
- Different tolerability profiles
- Limited by toxicity

Nezdokumentované 5-ročné podiely prežívania!

Schiller JH, et al. *N Engl J Med*. 2002;346:92–8.

Čo vieme o úlohe imunitného systému v onkológii?

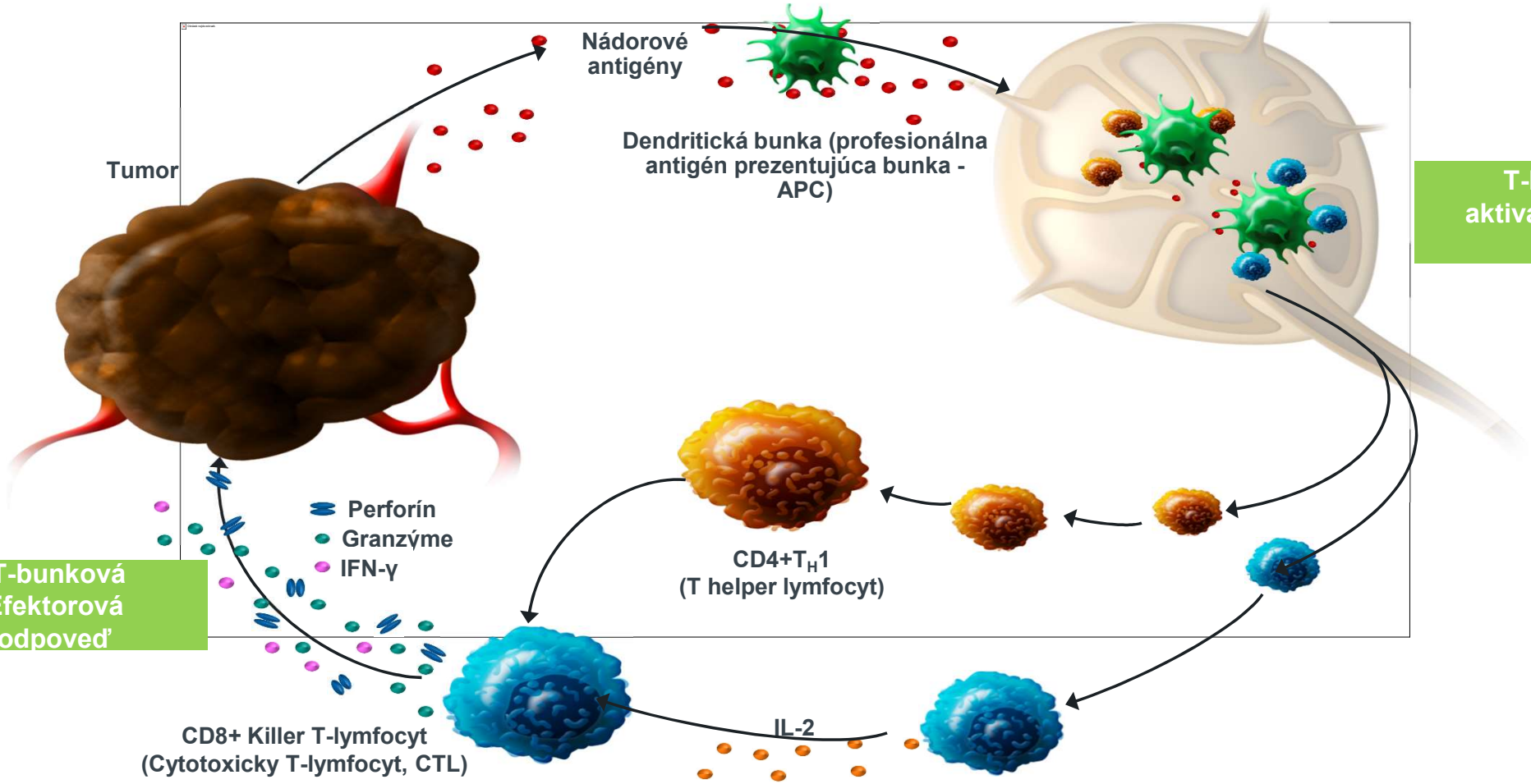


HIV = human immunodeficiency virus; LAK = lymphokine-activated killer; IL-2 = interleukin-2; NKT = natural killer T.

1. Coley WB. Am J Med Sci. 1893;105:487–511. 2. Ichim CV. J Transl Med. 20058;3:8. 3. Levine AM et al. Curr Probl Cancer. 1987;11:209–55. 4. Rosenberg SA et al. N Engl J Med. 1985;313:1485–1492. 5. van der Bruggen P et al. Science. 1991;254:1643–1647. 6. Tivol EA. et al. Immunity. 1995;3:541–547. 7. Vesely MD et al. Annu Rev Immunol. 2011;29:235–271. 8. Shankaran V. et al. Nature. 2001;410:1107–1111. 9. Drake CG et al. Nat. Rev. Clin. Oncol. 2014;11: 24–37.

Normálny imunitný dozor: aktivácia a odpoveď

Prezentácia nádorového antigénu

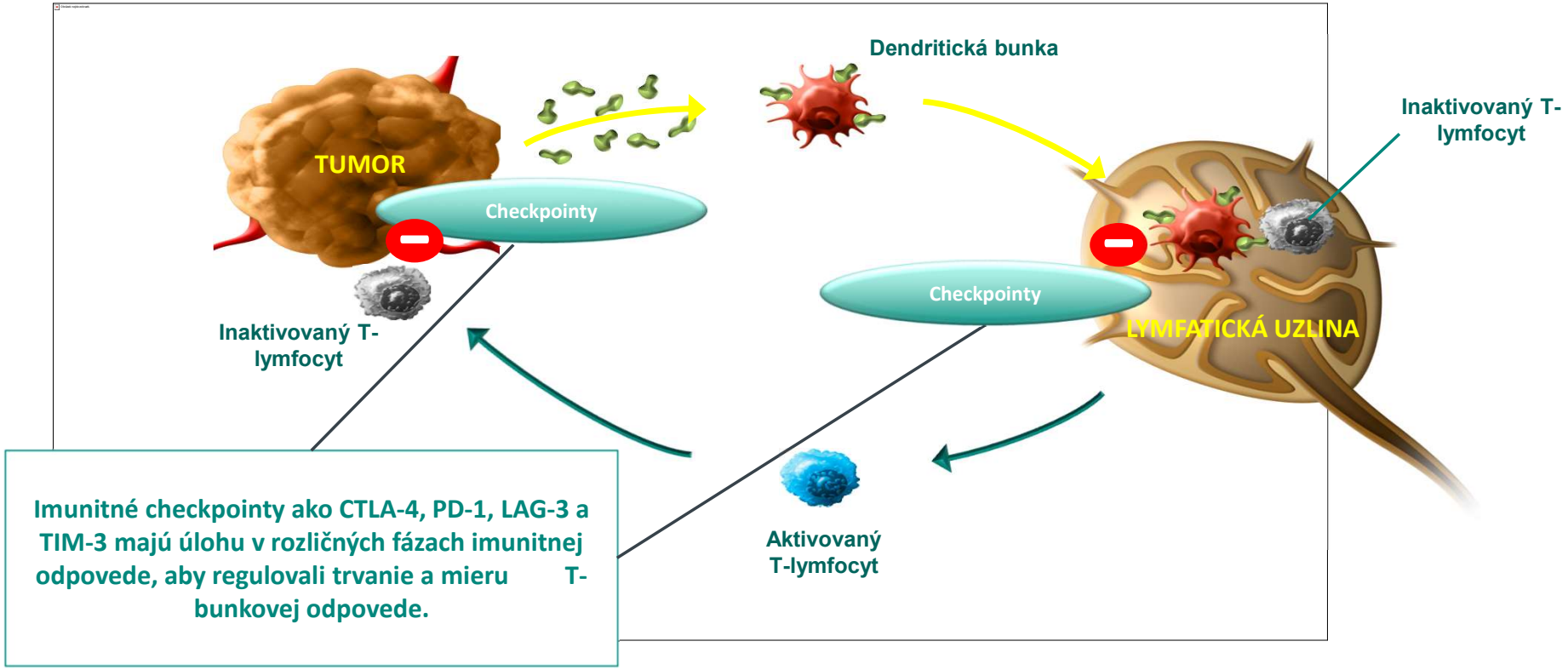


T-bunková aktivácia v lymf. uzline

T-bunková Efektorová odpoveď

Motz GT et al. Immunity. 2013;39:61–73. Chen DS et al. Immunity. 2013;39:1–10. Pardoll DM. Nat Rev Cancer. 2012;12:252–64. Janeway CA, et al. Immunobiology. 6th ed. New York and London: Garland Science; 2004:341-342. Liu CC et al. N Engl J Med. 1996 ;335:1651-1659. Mellman I et al. Nature. 2011;480:480-489

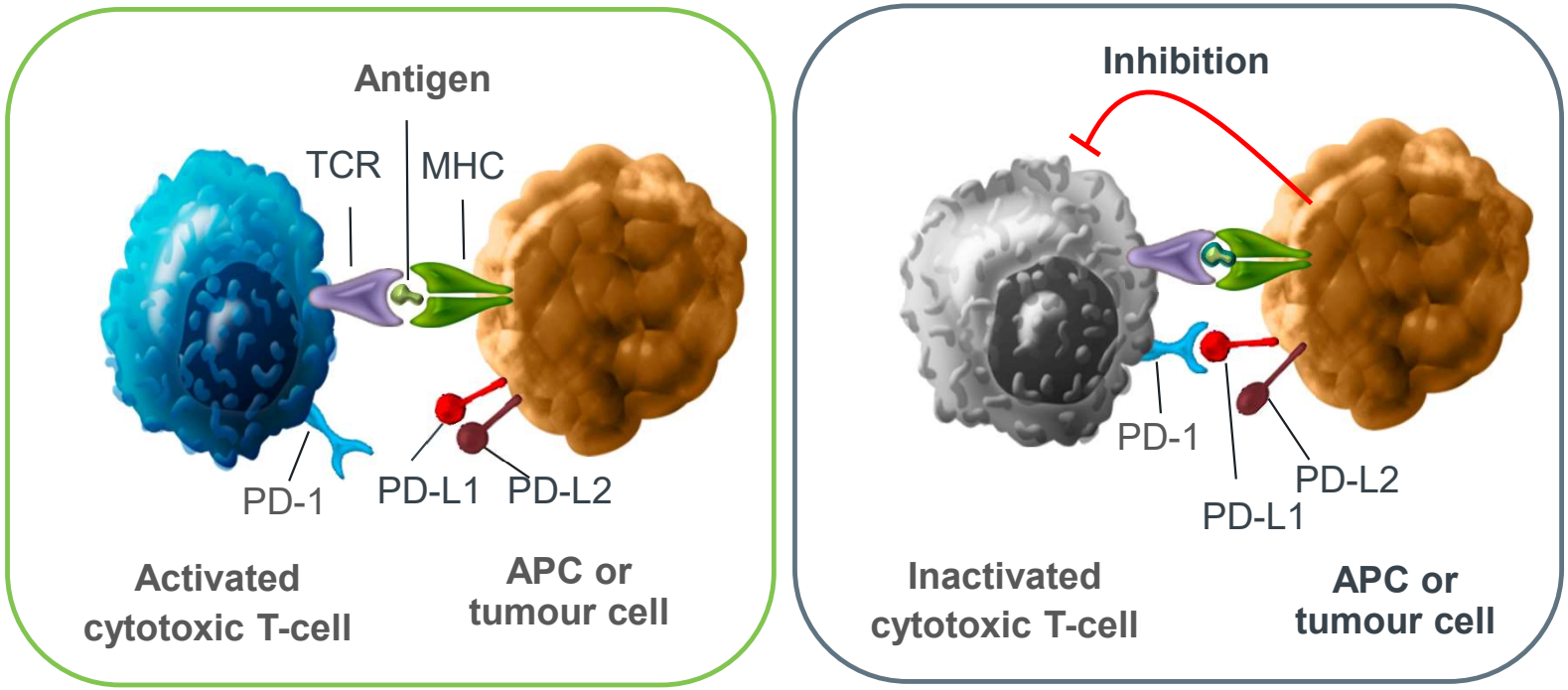
T-lymfocyty majú dôležitú úlohu v schopnosti imunitného systému rozpoznávať a ničiť nádorové bunky[1]

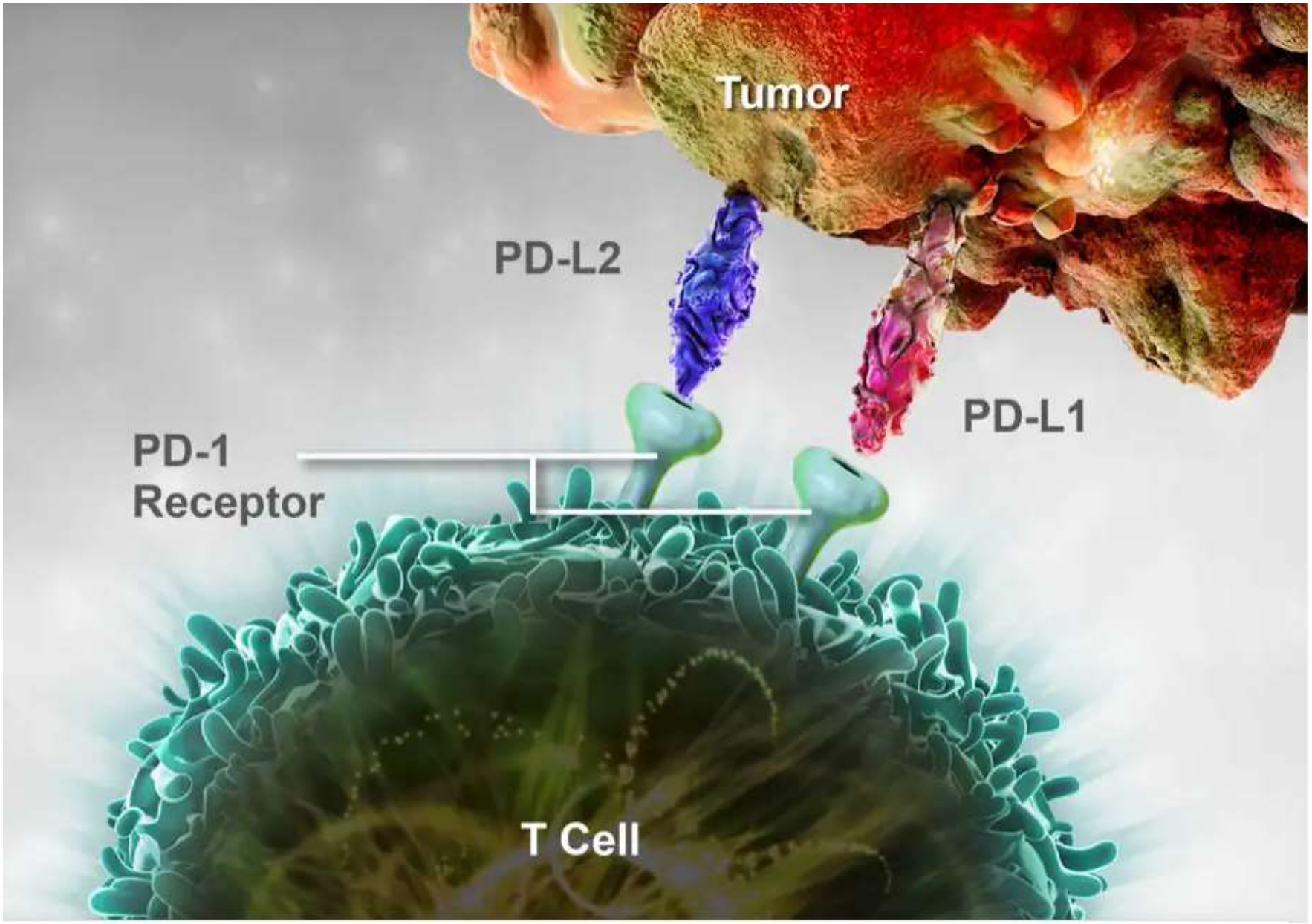


CTLA-4 = cytotoxic T-lymphocyte antigen 4; PD-1 = programmed cell death protein 1; LAG-3 = lymphocyte activation gene 3; TIM-3 = T-cell immunoglobulin and mucin protein 3.

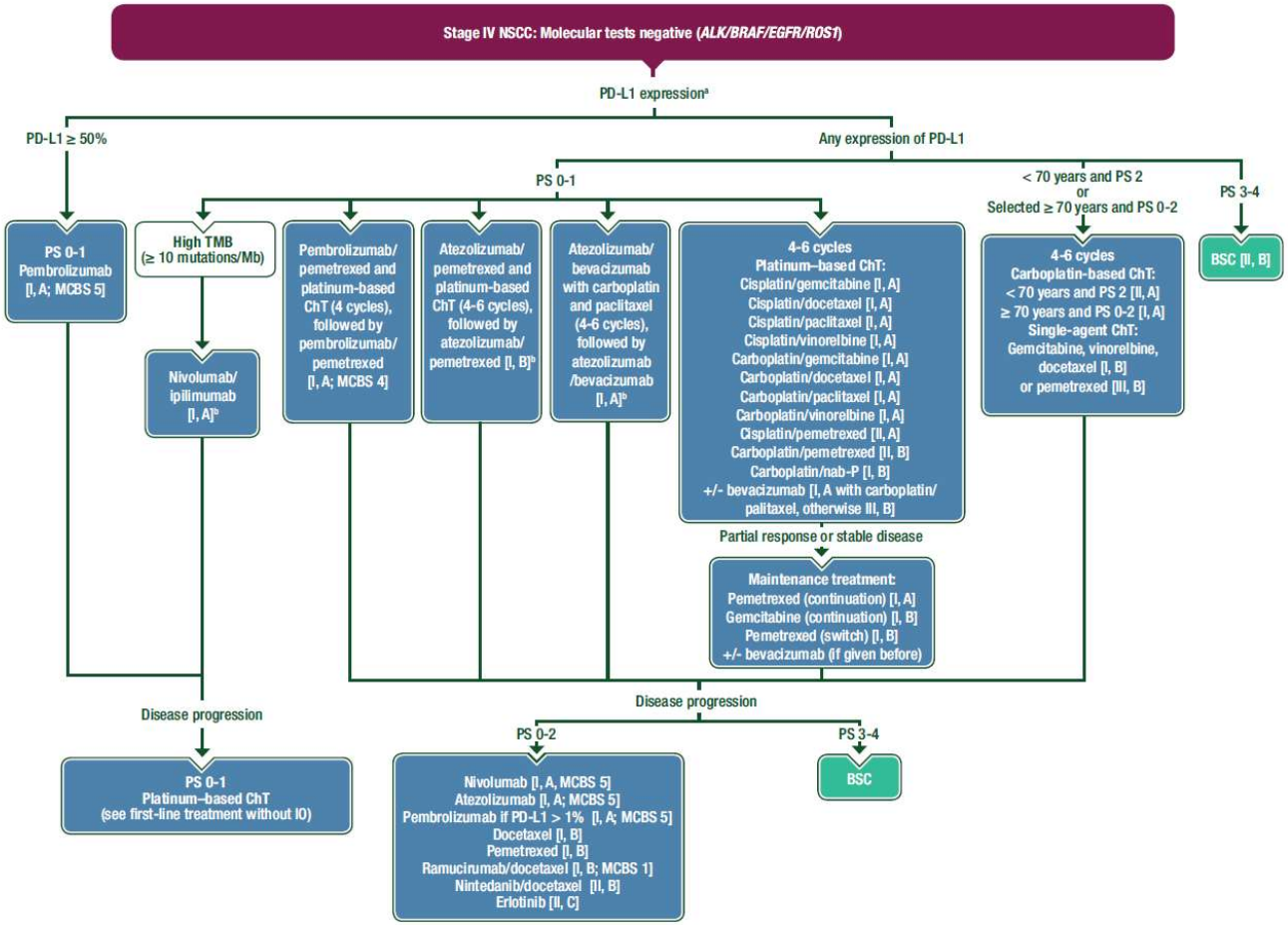
1. Pardoll DM. Nat Rev Cancer. 2012;12:252–264.

PD-1 pathways present a target for monoclonal antibody therapy



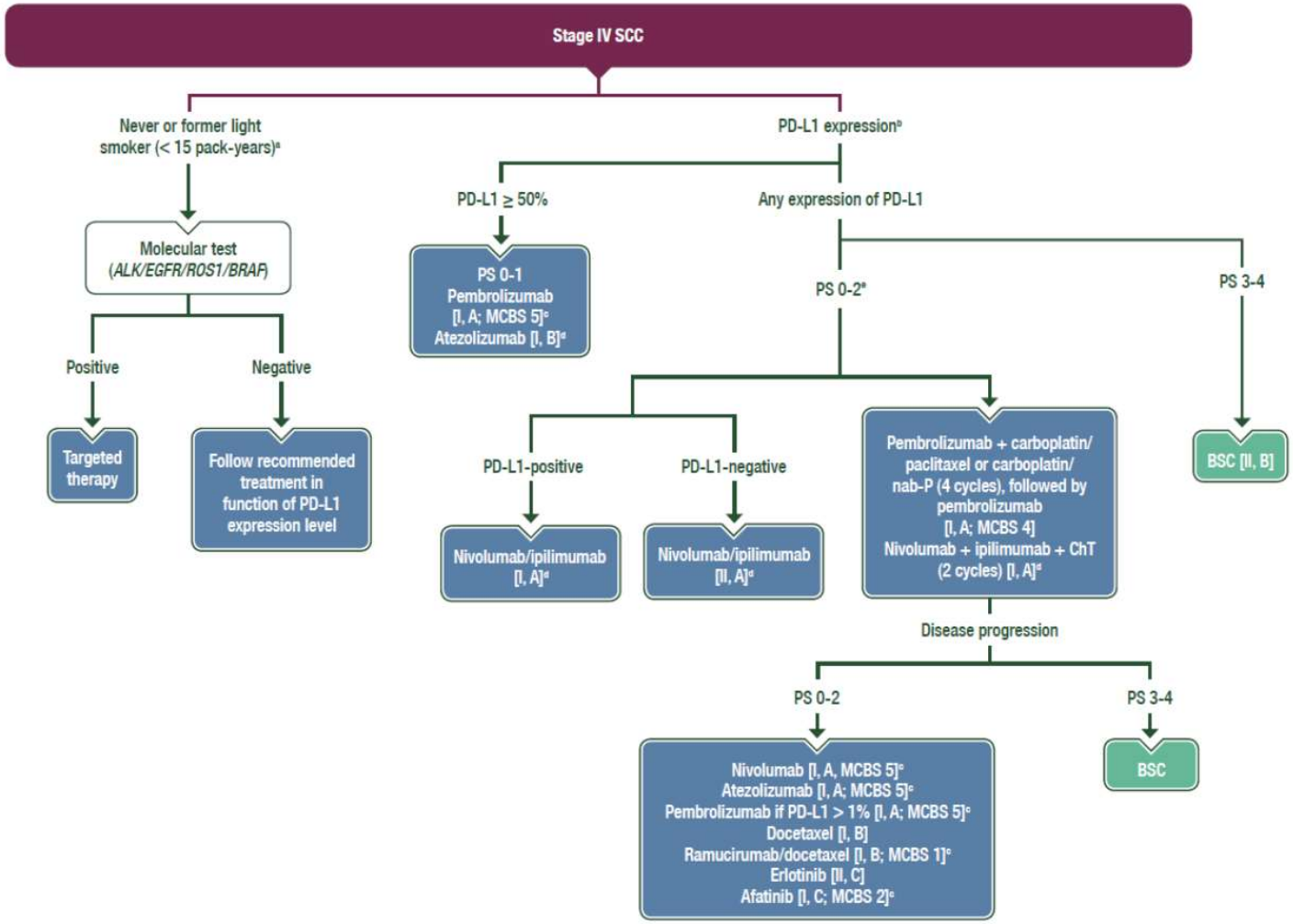

Tumor
PD-L2
PD-L1
PD-1
Receptor
T Cell

ESMO odporúčania pre NSCC IV. štádium



Updated version published 15 September 2020 by the ESMO Guidelines Committee

ESMO odporúčania pre SCC IV. štádium

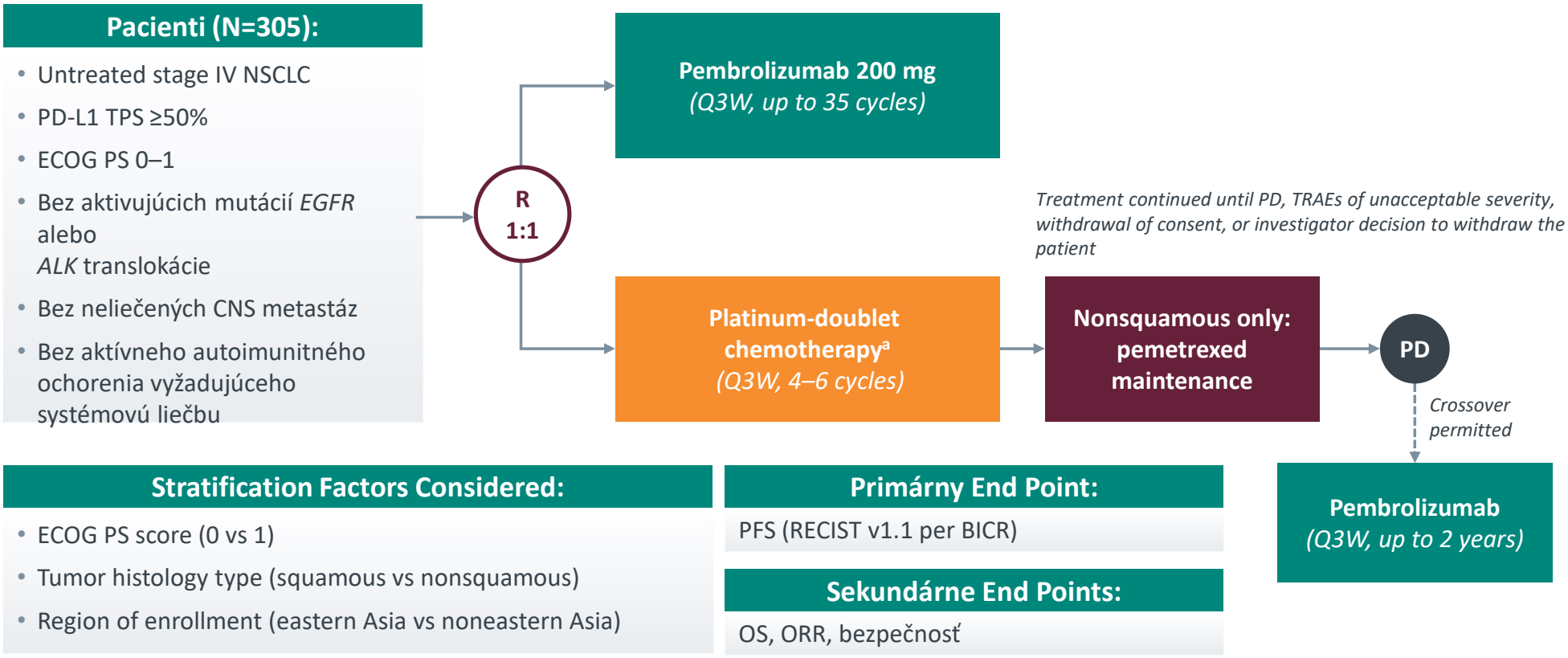


Updated version published 15 September 2020 by the ESMO Guidelines Committee

Pembrolizumab monoterapia 1L

KN-024

KN-024: Štúdia fázy 3 pembrolizumab vs platinum-doublet chemoterapia 1 L štádium IV NSCLC

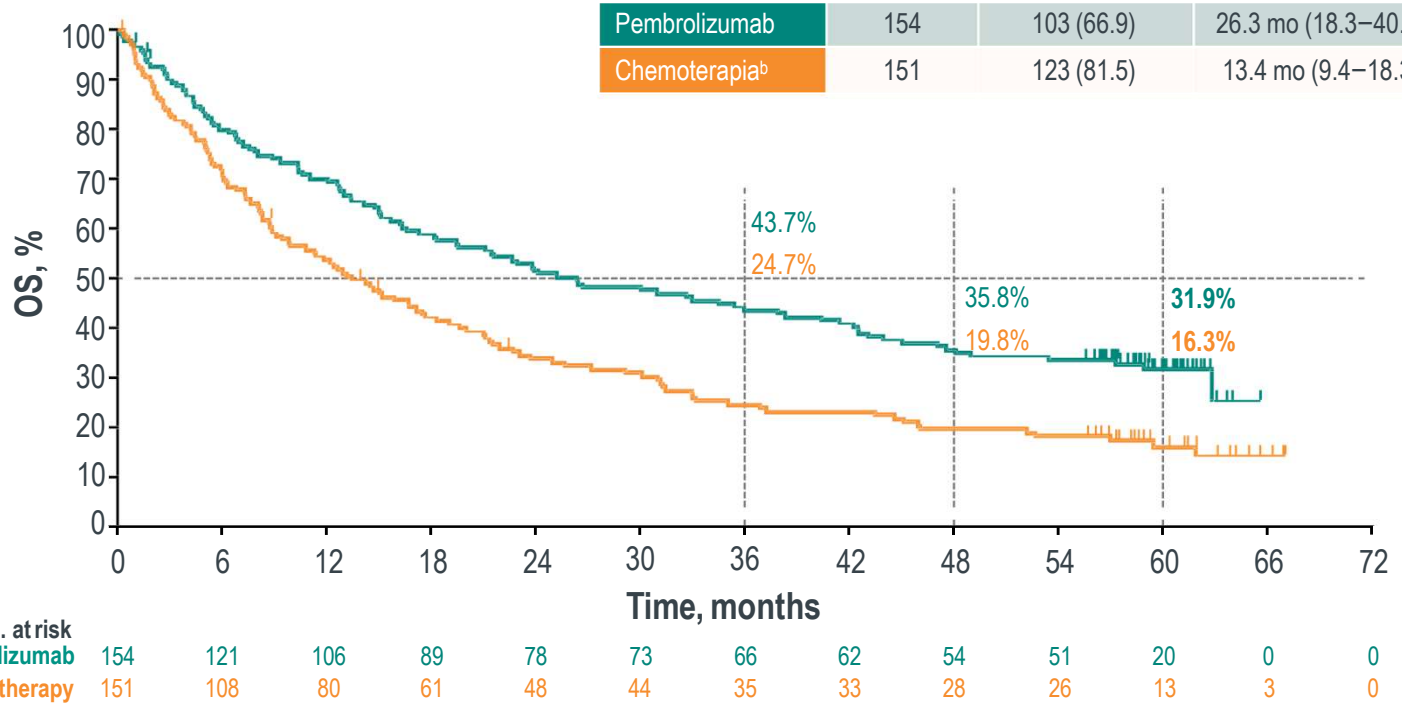


[a]Pemetrexed 500 mg/m^2 + carboplatin AUC 5 to 6, pemetrexed 500 mg/m^2 + cisplatin 75 mg/m^2, paclitaxel 200 mg/m^2 + carboplatin AUC 5 to 6, gemcitabine 1250 mg/m^2 + carboplatin AUC 5 to 6, or gemcitabine 1250 mg/m^2 + cisplatin 75 mg/m^2.

Reck M et al. *N Engl J Med.* 2016;375(19):1823–1833.

KN-024: 5- ročný update OS[a]

	N	Events, n (%)	Median (95% CI)	HR (95% CI)
Pembrolizumab	154	103 (66.9)	26.3 mo (18.3–40.4)	0.62 (0.48–0.81)
Chemoterapia[b]	151	123 (81.5)	13.4 mo (9.4–18.3)	



No. at risk													
Pembrolizumab	154	121	106	89	78	73	66	62	54	51	20	0	0
Chemotherapy	151	108	80	61	48	44	35	33	28	26	13	3	0

Median follow-up = 59.9 months (range: 55.1–68.4 months). Data cutoff: June 1, 2020.

[a]ITT population. [b]Effective crossover rate from chemotherapy to anti–PD-L1 therapy, 66.0% (99 patients in total crossed over to anti–PD-[L]1 therapy: 83 patients crossed over to pembrolizumab during the study, and 16 patients received subsequent anti–PD-L1 therapy outside of crossover; patients may have received >1 subsequent anti–PD-L1 therapy).

1. Reck et al. *J Clin Oncol*. 2021;epub ahead of print. **2**. Brahmer et al. Presented at ESMO 2020. Abstract LBA51.

Pembrolizumab v kombinácii 1L

KN-189

KN-189: Štúdia fázy 3 pemetrexed + platinum chemotherapy ± pembrolizumab 1L Therapy for Metastatic NSQ NSCLC

Pacienti (N=616):

- Histologically/cytologically confirmed stage IV NSQ NSCLC
- Measurable disease
- No sensitizing *EGFR* mutation or *ALK* alteration
- ECOG PS 0 or 1
- No prior treatment targeting PD-1, PD-L1, PD-L2, or any immuno-regulatory receptors
- No prior systemic treatment for advanced/metastatic NSCLC
- Provision of tumor tissue sample
- Life expectancy ≥3 months
- No active autoimmune disease
- No active CNS metastases
- No interstitial lung disease/pneumonitis requiring systemic steroids

R 2:1

n=410

Up to 4 cycles

Pembrolizumab 200 mg + Pemetrexed 500 mg/m² + [Carboplatin AUC 5 or Cisplatin 75 mg/m²] Q3W

Up to 31 cycles

Pembrolizumab 200 mg + Pemetrexed 500 mg/m² Q3W

PD

Second course therapy[a]

17 cycles (1 year)[a]

Pembrolizumab 200 mg Q3W

Treatment continued until PD, unacceptable toxic effects, withdrawal of consent, or investigator decision to withdraw the patient

n=206

Placebo (saline) + Pemetrexed 500 mg/m² + [Carboplatin AUC 5 or Cisplatin 75 mg/m²] Q3W

Placebo (saline) + Pemetrexed 500 mg/m² Q3W

PD

Crossover permitted

PD

Second course therapy[a]

Up to 35 cycles

Pembrolizumab 200 mg Q3W

Stratification Factors:

- PD-L1 expression (TPS <1% vs ≥1%)
- Platinum (cisplatin vs carboplatin)
- Smoking status (never vs former/current)

Primárne End Points:

PFS,[b] OS

Sekundárne End Points:

Safety, ORR,[b] DOR[b]

Exploratory End Point:

PFS2[c]

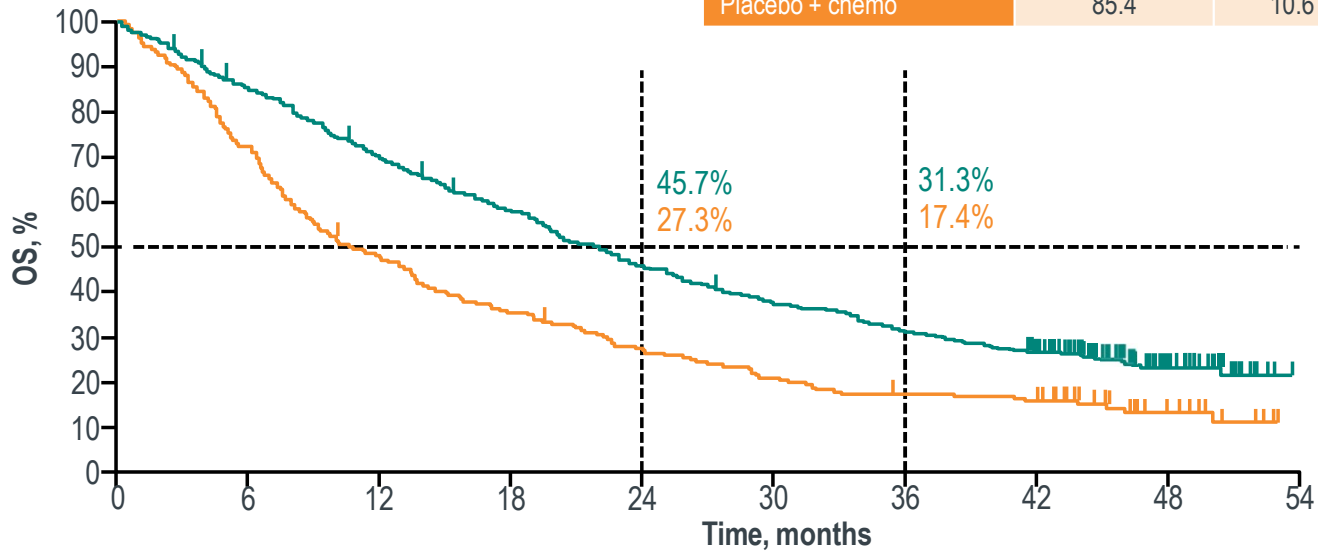
[a]Patients who had SD or better after completing 35 cycles of pembrolizumab or had stopped trial treatment after achieving CR and received ≥8 cycles of treatment, but then experienced PD, could receive second-course pembrolizumab for 17 cycles (~1 year) if they had received no new anticancer therapy since the last dose of pembrolizumab.

[b]Per RECIST v1.1 by BICR. [c]PFS2 defined as time from randomization to investigator-assessed disease progression that led to cessation of second-line therapy, start of third-line therapy, or death.

1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT02578680. Accessed October 8, 2020. **2.** Gandhi L et al. *N Engl J Med.* 2018;378(22):2078–2092. **3.** Gray et al. Presented at WCLC 2020. Abstract FP13.02.

KN-189: 4-ročný follow-up pre OS pembrolizumab + chemoterapia vs chemoterapia (ITT populácia)

	Events, %	mOS, months (95% CI)	HR (95% CI)
Pembro + chemo	74.4	22.0 (19.5–24.5)	0.60 (0.50–0.72)
Placebo + chemo	85.4	10.6 (8.7–13.6)	



No. at risk:										
Pembro + Chemo	410	347	283	234	184	149	125	99	28	0
Placebo + Chemo	206	149	98	72	55	42	34	29	10	0

Median follow-up = 46.3 months (range: 41.8–54.1 months). Data cutoff: August 28, 2020.

1. Gray et al. Presented at WCLC 2020. Abstract FP13.02.

KN-189: 4- ročný follow-up ORR[a] a OS u paceintov, ktorí dokončili 35 cyklov pembrolizumabu

Najlepšia odpoveď, n (%)	35 cycles (2 years) of pembrolizumab n=56
Objective response	49 (87.5)
Best objective response	
CR	6 (10.7)
PR	43 (76.8)
SD	7 (12.5)

- In patients who completed 35 cycles (2 years) of pembrolizumab:
  - 2-year OS rate from completion of 35 cycles (2 years) was 79.6%
  - At data cutoff, 45/56 patients (80.4%) were alive, 28 without PD
- 7 patients started second-course pembrolizumab
  - 2 had a second-course best response of SD by investigator assessment
  - 2 had best response of PD, and 3 were not assessed as of data cutoff

Median follow-up = 46.3 months (range: 41.8–54.1 months). Data cutoff: August 28, 2020.
[a]Per RECIST v1.1 by BICR.
1. Gray et al. Presented at WCLC 2020. Abstract FP13.02.

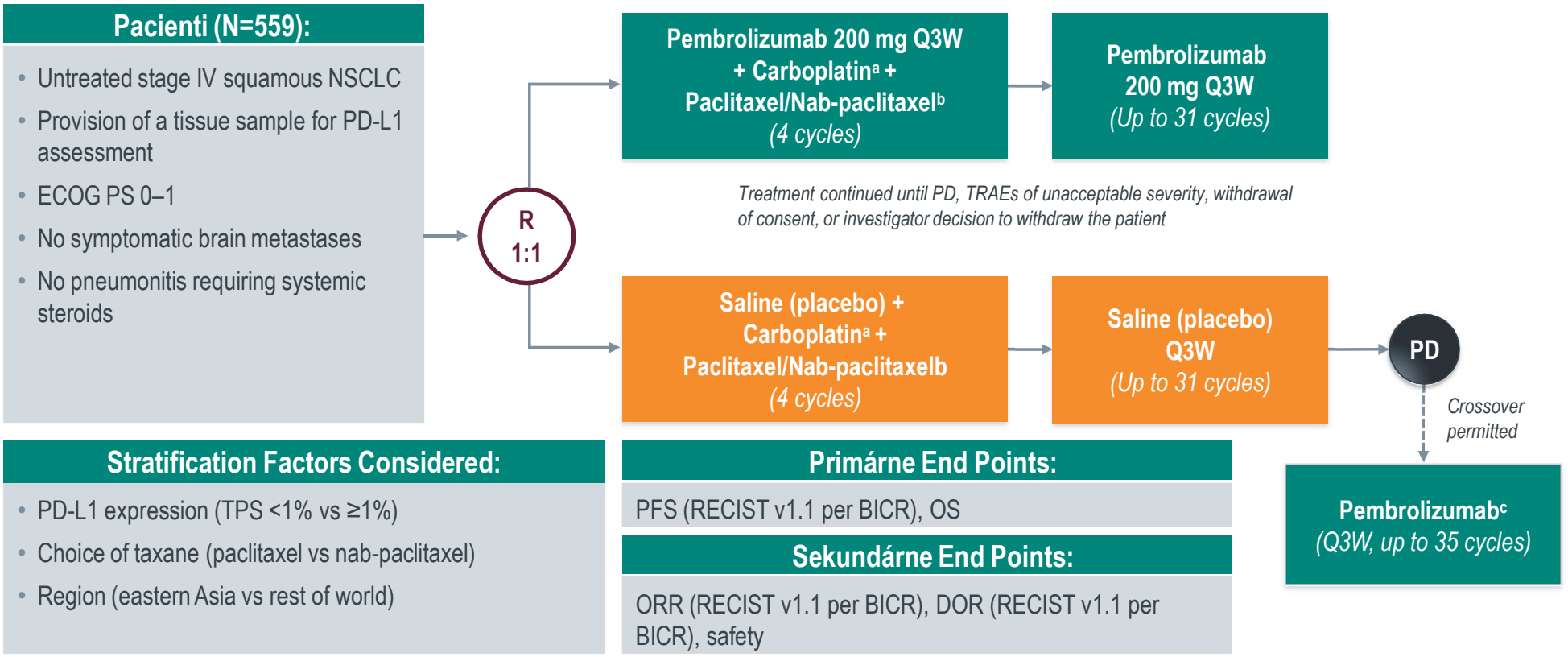
KN-189: 4-ročný follow-up NÚ (ITT populácia)

n (%)	Pembro + chemo n=405	Placebo + chemo n=202	35 cyklov (2 roky) pembrolizumab n=56
TRAEs[a]	376 (92.8)	183 (90.6)	55 (98.2)
Grade 3–5	211 (52.1)	85 (42.1)	26 (46.4)
Led to discontinuation	111 (27.4)	20 (9.9)	16 (28.6)[b]
Led to death	8 (2.0)	2 (1.0)	0 (0)
Immune-mediated AEs and infusion reactions	112 (27.7)	27 (13.4)	22 (39.3)
Grade 3–5	51 (12.6)	9 (4.5)	6 (10.7)
Led to discontinuation of pembro	37 (9.1)	-	0 (0)
Led to death	2 (0.5)[c]	0 (0)	0 (0)

Median follow-up = 46.3 months (range: 41.8–54.1 months). Data cutoff: August 28, 2020.
[a]AEs attributed to study treatment by the investigator. [b]All patients discontinued chemo; 1 patient discontinued pembro. [c]Pneumonitis (n=2).
1. Gray et al. Presented at WCLC 2020. Abstract FP13.02.

KN-407

KN-407: Štúdia fázy 3 karboplatina + paclitaxel/nab-paclitaxel ± pembrolizumab 1L liečby štádium IV Squamous NSCLC



[a]Carboplatin AUC 6 mg/mL/min Q3W. [b]Paclitaxel 200 mg/m^2 Q3W or nab-paclitaxel 100 mg/m^2 Q1W. [c]Patients could cross over during combination therapy or monotherapy. To be eligible for crossover, PD must have been verified by BICR, and all safety criteria had to be met.

1. Paz-Ares LG et al. Presented at ASCO Annual Meeting 2018. June 1–5, 2018; Chicago, IL: Abstract 105. **2.** Paz-Ares L et al. *N Engl J Med.* 2018;379(21):2040–2051. **3.** Paz-Ares L et al. *J Thorac Oncol.* 2020;15(10):1657-1669.
4. Robinson AG et al. Presented at ELCC Congress 2021; March 27–October 1, 2019; virtual. Abstract FP97O.

KN-407 3-ročný follow-up: OS pre pembrolizumab + chemoterapia vs placebo + chemoterapia (ITT)

	n	Events, n (%)	Median (95% CI) OS, mo	HR (95% CI)
Pembro + chemo	278	204 (73.4)	17.2 (14.4–19.7)	0.71 (0.59–0.86)
Placebo + chemo	281	230 (81.9)	11.6 (10.1–13.7)	

No. at risk																	
Pembro + chemo	278	256	232	203	180	150	134	117	100	93	91	84	65	44	18	5	0
Placebo + chemo	281	245	210	163	137	113	100	87	83	70	62	58	42	29	14	4	0

Median follow-up = 40.1 months (range: 33.1–49.4 months). Data cutoff: September 30, 2020.

1. Robinson AG et al. Presented at ELCC Congress 2021; March 27–October 1, 2019; virtual. Abstract FP97O.

CheckMate 9LA: dizajn štúdie

- Randomized, open-label, phase III study

Stratified by PD-L1 expression (≥ 1% vs < 1%), sex, and histology (squamous vs nonsquamous)

Patients with stage IV or recurrent NSCLC, no previous systemic Tx, no sensitizing *EGFR/ALK* alterations, ECOG PS 0/1 (N = 719)

Nivo 360 mg Q3W + **Ipi** 1 mg/kg Q6W + **CT*** Q3W (2 cycles) (n = 361)

CT* Q3W (4 cycles) Optional pemetrexed maintenance (NSQ) (n = 358)

Until PD, unacceptable toxicity, or for 2 yrs for immunotherapy

*Pts with NSQ: pemetrexed + cisplatin or carboplatin; pts with SQ: paclitaxel + carboplatin.

- Primárny cieľ: OS
- Sekundárne ciele: PFS, ORR, efficacy by tumor PD-L1 expression

Reck. ASCO 2020. Abstr 9501.

Závery

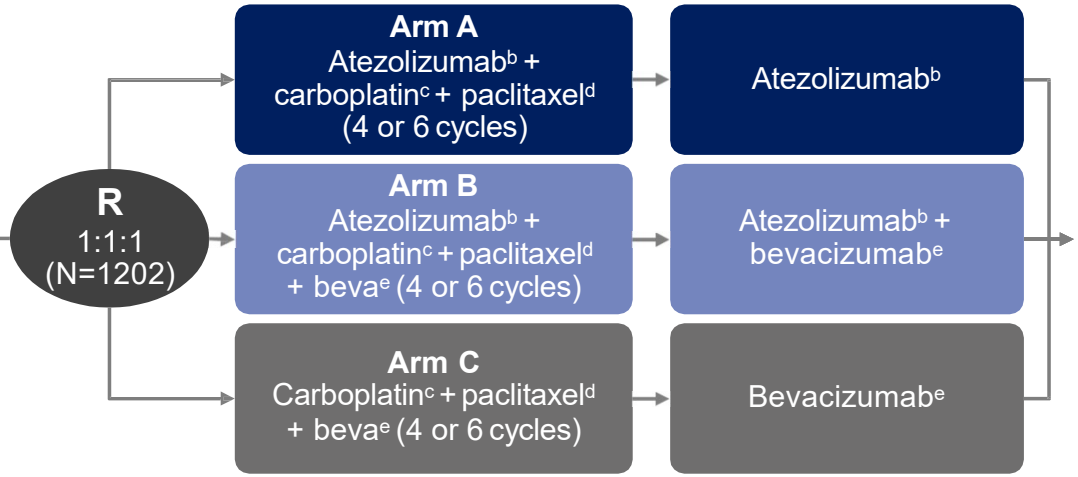
- In this analysis of patients with advanced NSCLC, OS (the primary endpoint) was improved with Nivo + Ipi + CT (2 cycles) vs CT (4 cycles) at the interim analysis (minimum FU 8.1 mos)
  - Median OS 14.1 vs 10.7 mos; HR: 0.69 (95% CI: 0.55-0.87); *P* = .0006
  - OS benefit maintained with minimum 12 mos FU; HR: 0.66
- Patients with NSCLC of NSQ or SQ histology and all levels of PD-L1 expression (including < 1% and 1-49% subpopulations) showed similar benefit with Nivo + Ipi + CT vs CT
- No new TRAEs observed with Nivo + Ipi + CT
- Investigators concluded that Nivo + Ipi + CT should be considered as a potential first-line treatment option for patients with advanced NSCLC

Reck. ASCO 2020. Abstr 9501.

IMpower150: dizajn štúdie

Key eligibility criteria

- Stage IV or recurrent metastatic, non-squamous NSCLC
- Chemotherapy-naive[a]
- Tumour tissue available for biomarker testing
- Any PD-L1 status



Stratification factors

- Sex
- PD-L1 expression
- Liver metastases

Endpoints

- Primary: PFS and OS in ITT-WT population, PFS in Teff-high-WT population
- Secondary: PFS and OS in ITT population, PFS in PD-L1 subgroups, ORR,[f] DOR,[f] safety

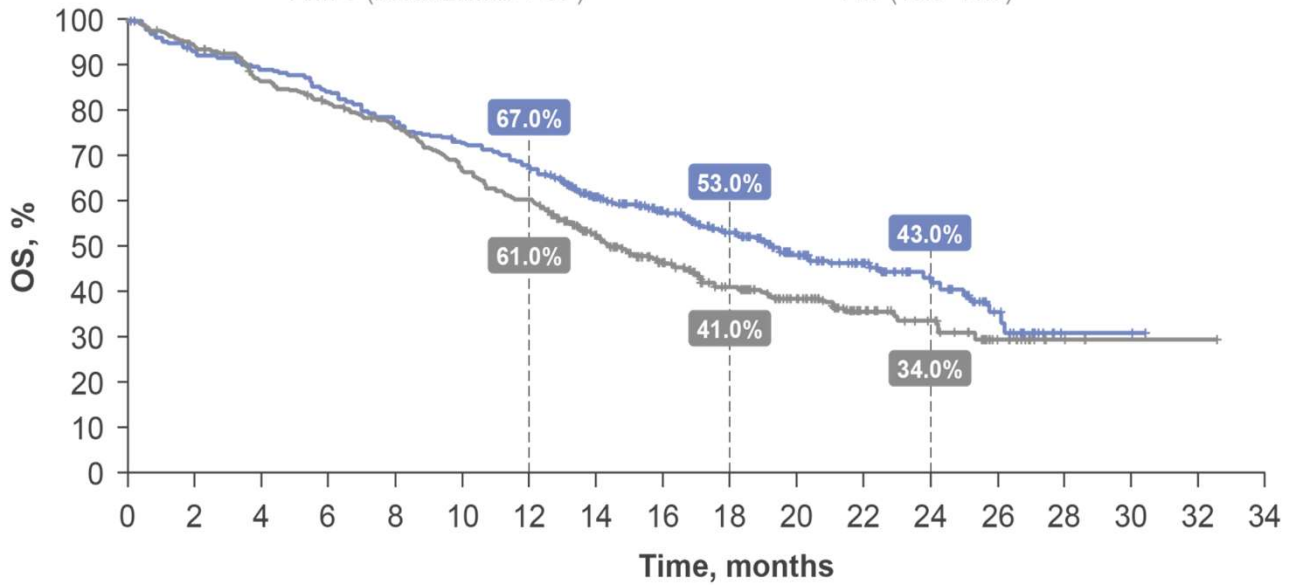
Adapted from: Socinski MA et al. ASCO 2018.

[a]Patients with a sensitising *EGFR* mutation or *ALK* translocation must have had disease progression or intolerance of treatment with ≥1 approved targeted therapies. [b]Atezolizumab 1200 mg Q3W. [c]Carboplatin AUC 6 Q3W.
[d]Paclitaxel 200 mg/m^2 Q3W. [e]Bevacizumab 15 mg/kg Q3W. [f]Per RECIST v1.1. *ALK*, anaplastic lymphoma kinase; AUC, area under the curve; Beva, bevacizumab; DOR, duration of response; *EGFR*, epidermal growth factor receptor; ITT, intention-to-treat; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-L1, programmed death ligand-1; PFS, progression-free survival; Q3W, every 3 weeks; R, randomised; RECIST v1.1, Response Evaluation Criteria in Solid Tumors Version 1.1; Teff, T-effector; WT, wild-type.
Socinski MA et al. Presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting, 1–5 June, 2018, Chicago, USA.

IMpower150: OS in the ITT-WT population (Arm B vs. Arm C)

Median follow up: ~20 months

Treatment arm	Median (95% CI), months	HR[a] (95% CI)	p value
Arm B (atezolizumab + bevacizumab + CP)	19.2 (17.0–23.8)	0.78 (0.64–0.96)	0.0164
Arm C (bevacizumab + CP)	14.7 (13.3–16.9)	—	—



No. at risk

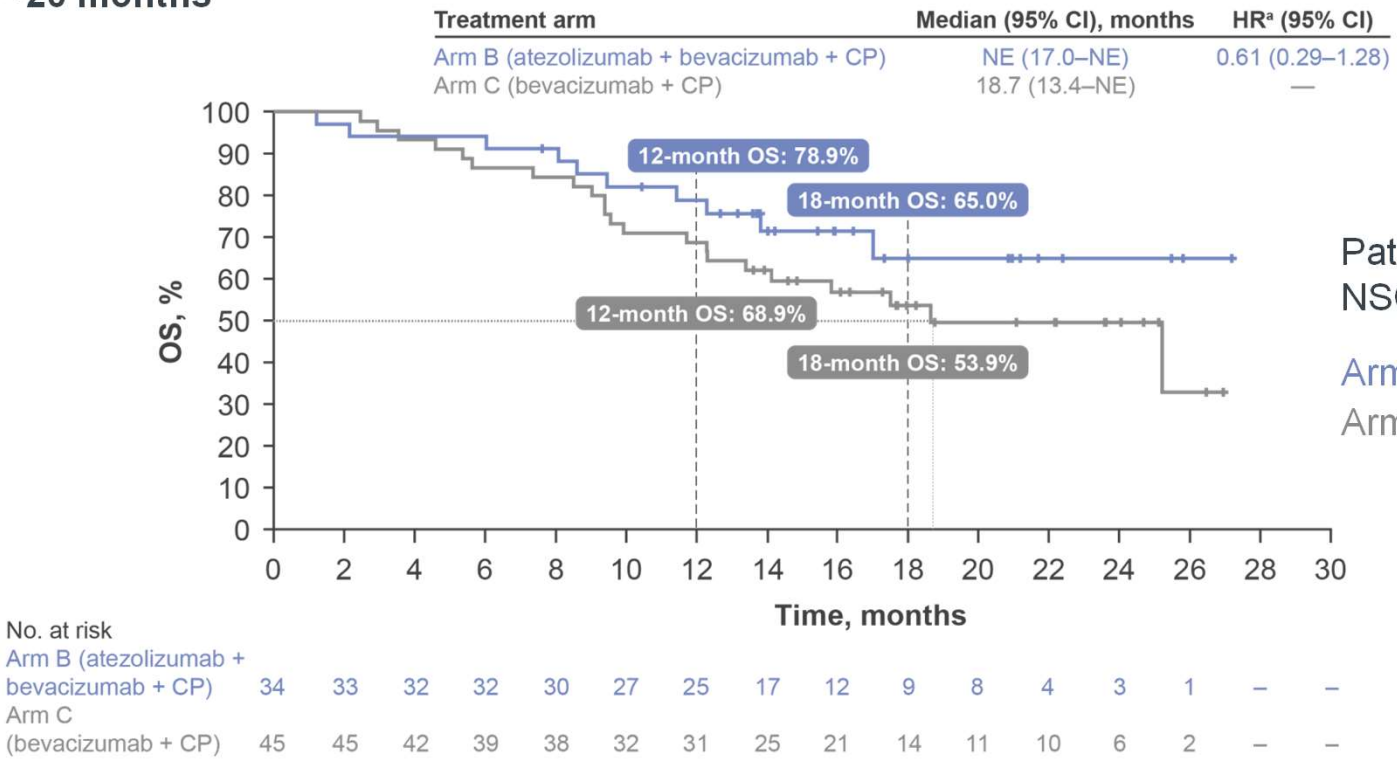
Arm B (atezolizumab + bevacizumab + CP)	359	328	314	296	273	256	235	188	147	119	84	57	34	16	2	2	–	–
Arm C (bevacizumab + CP)	337	315	287	268	247	216	196	152	115	87	66	40	29	13	3	1	1	–

Adapted from: Socinski MA et al. ASCO 2018.

Analysis cut-off date: 22 January 2018.
[a]Stratified HR.
CI, confidence interval; CP, carboplatin + paclitaxel; HR, hazard ratio; ITT, intention-to-treat; NE, not estimable; NSCLC, non-small cell lung cancer; OS, overall survival.
Socinski MA et al. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, 1–5 June, 2018, Chicago, USA.

IMpower150: OS u pacientov s *EGFR*-positive NSCLC (Arm B vs. Arm C)

Median follow up: ~20 months



Patients with *EGFR*-positive NSCLC, n (% of ITT)

Arm B[b]: 34 (9)

Arm C: 45 (11)

Adapted from: Reck M et al. Lancet Respir Med 2019.

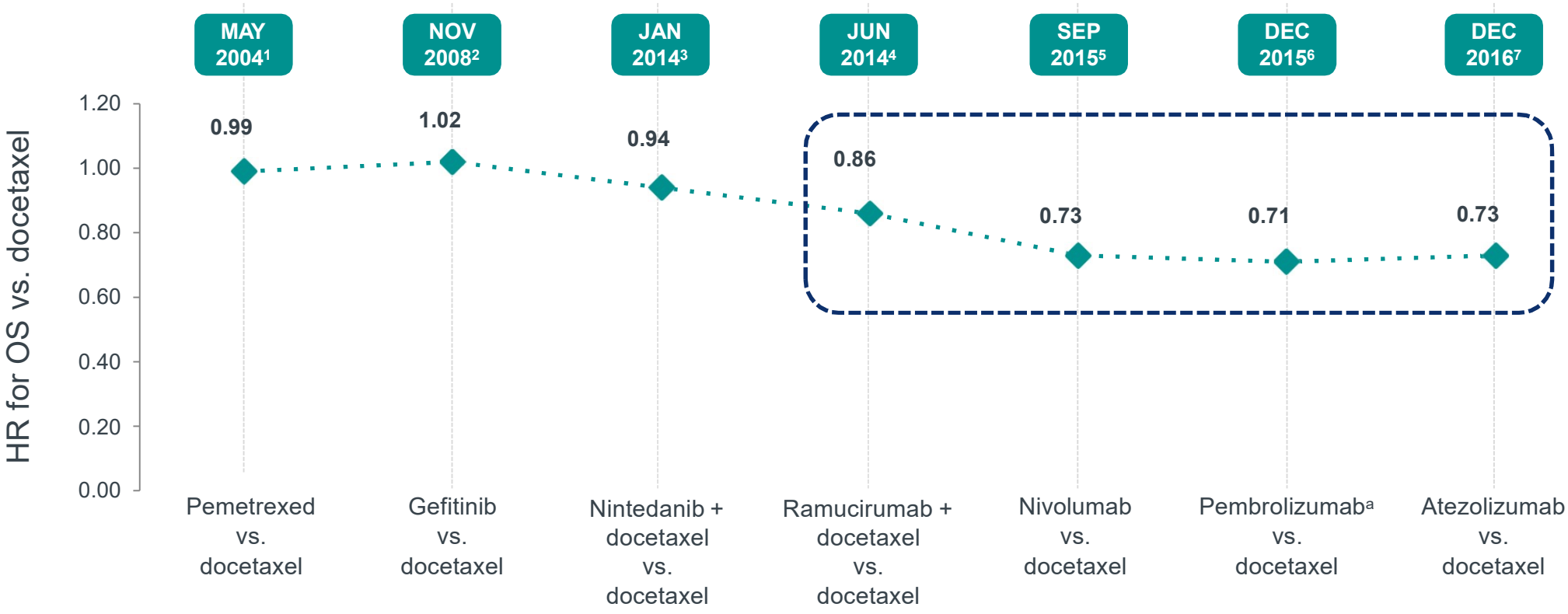
Analysis cut-off date: 22 January 2018.

[a]Unstratified HR. [b]One patient in Arm B (atezolizumab + bevacizumab + CP) had an *EGFR* exon 19 deletion and also tested *ALK*-positive per central laboratory testing.

ALK, anaplastic lymphoma kinase; CI, confidence interval; CP, carboplatin + paclitaxel; *EGFR*, epidermal growth factor receptor; HR, hazard ratio; ITT, intention-to-treat; NE, not estimable; NSCLC, non-small cell lung cancer; OS, overall survival.

Reck M et al. *Lancet Respir Med* 2019;7:387–401.

Druholíniová liečba IO významne zlepšila OS pri NSCLC v porovnaní s docetaxelom

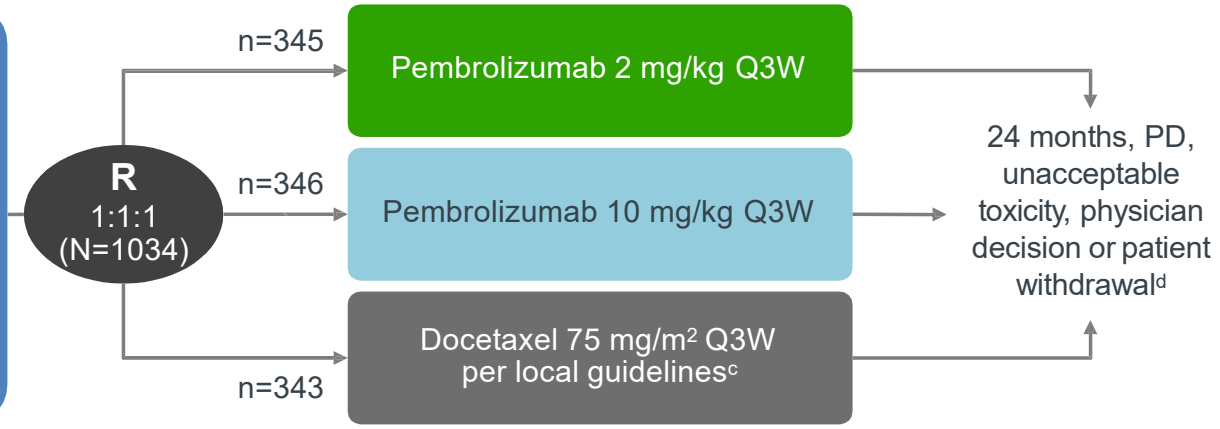


[a]2 mg/kg dose.
HR, hazard ratio; IO, immuno-oncology; NSCLC, non-small cell lung cancer; OS. overall survival.
1. Hanna N et al. *J Clin Oncol* 2004;22:1589–1597; 2. Kim ES et al. *Lancet* 2008;372:1809–1818; 3. Reck M et al. *Lancet Oncol* 2014;15:143–155; 4. Garon EB et al. *Lancet* 2014;384:665–673;
5. Borghaei H et al. *N Engl J Med* 2015;373:1627–1639; 6. Herbst RS et al. *Lancet* 2016;387:1540–1550; 7. Rittmeyer A et al. *Lancet* 2017;389:255–265.

KEYNOTE-010: dizajn štúdie

Key eligibility criteria

- Advanced NSCLC
- Confirmed PD after ≥1 line of chemotherapy[a]
- No active brain metastases
- ECOG PS 0–1
- PD-L1 TPS ≥1%
- No active autoimmune disease
- No ILD or pneumonitis requiring systemic steroids



Stratification factors

- ECOG PS (0 vs. 1)
- Region (East Asia vs. non-East Asia)
- PD-L1 expression[b] (TPS ≥50% vs. 1–49%)

Endpoints

- Primary: OS, PFS
- Secondary: ORR, DOR, safety

Adapted from: Herbst RS et al. Lancet 2016.

[a]Prior therapy must have included ≥2 cycles of platinum-doublet chemotherapy. An appropriate tyrosine kinase inhibitor was required for patients whose tumours had an *EGFR*-sensitising mutation or an *ALK* translocation. [b]Added after 441 patients enrolled based on results from KEYNOTE-001.[2] [c]Patients received the maximum number of cycles permitted by the local regulatory authority. [d]Or other reasons.

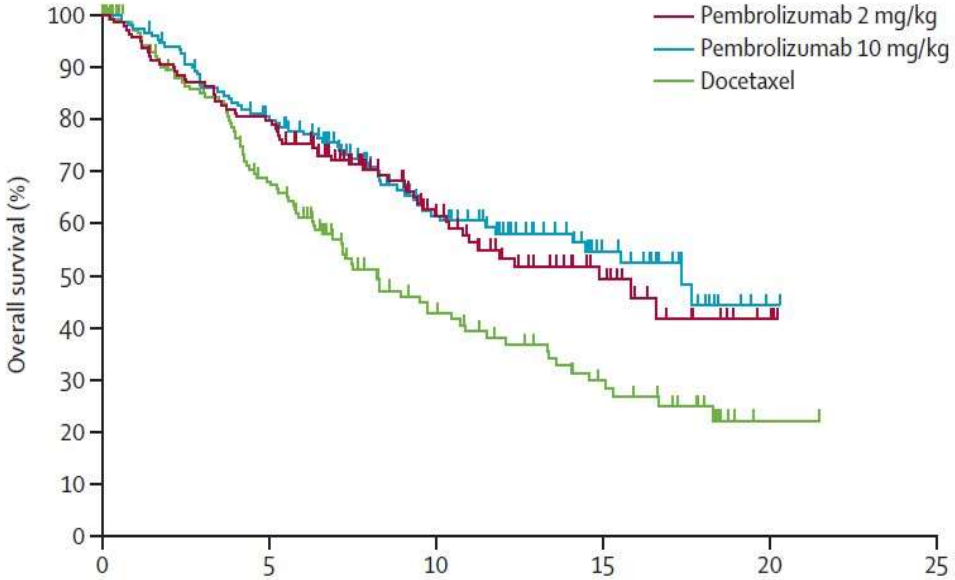
ALK, anaplastic lymphoma kinase; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; *EGFR*, epidermal growth factor receptor; ILD, interstitial lung disease; IV, intravenous; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD, progression of disease; PD-L1, programmed death ligand-1; PFS, progression-free survival; Q3W, every 3 weeks; R, randomised; TPS, tumour proportion score.

1. Herbst RS et al. *Lancet* 2016;387:1540–1550 (and supplementary appendix); 2. Garon EB et al. *N Engl J Med* 2015;372:2018–2028.

KEYNOTE-010: OS (original analysis)

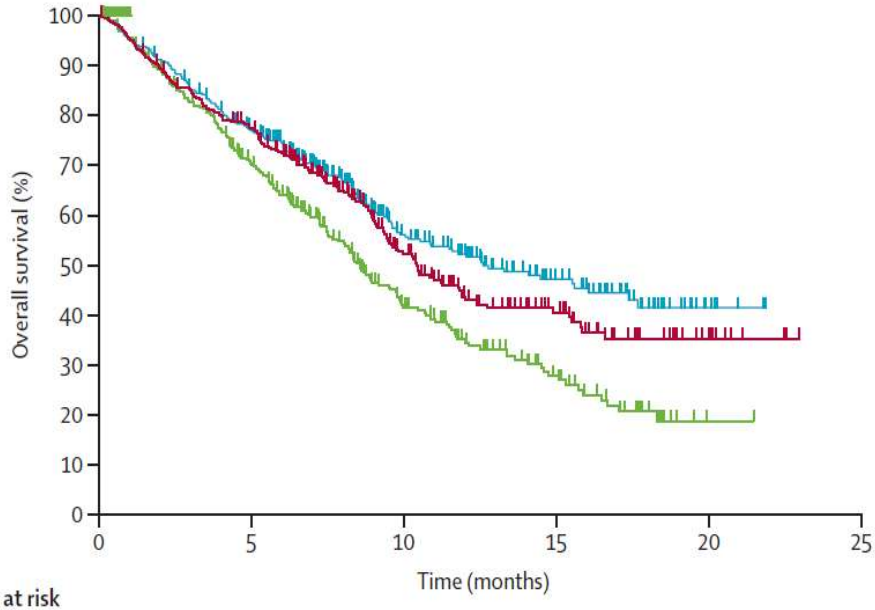
Median follow up: 13.1 months

PD-L1 TPS ≥50%



Number at risk						
Pembrolizumab 2 mg/kg	139	110	51	20	3	0
Pembrolizumab 10 mg/kg	151	115	60	25	1	0
Docetaxel	152	90	38	19	1	0

Všetci pacienti



Number at risk						
Pembrolizumab 2 mg/kg	344	259	115	49	12	0
Pembrolizumab 10 mg/kg	346	255	124	56	6	0
Docetaxel	343	212	79	33	1	0

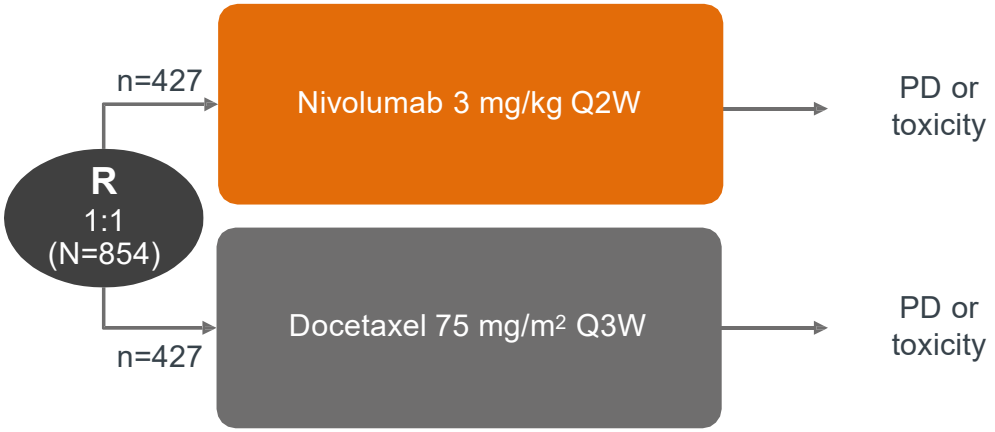
Adapted from: Herbst RS et al. Lancet 2016.

Analysis cut-off date: 30 September 2015.
OS, overall survival; PD-L1, programmed death ligand-1; TPS, tumour proportion score.
Herbst RS et al. *Lancet* 2016;387:1540–1550.

CheckMate-017 a CheckMate-057: dizajn štúdie[1,2]

Key eligibility criteria

- Stage IIIB/IV NSCLC
  - Squamous NSCLC (CM-017, N=272)
  - Non-squamous NSCLC (CM-057, N=582)
- Pretreatment (archival or recent) tumour samples available for retrospective PD-L1 testing
- ECOG PS 0–1
- Failed one prior platinum doublet



Stratification factors

- Prior maintenance therapy
- Line of therapy (second vs. third)

Endpoints

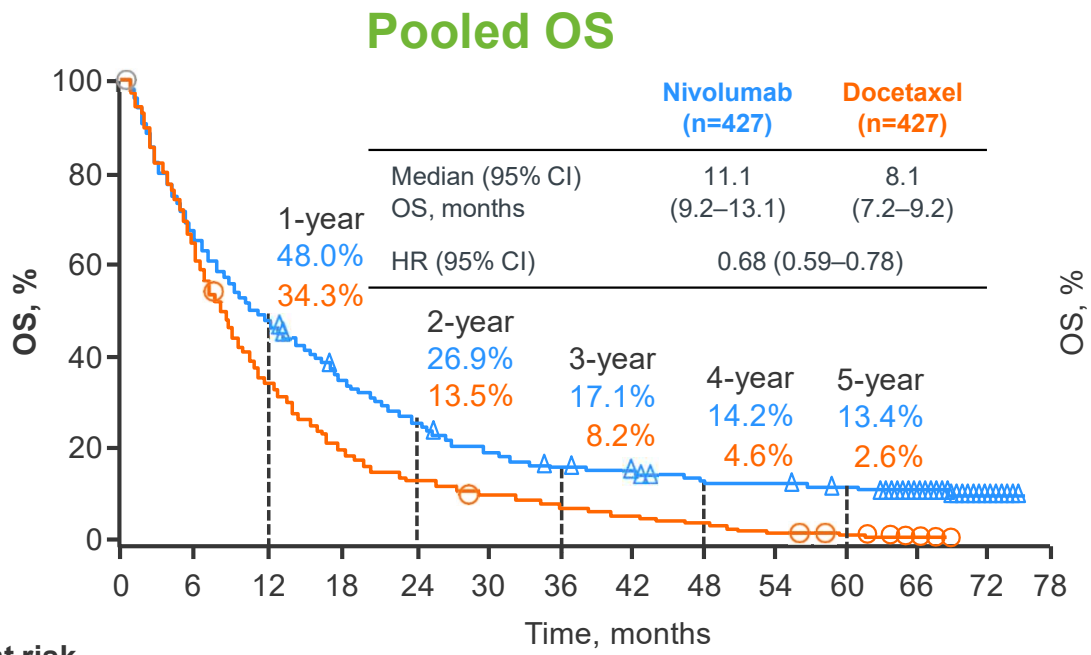
- Primary: OS
- Secondary: ORR, PFS, efficacy by PD-L1 expression, safety, QoL

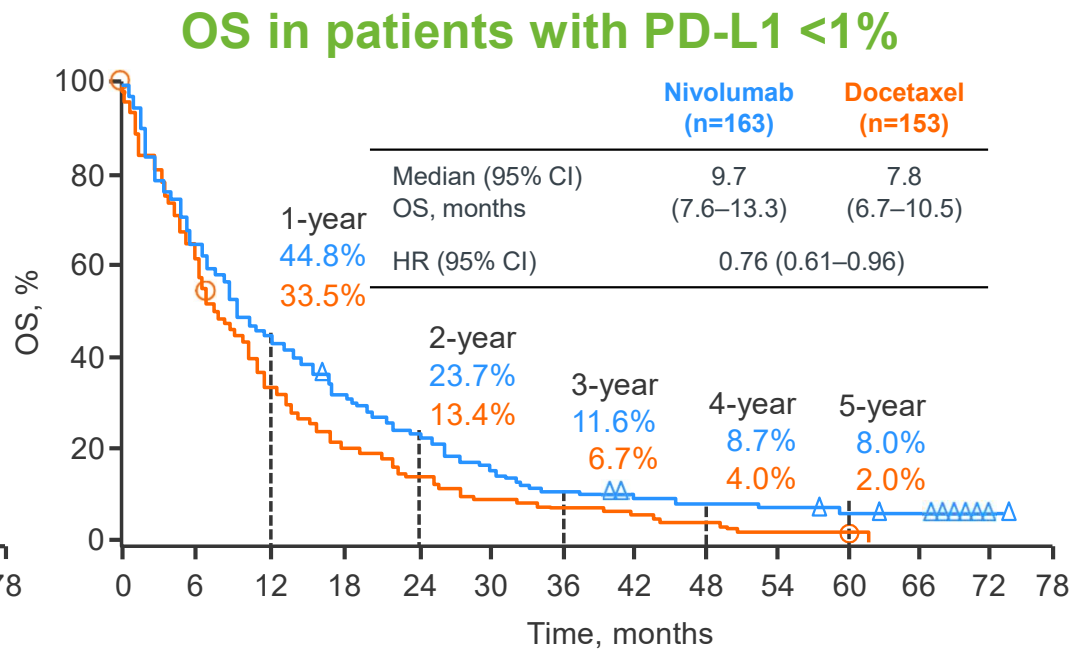
Adapted from: Borghaei H et al. N Engl J Med 2015; Brahmer J et al. N Engl J Med 2015.

ECOG PS, Eastern Cooperative Oncology Group performance status; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-L1, programmed death ligand 1; PFS, progression-free survival; R, randomised; Q2W, every 2 weeks; Q3W, every 3 weeks; QoL, quality of life.

1. Borghaei H et al. *N Engl J Med* 2015;373:1627–1639; 2. Brahmer J et al. *N Engl J Med* 2015;373:123–135.

CheckMate-017 a CheckMate-057: 5-ročné OS (updated analysis)





No. at risk

Nivolumab	427	280	205	150	113	84	70	64	55	54	50	30	6	0
Docetaxel	427	264	145	84	57	45	34	26	19	12	9	4	0	0

Nivolumab	163	105	73	52	38	27	18	15	12	11	10	8	3	0
Docetaxel	153	95	50	31	20	13	10	9	6	3	3	0	0	0

Adapted from: Gettinger S et al. WCLC 2019.

CI, confidence interval; HR, hazard ratio; OS, overall survival; PD-L1, programmed death ligand-1.
Gettinger S et al. Presented at the IASLC 2019 WCLC World Conference on Lung Cancer, 7–10 September, 2019, Barcelona, Spain.

CheckMate-017 and CheckMate-057: 5-ročné PFS a DOR (updated analysis)

	PFS		DOR	
%[a]	Nivolumab (n=427)	Docetaxel (n=427)	Nivolumab (n=84)	Docetaxel (n=48)
Median (95% CI), months	2.5 (2.2–3.5)	3.5 (3.1–4.3)	19.9 (11.4–30.8)	5.6 (4.4–7.0)
HR (95% CI)	0.79 (0.68–0.92)		–	
1-year rate	19.7	8.9	60.3	15.2
2-year rate	13.4	2.1	48.6	5.1
3-year rate	10.2	0.5	38.6	0
4-year rate	9.1	0	35.5	0
5-year rate	8.0	0	32.2	0

- Grade 3–4 TRAEs occurred in 45 (11%) patients receiving nivolumab

Conclusion

- In patients with advanced NSCLC, nivolumab demonstrated durable survival benefits and displayed an acceptable tolerability profile

[a]Unless stated otherwise.

CI, confidence interval; DOR, duration of response; HR, hazard ratio; NSCLC, non-small cell lung cancer; PFS, progression-free survival; TRAE, treatment-related adverse event.

Gettinger S et al. Presented at the IASLC 2019 WCLC World Conference on Lung Cancer, 7–10 September, 2019, Barcelona, Spain.

- Otázka :
- Ako môžeme my pneumológovia prispieť ku kvalitnej onkologickej liečbe ?

- Jednoznačná odpoveď :
- Kvalitnou a rýchlou diagnostikou podloženou odbornými znalosťami

Prehľad bronchoskopických pracovísk na Slovensku

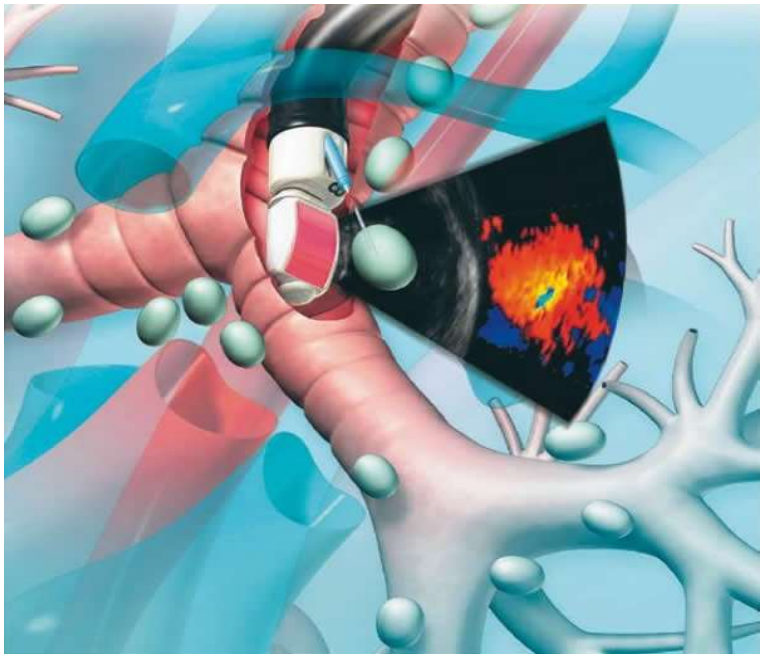
Bojnice, Humenné, Košice, Lučenec,

Michalovce,Nové Mesto nad Váhom, ,

NovéZámky, Považská Bystrica, Ružomberok,

Trebišov, Trenčín, Trnava,

Banská Bystrica, Bratislava, Martin, Nitra, Vyšné Hágy



Registrované indikácie imunoterapie pri karcinóme pľúc

Nemalobunkový karcinóm pľúc

III. klinické štádium (neresekabilné po chemo-rádioterapii) – durvalumab

IV. klinické štádium – atezolizumab, pembrolizumab, nivolumab

Malobunkový karcinóm pľúc

IV. klinické štádium - atezolizumab

Svet vs SR – postavenie imunoterapie

- **Svet /Európa** jasne stanovené pravidlá - NCCN , EMA

- **SR**
- VšZP - do prvej línie metastazujúceho ochorenia ak PDL 1 je viac ako 50 % , u iných nie ,pacient nesmie absolvovať ani jeden cyklus chemoterapie - potreba rýchlej diagnostiky !!!
- Dôvera - do druhej línie u lokálne pokročilého a metastazujúceho ochorenia / momentálne neschvaľuje nič/
- UNION - po vyčerpaní všetkých možností liečby

Ďakujem za pozornosť