SYSTÉMOVÁ LIEČBA POKROČILÉHO SPINOCELULÁRNEHO KARCINÓMU KOŽE

I. Andrašina

LF UPJŠ, VOU a.s. Košice

Košice, 13.10. 2020

Vyhlásenie o konflikte záujmov autora

x Nemám potenciálny konflikt záujmov

☐ Deklarujem nasledujúci konflikt záujmov

Forma finančného prepojenia	Spoločnosť
Participácia na klinických štúdiách/firemnom grante	
Nepeňažné plnenie (v zmysle zákona)	
Prednášajúci	
Akcionár	
Konzultant/odborný poradca	
Ostatné príjmy (špecifikovať)	

Podľa UEMS (upravené v zmysle slovenskej legislatívy

Prezentácia je podporená spoločnosťou sanofi-aventis Slovakia s.r.o.

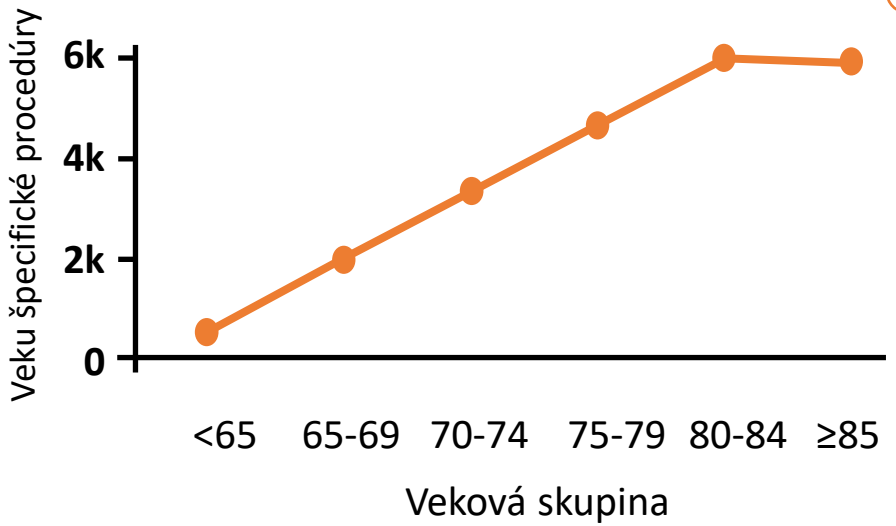
CSCC Epidemiológia

Karcinómy kože predstavujú najčastejší nádor vôbec

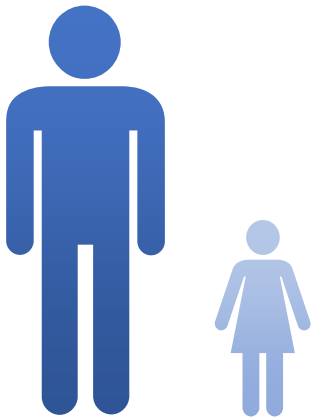
CSCC je druhý najčastejší po BCC

1 CSCC / 4 BCC

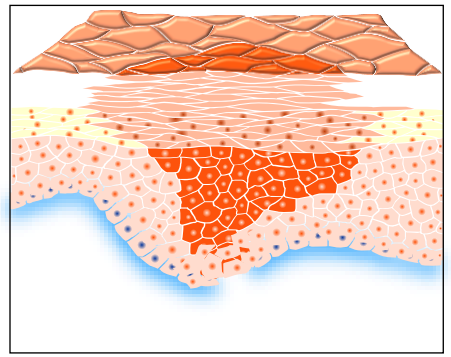
Priemerný vek je 70 rokov



Muži vs ženy incidencia 3:1



Často začína ako prekancerózna lézia

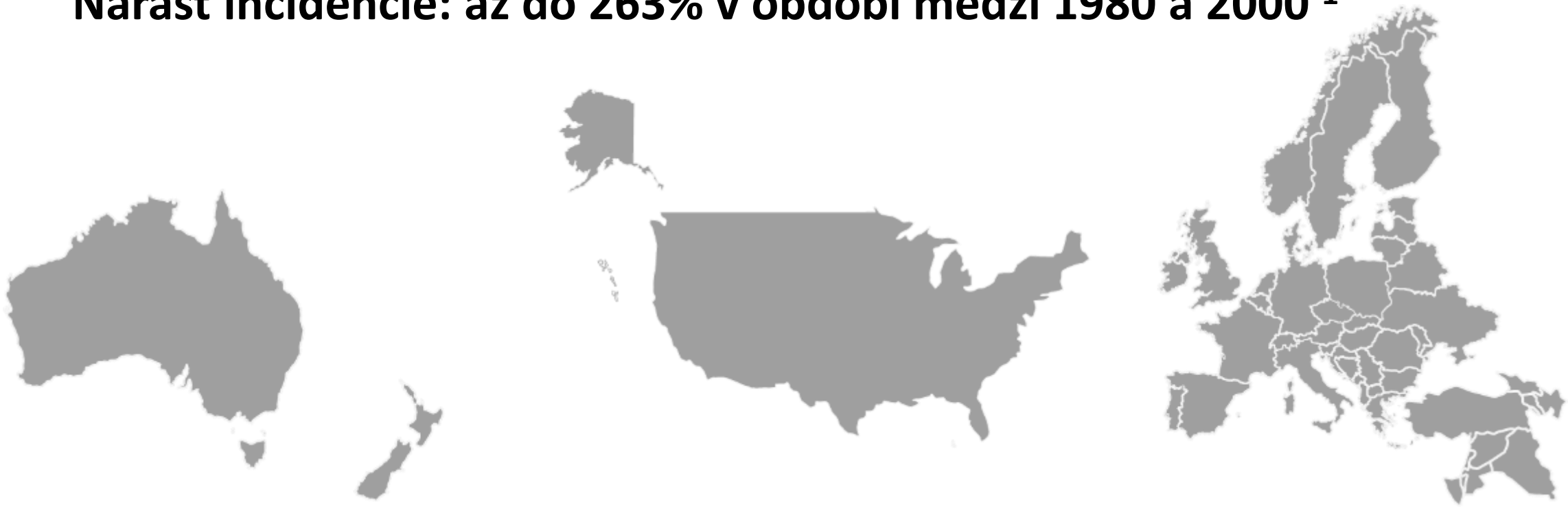


BCC, basal cell carcinoma; CSCC, cutaneous squamous cell carcinoma

Que SKT, et al. *J Am Acad Dermatol*. 2018;78:249-26118.

Incidencia CSCC

Nárast incidencie: až do 263% v období medzi 1980 a 2000 [1]



2012: ≤ 499/100,000 ľudí [2]
(2011: 2/100,000 mortalita)

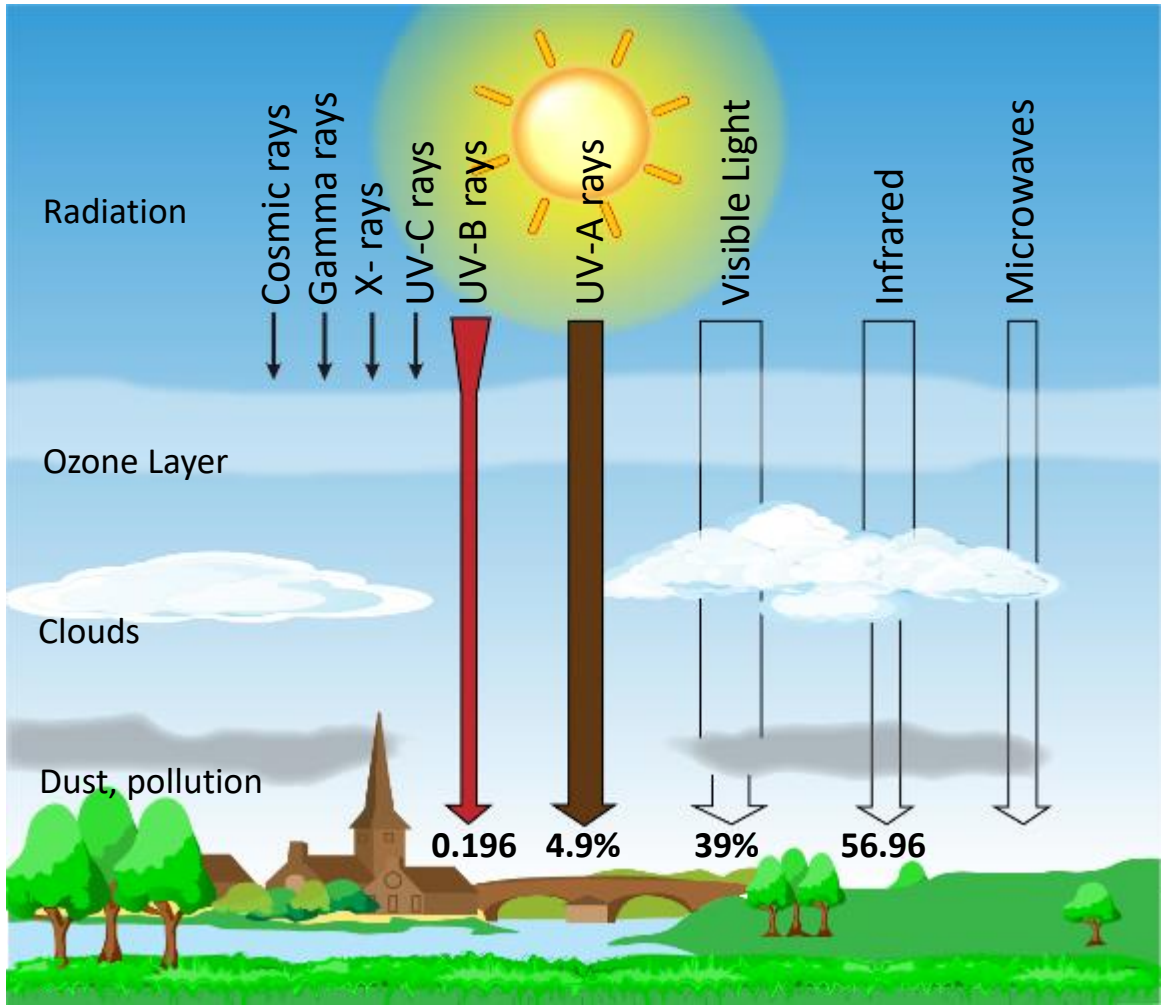
2012: 15 - 233.3/100,000 ľudí [3]
2012 est: 4 do 8k ročná mortalita [2]

5 - 96/100,000 ľudí [2]

1. Muzic JG, et al. *Mayo Clin Proc.* 2017;92:890-898; 2. Que SKT, et al. *J Am Acad Dermatol*. 2018;78:249-26118;
3. Karia PS, et al. *J Am Acad Dermatol*. 2013;68:957-66.

Rizikové faktory asociované so vznikom CSCC

- UV žiarenie: priame a umelé s kumulatívnou dávkou
- Ionizujúce žiarenie
- Chemické karcinogény: arzén a ďalšie …..
- Imunosupresívny status:
  - transplantovaní pacienti +++
  - hematologické komorbidity
- Zle hojace sa rany, ulcerácie



UV, ultraviolet

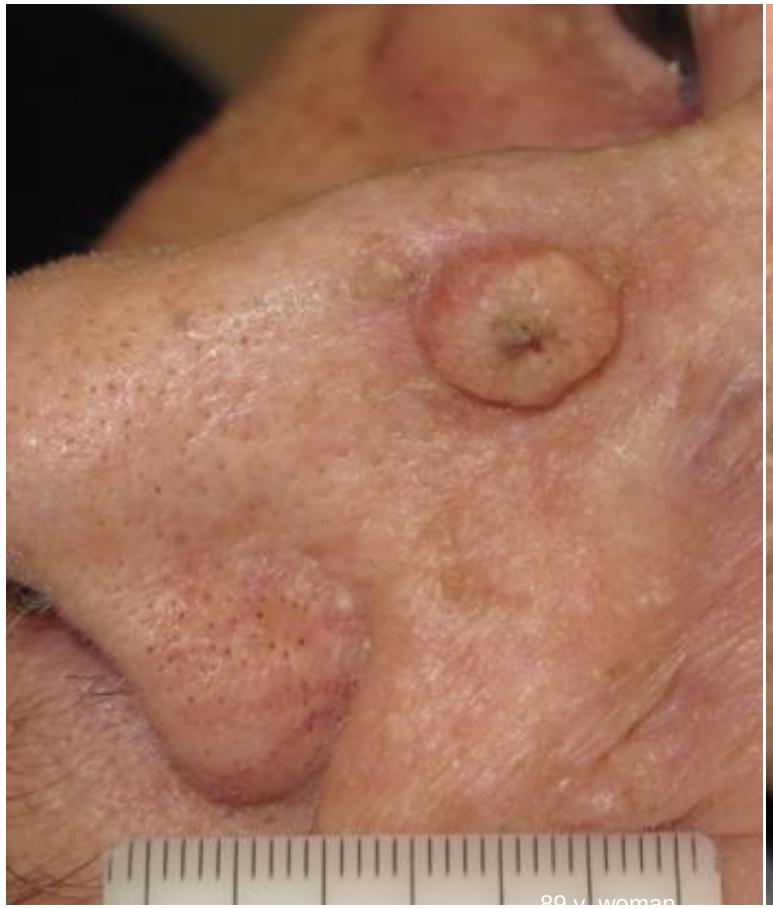
Schmults C.D. editor. High-Risk Cutaneous Squamous Cell Carcinoma. Springer-Verlag Berlin Heidelberg 2016.

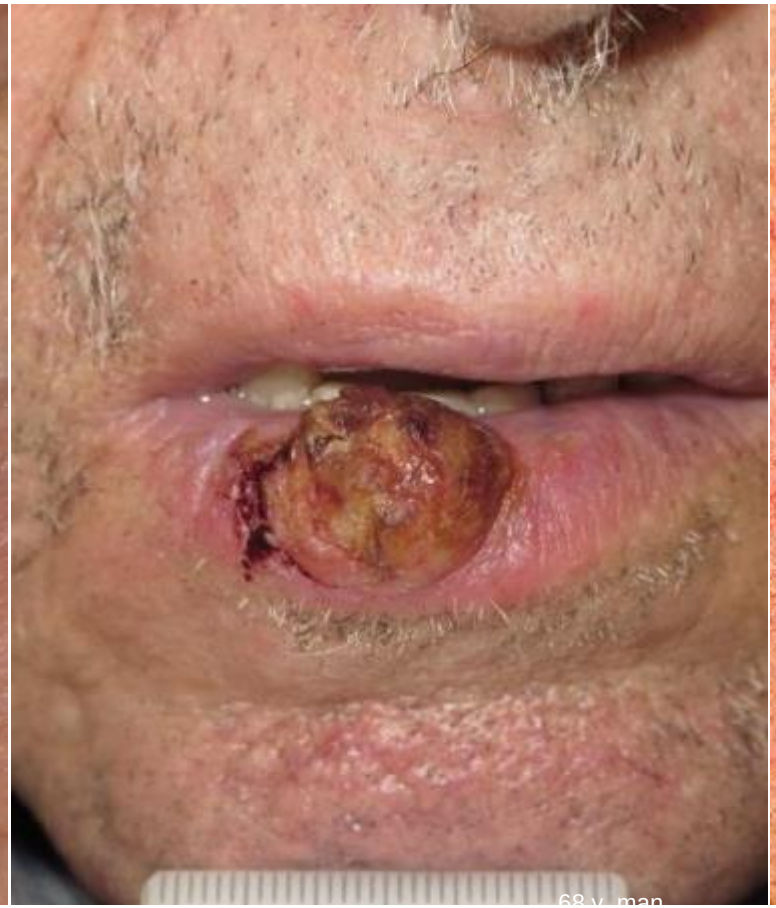
Vysoké vs nízke - rizikové črty vzniku CSCC

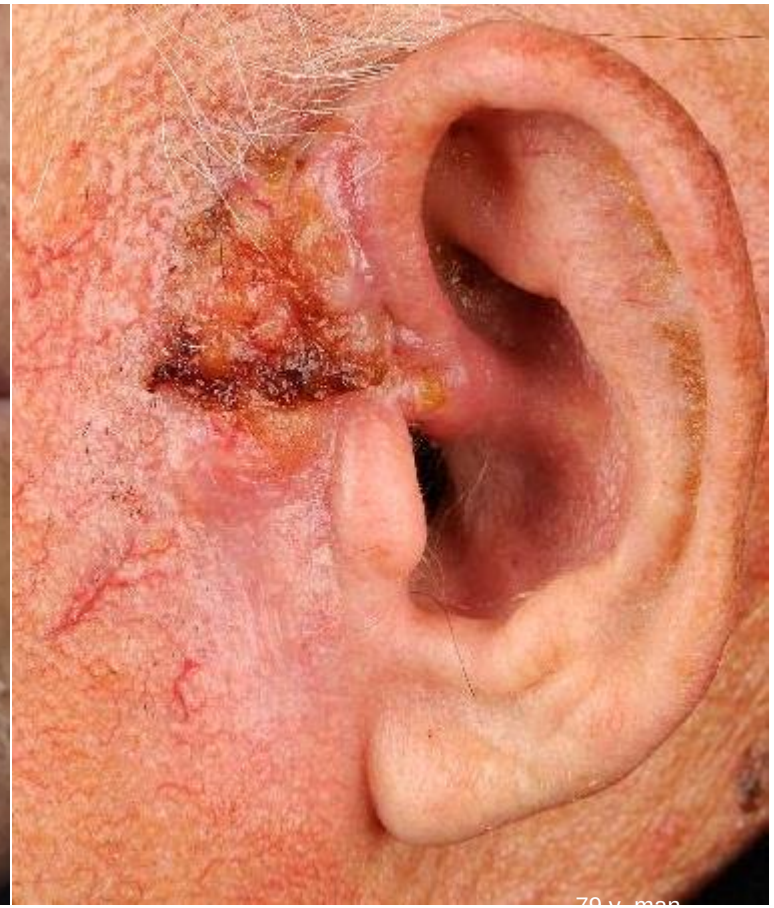
Klinické črty	Nízke riziko	Vysoké riziko
Lokalizácia	Trup a končatiny < 20mm Hlava/krk < 10 mm Periorificiálne zóny: nie	Trup a končatiny > 20mm Hlava/krk > 10mm Periorificiálne zóny: áno
Okraje	Dobre definované	Zle definované
Nádor	Primárny	Rekurentný
Imunosupresia	Nie	Áno
Predošlá rádioterapia alebo chronický zápal	Nie	Áno
Rýchlo rastúci nádor	Nie	Áno
Neurologické symptómy	Nie	Áno
Histopatologické črty	**Nízke riziko**	**Vysoké riziko**
Stupeň diferenciácie	Dobre/stredne diferencovaný	Nízko diferencovaný
Akantolytický, adenoskvamózny, desmoplastický, metaplastický subtyp	Nie	Áno
Hĺbka: hrúbka a stupeň invázie	≤ 6 mm resp. žiadna invázia ďalej ako do podkožného tuku	> 6 mm resp. prítomná invázia ďalej ako do podkožného tuku
Perineurálna, lymfatická invázia	Nie	Áno

NCCN Guidelines. V2.2019. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf Accessed June 2, 2019.

Prognostická klasifikácia CSCC







Photos provided by Dr. Iris Zalaudek. Patients granted permission

Nízke riziko

Primárny nádor, dobre diferencovaný, vystavený slnku (okrem uší a pier)

Vysoké riziko

Rekurentný nádor, priemer > 2cm, periorificiálne zóny, Imunosupresia

Vysoké riziko

Zle diferencovaný, akantolytický, desmoplastický, adenoskvamózny, perineurálna invázia

TNM klasifikácia podľa - AJCC 8 Edition 2018

	T Category		N Category
TX	Primary tumor not assessable	**Nx**	Nodal lymphnodes not assessable
T0	Unknown primary tumor	**N0**	Absence of metastatic lymphnodes
Tis	Carcinoma in situ	**N1**	Single metastatic node with diameter ≤ 3 cm
T1	Primary tumor with a horizontal diameter of < 2 cm	**N2**	Single ipsilateral node with diameter > 3 cm but ≤ 6 cm; or multiple ipsilateral nodes with a max. diameter of ≤ 6 cm
T2	Primary tumor with a horizontal diameter of ≥ 2 cm and < 4 cm without associated risk factors	**N3**	Metastatic nodes > 6 cm
T3	Primary tumor with a horizontal diameter of ≥ 4 cm a/o at least 1 risk factor (bone erosion, perineurial invasion, infiltration beyond subcutaneous fat)		**M Category**
T4a	Primary tumor with cortical or medulla infiltration	**M0**	Absence of distant metastases
T4b	Primary tumor with skull base invasion and/or skull base foramen involvement	**M1**	Presence of distant metastases incl. contralateral nodes metastases

Amin MB, et al. (Eds.). *AJCC Cancer Staging Manual (8th edition).* Springer International Publishing: American Joint Commission on Cancer; 2017.

European Journal of Cancer 96 (2018) 34–43

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.ejcancer.com

To date there is **no standard of care** for patients with locally advanced a/o metastatic cutaneous squamous cell carcinoma

Hillen U, et al. *Eur J Cancer*. 2018; 96:34-43.

Možnosti systémovej liečby u pokročilého CSCC

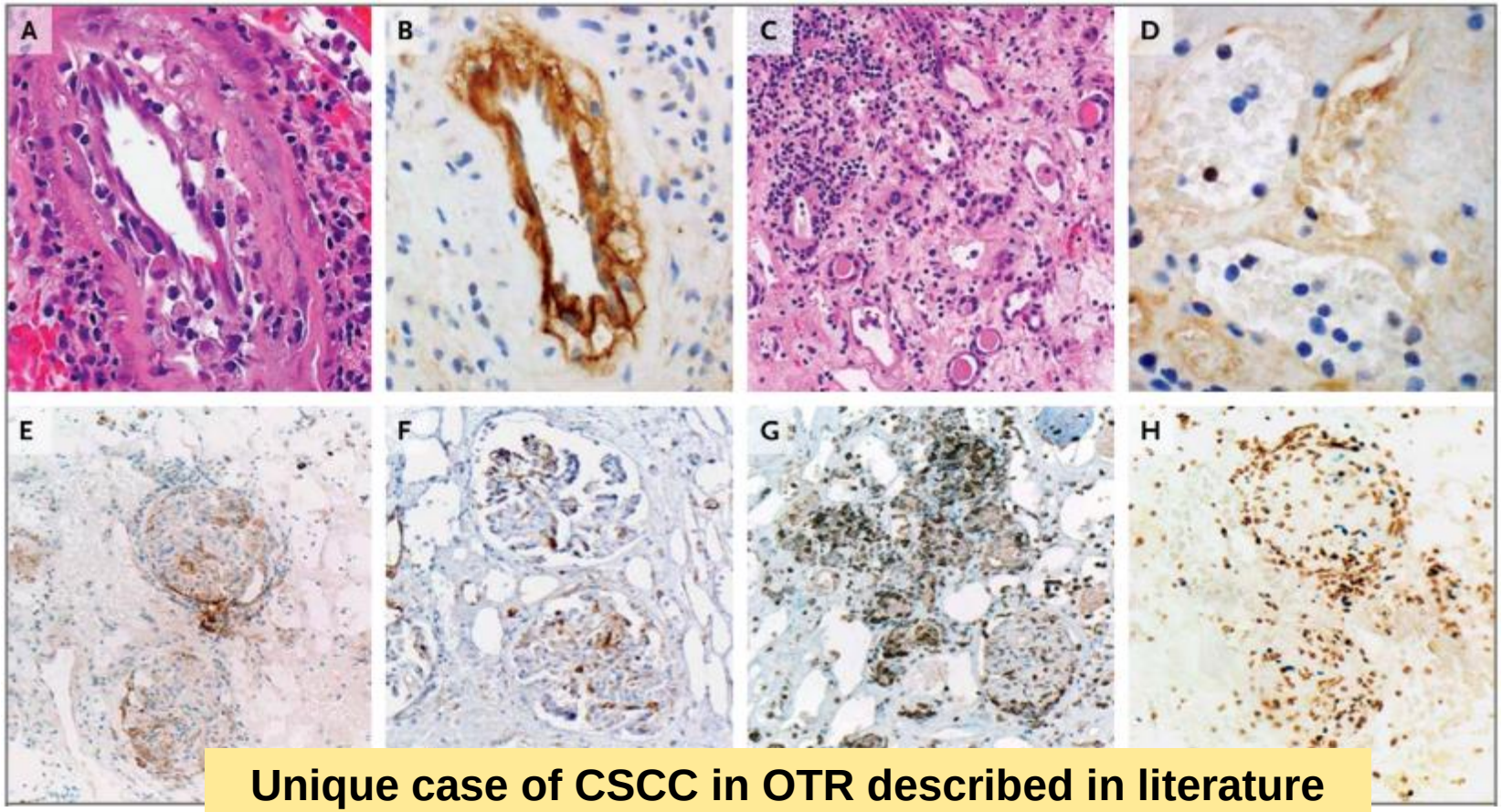
- **Chemoterapia**
  - chemo-rádioterapia: na báze platiny
  - elektrochemoterapia
- **Anti-EGFR**
  - lapatinib
  - cetuximab
  - gefitinib/erlotinib
- **Imunoterapia**: anti-PD1
  - cemiplimab
  - pembrolizumab
- → Pacienti po orgánových transplantáciach ?

1. Nottage M, et al. *Head and Neck.* 2017;39:679-683; 2. Di Monta G, et al. *J of Transl Med.* 2017; 15:82;
3. Jenni D, et al. *ESMO Open.* 2015; 1:e000003; 4. Dereure O, et al. *Dermatology.* 2016; 323:721-730;
5. Stratigos A, et al. *Eur J Cancer*. 2015;51:1989-2007; 6. Migden M, et al. *N Engl J Med*. 2018; 379:341-351;
7. Degache E, et al. *J Eur Acad Dermatol Venereol.* 2018;32:e257-e258.

Tumor Regression and Allograft Rejection after Administration of Anti–PD-1

TO THE EDITOR: Although antibodies against the programmed death 1 (PD-1) receptor and one of its ligands (PD-L1) have produced tumor regressions in multiple cancer types, these therapies are untested in patients treated with long-term immunosuppressive medications.[1] Here, we re-

N ENGL J MED 374;9 NEJM.ORG MARCH 3, 2016



Unique case of CSCC in OTR described in literature

Lipson E, et al. *N Enlg J Med*. 2016; 374:896-898.

Najčastejšie používané preparáty na liečbu CSCC

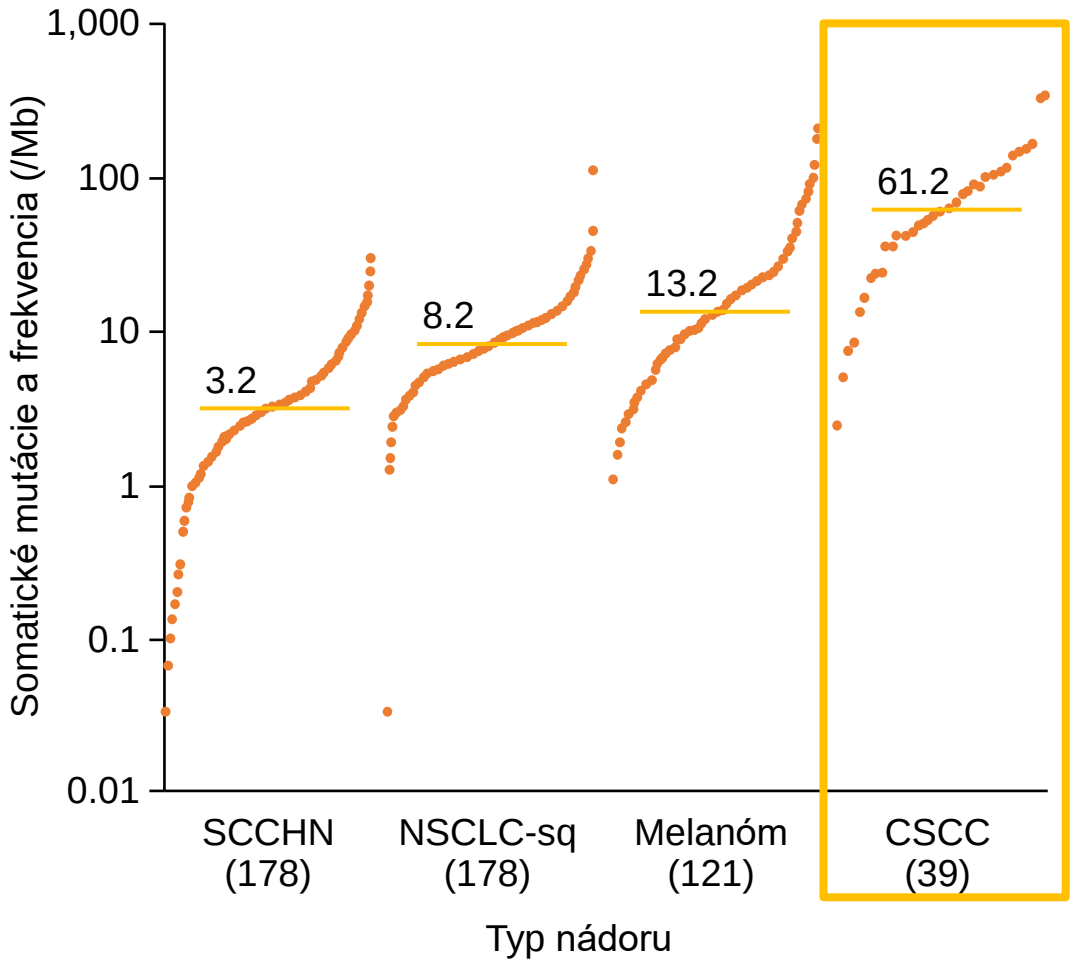
V monoterapii alebo kombinácii, ak chirurgická liečba a rádioterapia už nie je indikovaná

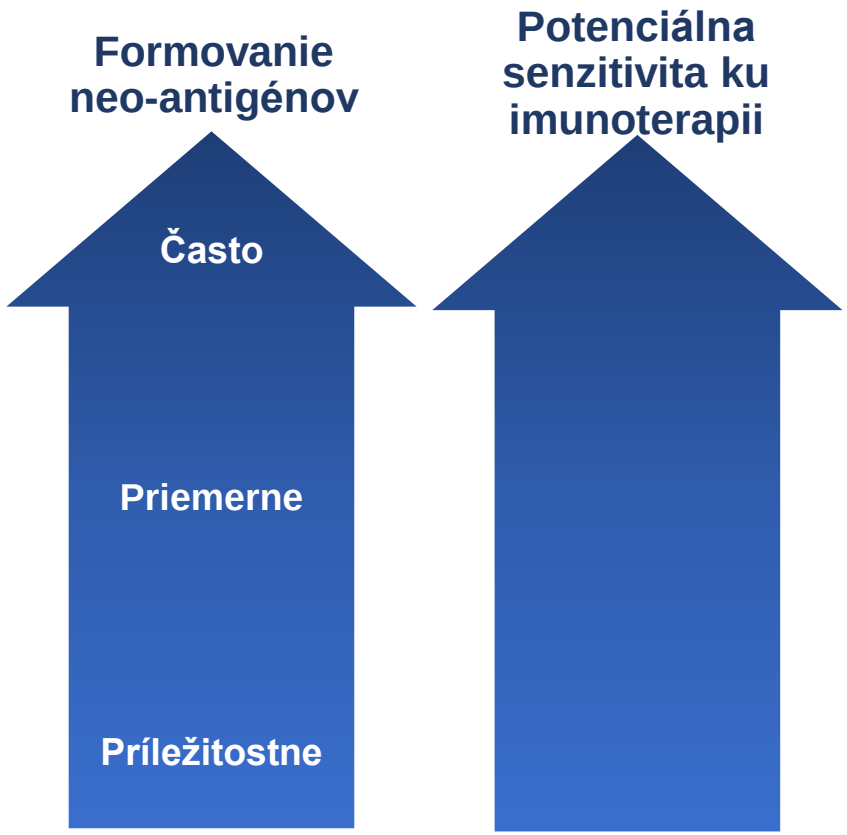
Chemoterapia
Platinové preparáty
Taxány
5-FU
Capecitabín

Anti EGFR-preparáty
Cetuximab
Erlotinib
Gefitinib
Panitumumab

NCCN Guidelines. V2.2018. https://www.nccn.org/professionals/physician_gls/pdf/squamous.pdf. Accessed 29 Aug 2018.

„Tumor Mutation Burden„ u CSCC





Red horizontal line and associated number in figurer = median mutations per MB.
CSCC, cutaneous squamous cell carcinoma; NSCLC, sq - lung squamous cell carcinoma; Mb, megabase of DNA; SCCHN, Squamous cell carcinoma of the head and neck.
Pickering CR, et al. *Clin Cancer Res*. 2014;20:6582–6592.

Racionale pre použitie IO u CSCC

- Vysoká miera ,,tumor mutation burden (TMB) a imunogénne mikroprostredie
  - vysoká miera TMB prispieva k tvorbe neo-antigénov, ktoré zvyšujú antigenicitu[1]
- Imunosupresia je dobre definovaný rizikový faktor pre vznik CSCC (hlavne po orgánových transplantáciach) [2]
- PD-L1 expresia často prítomná vo vysokej miere [3]

1. Pickering CR, et al. *Clin Cancer Res*. 2014;20:6582-92; 2. Euvrard E, et al. *N Engl J Med*. 2003;348:1681-1691. 3. Slater NA, et al. *J Cutan Pathol*. 2016;43:663-70.

Pacienti vhodní na imunoterapiu s pokročilým CSCC

- Pacienti s pokročilým ochorením
- Lokálne pokročilý a metastatický nádor
- Pacienti, ktorí došli k progresii po chirurgickej liečbe
- Pacienti, ktorí nie sú kandidáti na chirurgickú liečbu z rôznych dôvodov, komorbidity, nízka pravdepodobnosť dosiahnutia R0 resekcie a ďalšie
- Pacienti, u ktorých nie je indikovaná kuratívna rádioterapia

Cemiplimab – mechanizmus účinku

- Cemiplimab je plne humanizovaná monoklonálna protilátka imunoglobulínu G4 (IgG4), ktorá sa viaže na receptor programovanej bunkovej smrti PD-1 a blokuje jeho interakciu s ligandmi PD-L1 a PD-L2.
- Cemiplimab zosilňuje odpovede T buniek, vrátane protinádorových odpovedí, prostredníctvom blokády väzby PD-1 na ligandy PD-L1 a PD-L2.
-

FDA Approval schválenie pre Cemiplimab-rwlc vydané 28. septembra 2018, v znení:

- Cemiplimab-rwlc is indicated in the U.S. for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation

- *On 26 April 2019, the EMA Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorization for Libtayo for the treatment of advanced CSCC*

Papadopoulos KP, et al. *J Clin Oncol.* 2017;35(suppl; abstr. 9503).

Investigator Assessed Preliminary Response Rate by RECIST 1.1 is 46.2% (ITT Population)

Investigator assessment	Metastatic (N=10), n (%)	Locally advanced (N=16), n (%)	Overall (N=26), n (%)
Complete response	0	2 (12.5)	2 (7.7)
Partial response	6 (60.0)†	4 (25.0)	10 (38.5)
Stable disease	1 (10.0)	5 (31.3)	6 (23.1)
Progressive disease	2 (20.0)	4 (25.0)	6 (23.1)
Not evaluated	1 (10.0)	1 (6.3)	2 (7.7)

ORR (CR + PR + one unconfirmed PR) = 46.2% (12/26 patients; 95% CI: 26.6–66.6)
DCR (ORR + SD) = 69.2% (18/26 patients; 95% CI: 48.2–85.7)

†Includes 5 confirmed partial responses and 1 unconfirmed partial response.
CR, complete response; DCR, disease control rate; ITT, intention-to-treat; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease; RECIST, Response Evaluation Criteria In Solid Tumors.

Data cut-off date: 27 April 2017

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

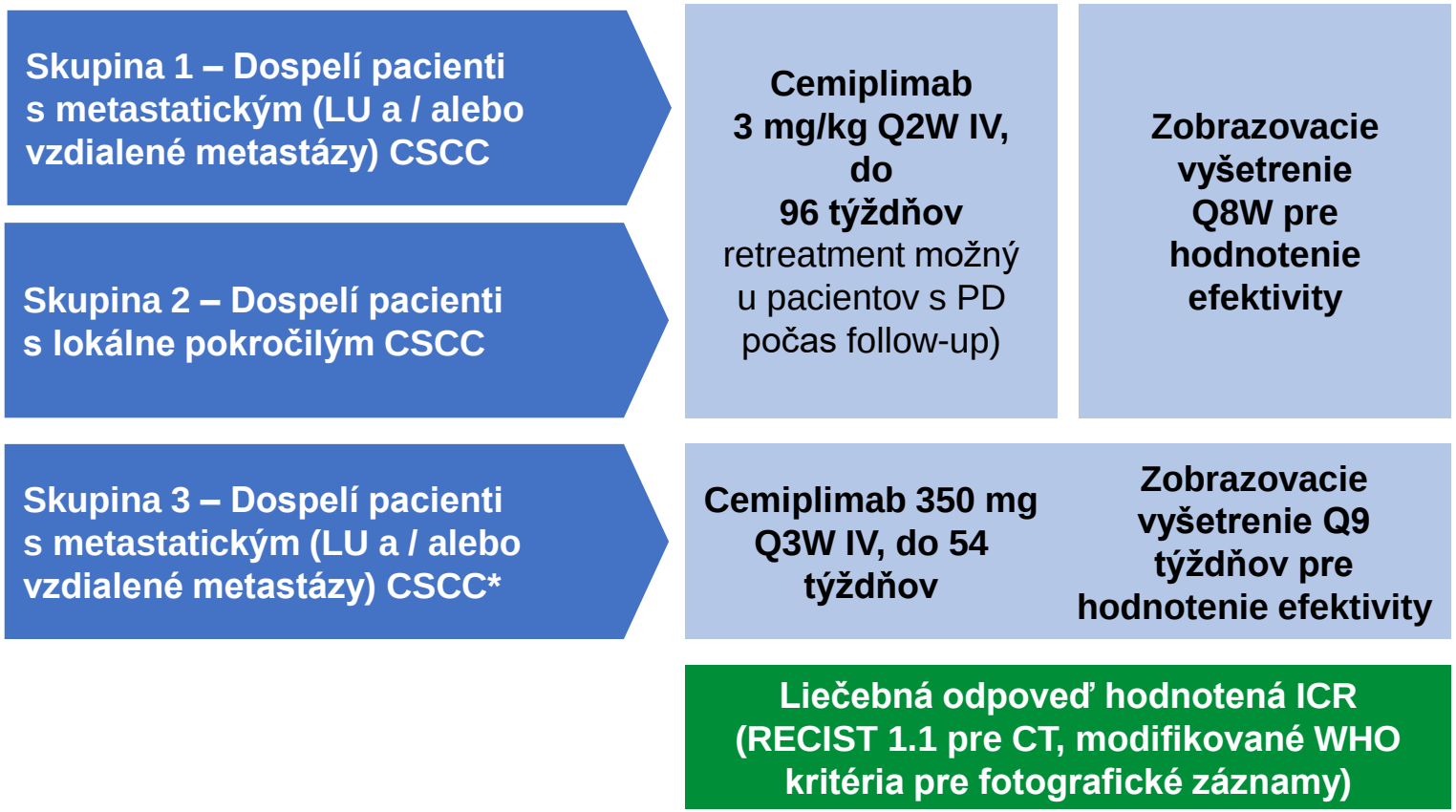
PD-1 Blockade with Cemiplimab in Advanced Cutaneous Squamous-Cell Carcinoma

M.R. Migden, D. Rischin, C.D. Schmults, A. Guminski, A. Hauschild, K.D. Lewis, C.H. Chung, L. Hernandez-Aya, A.M. Lim, A.L.S. Chang, G. Rabinowits, A.A. Thai, L.A. Dunn, B.G.M. Hughes, N.I. Khushalani, B. Modi, D. Schadendorf, B. Gao, F. Seebach, S. Li, J. Li, M. Mathias, J. Booth, K. Mohan, E. Stankevich, H.M. Babiker, I. Brana, M. Gil-Martin, J. Homsi, M.L. Johnson, V. Moreno, J. Niu, T.K. Owonikoko, K.P. Papadopoulos, G.D. Yancopoulos, I. Lowy, and M.G. Fury

Dostupné na www.nejm.org

Migden MR, et al. *N Engl J Med*. 2018;379:341-351.

Štúdia EMPOWER-CSCC-1- Dizajn (NCT02760498)



Hlavné inklúzne kritéria

- ECOG 0 / 1
- Adekvátne orgánové funkcie
- Skupina 1 & 3:
  - Aspoň jedna merateľná lézia podľa RECIST 1.1
- Skupina 2:
  - Aspoň jedna merateľná lézia podľa RECIST 1.1 kritérií (pre CT skeny) alebo modifikované WHO kritéria (pre foto dokumentáciu)
  - CSCC lézie, nevhodné na chirurgickú liečbu alebo rádioterapiu podľa investigátora

Hlavné exklúzne kritéria

- Predošlá anti–PD-1 alebo anti–PD-L1 liečba
- Anamnéza transplantácie orgánu, duplicitný solídny nádor alebo hematologická malignita
- Autoimúnne ochorenia aktuálne alebo v minulosti

*Data not yet available

CSCC, cutaneous squamous cell carcinoma; ECOG, Eastern Cooperative Oncology Group; IV, intravenous; PD, programmed cell death; PD-L, PD-ligand; Q[n]W, every [n] weeks; RECIST 1.1, Response Evaluation Criteria In Solid Tumours version 1.1; WHO, World Health Organisation.

Group 1: Data cut-off date: September 20, 2018
Group 2: Data cut-off date: October 10, 2018

1. Guminski et al. *J Clin Oncol*. 2019:37 (suppl; abstr 9526) [poster presentation]. 2. Migden MR, et al. *J Clin Oncol*. 2019:37 (suppl; abstr 6015) [poster presentation].

Baseline charakteristika pac. v EMPOWER-CSCC-1 s pokročilým CSCC (skupina 1 a skupina 2)

	Metastatický CSCC (N=59)[1]	Lokálne pokročilí CSCC (N=78)[2]
Median age, years (range)	71 (38–93)	74 (45–96)
≥ 65 years, n (%)	43 (72.9)	59 (75.6)
Male sex, n (%)	54 (91.5)	59 (75.6)
ECOG performance status, n (%)		
0 / 1	23 (39.0) / 36 (61.0)	38 (48.7) / 40 (51.3)
Primary CSCC site, n (%)		
Head/neck	38 (64.4)	62 (79.5)
Extremity	12 (20.3)	14 (17.9)
Trunk	9 (15.3)	2 (2.6)
Prior systemic therapy for CSCC, n (%)		
Any	33 (55.9)	12 (15.4)
1	22 (37.3)	10 (12.8)
≥2	11 (18.6)	2 (2.6)
Prior radiotherapy for CSCC, n (%)	50 (84.7)	43 (55.1)
Median duration of follow-up, months (range)	16.5 (1.1–26.6)	9.3 (0.8–27.9)

Data cut-off date: Sept 20, 2018 (Group 1)1; Oct 10, 2018 (Group 2)
CSCC, cutaneous squamous cell carcinoma; ECOG PS, Eastern Cooperative Oncology Group
†excludes ear and temple ‡ includes arms/hands and legs/feet
1. Guminski et al. *J Clin Oncol*. 2019:37 (suppl; abstr 9526) [poster presentation]. 2. Migden MR, et al. *J Clin Oncol*. 2019:37 (suppl; abstr 6015) [poster presentation].

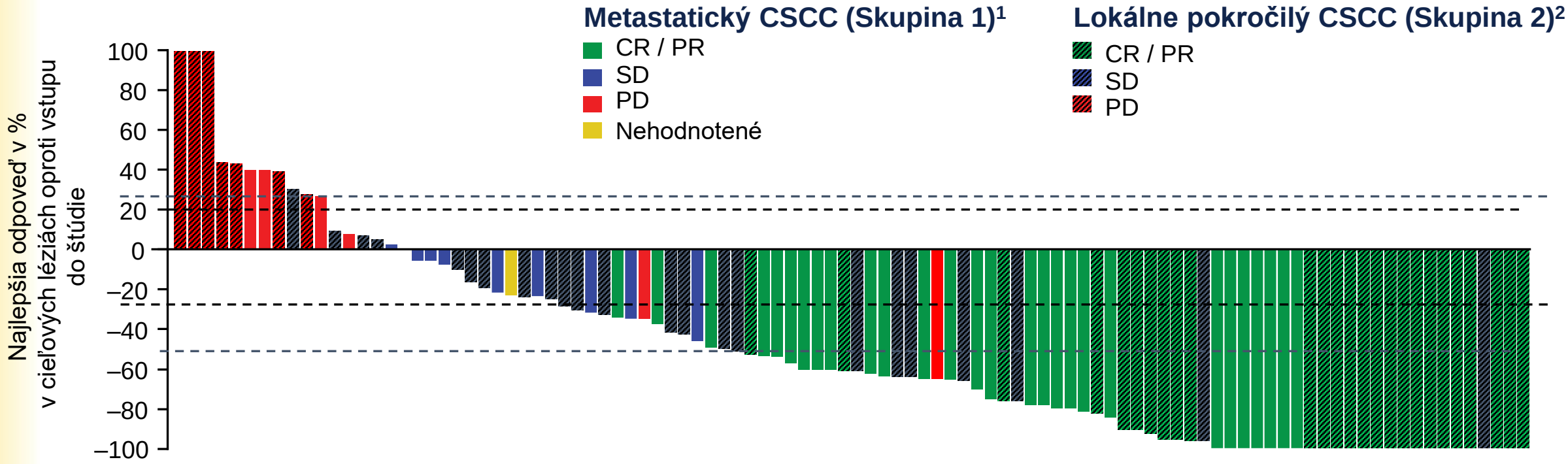
Liečebná odpoveď – Nezávislá hodnotiaca komisia - pacienti s pokročilým CSCC (skupiny 1 a 2)

	Metastatický CSCC (n=59)[1]	Lokálne pokročilý CSCC (n=78)[2]
Medián trvania follow-up, mesiace (rozsah)	16.5 (1.1 – 26.6)	9.3 (0.8 – 27.9)
Najlepšia odpoveď, n (%)		
CR	10 (16.9)	10 (12.8)
PR	19 (32.2)	24 (30.8)
SD	9 (15.3)	28 (35.9)
Non-CR/non-PD†	4 (6.8)	0
PD	10 (16.9)	9 (11.5)
Nedostupné ‡	7 (11.9)	7 (9.0)
ORR, % (95% CI)	49.2 (35.9–62.5)	43.6 (32.4–55.3)
ORR podľa INV % (95% CI)	49.2 (35.9-62.6)	52.6 (40.9-64.0)
CR / PR	4 (6.8) / 25 (42.3)	13 (16.7) / 28 (35.9)
DCR % (95% CI)	71.2 (57.9–82.2)	79.5 (68.8–87.8)
Kontrola trvania odpovede, % (95% CI)§	62.7 (49.1–75.0)	62.8 (51.1–73.5)
Median času do odpovede, meesiace (rozsah) ¶	1.9 (1.7–9.1)	1.9 (1.8–8.8)

Data cut-off date: Sept 20, 2018 (Group 1); Oct 10, 2018 (Group 2)
†Patients with non-measurable disease on central review of baseline imaging. ‡Include missing and unknown tumor response. §Defined as the proportion of patients without progressive disease for at least 105 days.
¶Data shown are from patients with confirmed responses.
INV investigator assessment

1. Guminski et al. *J Clin Oncol*. 2019:37 (suppl; abstr 9526) [poster presentation]. 2. Migden MR, et al. *J Clin Oncol*. 2019:37 (suppl; abstr 6015) [poster presentation].

Najlepšia odpoveď v cieľových léziách u pacientov s pokročilým CSCC podľa ICR

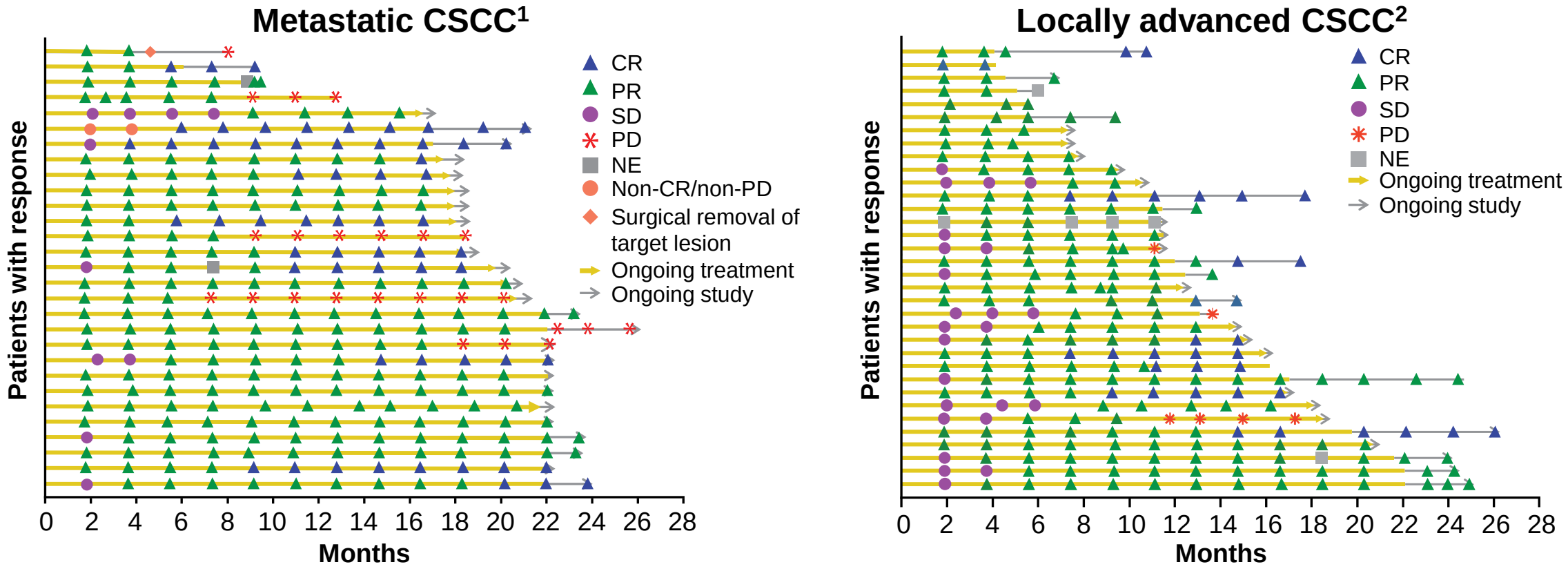


Data cut-off date: Sept 20, 2018 (Group 1); Oct 10, 2018 (Group 2)
Bars show the best percentage change in the sum of target lesion diameters from baseline for 45 patients with metastatic CSCC who underwent radiologic evaluation per ICR and 56 patients with locally advanced CSCC who underwent photography evaluation per modified WHO criteria by ICR after treatment initiation. Lesion measurements after progression were excluded. Black horizontal dashed lines indicate RECIST 1.1 criteria for partial response (≥30% decrease in the sum of target lesion diameters) and progressive disease (≥20% increase in the target lesion diameters). Blue horizontal dashed lines indicate WHO criteria for partial response (≥50% decrease in the sum of target lesion diameters) and progressive disease (≥25% increase in the target lesion diameters).
CSCC, cutaneous squamous cell carcinoma; ICR, independent central review; RECIST 1.1, Response

Evaluation Criteria In Solid Tumors version 1.1; WHO, World Health Organization

1. Guminski AD, et al. *J Clin Oncol* 2019;37 (suppl; abstr 9526); 2. Migden MR, et al. *J Clin Oncol* 2019;37 (suppl; abstr 6015)

Čas do odpovede a trvanie odpovede u odpovedajúcich pac. s pokročilým CSCC



Data cut-off date: Sept 20, 2018 (Group 1); Oct 10, 2018 (Group 2)

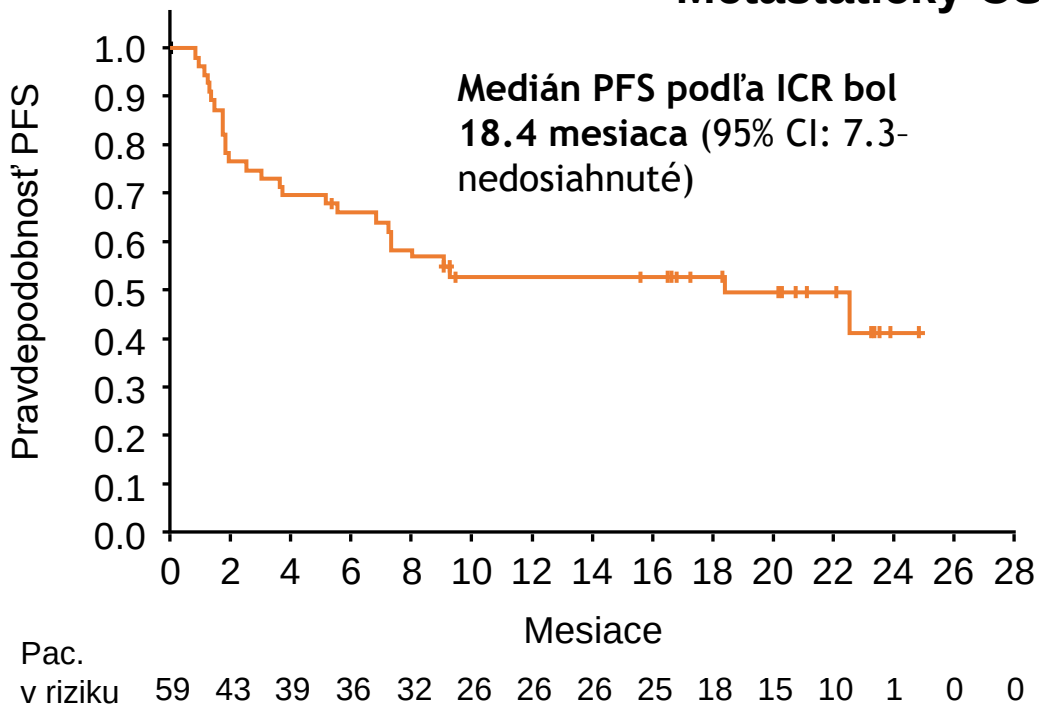
†Twenty-three of the 29 patients remain in response at time of data cut-off; of the 23 patients, 10 were still on study, 11 were in post-treatment follow-up and two were off study. Multiple progression events for a single patient were possible due to discrepancies between investigator and ICR assessments of tumour response and because the protocol allowed option for treatment past progression in patients whom the investigator felt were experiencing clinical benefits. ‡Of the 34 responding patients, three had subsequent progressive disease. Among the remaining 31 patients who were in response at the time of data cut-off, 12 were still on study treatment, nine were in post-treatment follow-up, and 10 were off study. One patient (sixth from bottom) had four progressive disease assessments due to discordance between investigator and ICR assessments of tumour response.

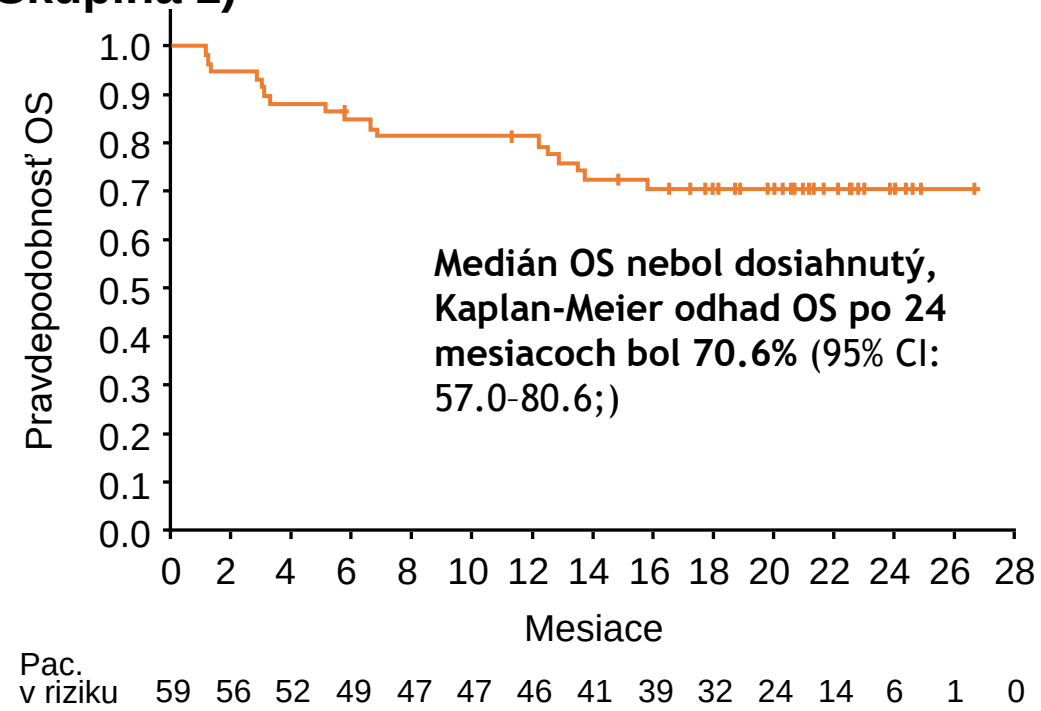
CR, complete response; CSCC, cutaneous squamous cell carcinoma; ICR, independent central review; NE, not evaluable; PD, progressive disease; PR, partial response; SD, stable disease.

1. Guminski et al. *J Clin Oncol*. 2019:37 (suppl; abstr 9526) [poster presentation]. 2. Migden MR, et al. *J Clin Oncol*. 2019:37 (suppl; abstr 6015) [poster presentation].

Hodnotenie ORR, PFS, a DOR u pacientov s pokročilým CSCC

Metastatický CSCC (Skupina 1)[1]





Medián DOR nedosiahnutý

	Lokálne pokročilý CSCC (Skupina 2)[2]
Medián PFS	NR
K-M odhad PFS po 12 mesiacoch	58.1% (95% CI: 43.7–70.0)
Medián OS	NR
K-M odhad OS po 12 mesiacoch	93.2% (95% CI: 84.4–97.1)
Medián DOR	NR

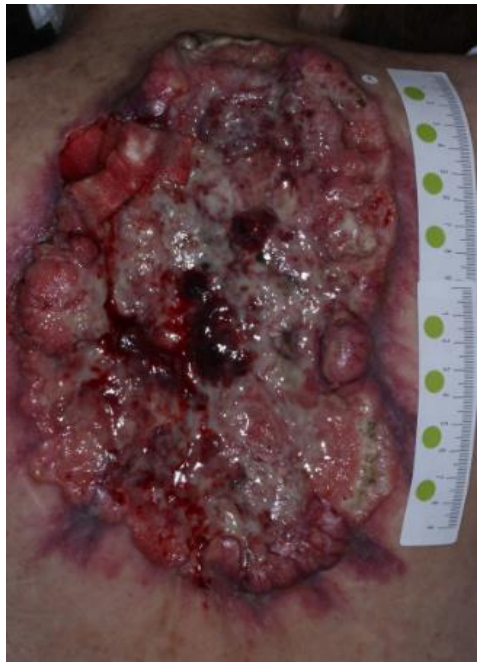
Group 1: Median duration of follow-up = 16.5 mos (range 1.1 – 26.6); Group 2: Median duration of follow-up = 9.3 mos (range 0.8 – 27.9)
Data cut-off date: Sept 20, 2018 (Group 1); Oct 10, 2018 (Group 2)
CI, confidence interval; CSCC, cutaneous squamous cell carcinoma; ICR, independent central review; OS, overall survival; PFS, progression-free survival; NR, not reached

1. Guminski et al. J Clin Oncol. 2019:37 (suppl; abstr 9526) [poster presentation]. 2. Migden MR, et al. J Clin Oncol. 2019:37 (suppl; abstr 6015) [poster presentation].

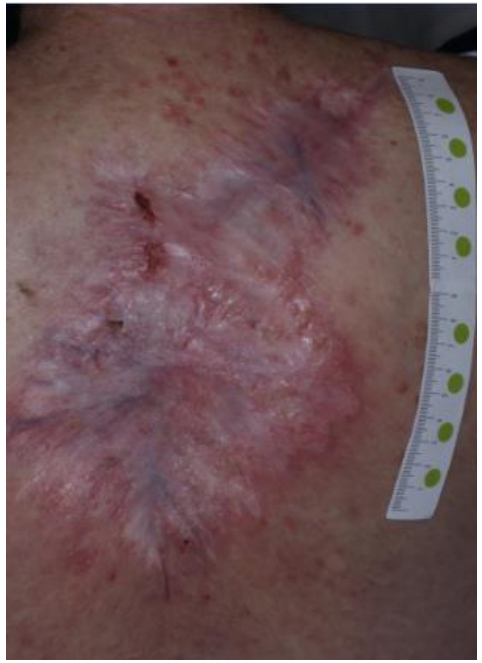
PRÍKLAD REDUKCIE VIDITEĽNYCH LÉZIÍ CSCC PO LIEČBE CEMIPLIMABOM ZO ŠTÚDIE

70-ročná žena s veľkým CSCC nádorom v oblasti chrbta

Úvodne

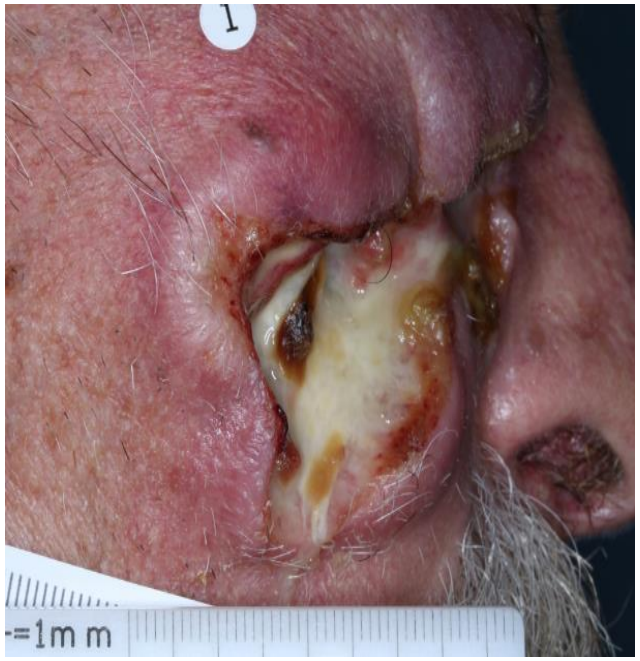


Týždeň 48

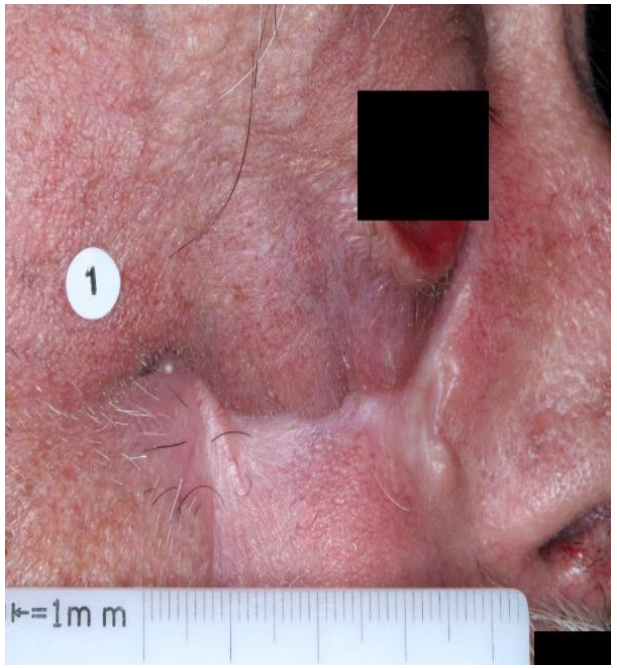


70-ročný muž s veľkým CSCC na tvári

Úvodne



Týždeň 18



Žiadny pacient predtým nebol liečený rádioterapiou alebo inou systémovou liečbou

CSCC, cutaneous squamous cell carcinoma .

1.Guminski et al. *J Clin Oncol*. 2019:37, 2. Migden MR, et al. *J Clin Oncol*. 2019:37

Data cut-off date: 20 Sep 2018 (Group 1); 10 Oct 2018 (Group 2).

Treatment-emergent Adverse Events (TEAEs) Regardless of Attribution u pacientov s pokročilým CSCC

	Skupina 1 Metastatický CSCC (n=59)[1]		Skupina 2 Lokálne pokročilý CSCC (n=78)[2]		Spolu (n=137)[3]	
	Všetky grade	Grade ≥3	Všetky grade	Grade ≥3	Všetky grade	Grade ≥3
Všetky	59 (100.0)	30 (50.8)	78 (100.0)	34 (43.6)	137 (100.0)	64 (46.7)
Závažné	24 (40.7)	20 (33.9)	23 (29.5)	19 (24.4)	47 (34.3)	39 (28.5)
Vedúce k prerušeniu liečby	6 (10.2)	4 (6.8)	6 (7.7)	5 (6.4)	12 (8.8)	9 (6.6)

Metastatický CSCC (Skupina 1)[1]

Grade ≥3 TEAEs pozorované u >1 pacienta

- Cellulitída (n=4; 6.8%)
- Pneumonitída (n=3; 5.1%)
- Anémia, dyspnoe, hyperkalcémia, nový primárny CSCC, pleurálny výpotok, pneumónia (každá n=2; 3.4%)

Grade ≥3 TEAEs vedúce k prerušeniu liečby

- Pneumonitída (n=3; 5.1%)
- Aseptická meningitída, zmätenosť, bolesti krku, (u toho istého pacienta: n=1; 1.7%)

Lokálne pokročilý CSCC (Skupina 2)[2]

Grade ≥3 TEAEs pozorované u >1 pacienta

- Hypertenzia (n=6; 7.7%)
- Pneumónia (n=4; 5.1%)
- Hyperglykémia a cellulitída (každá n=3; 3.8%)
- Karcinóm prsníka, pády, hyponatrémia, lymfopénia, svalová slabosť, pneumonitis, sepsa, uroinfekcia (každá n=2; 2.6%)

Grade ≥3 TEAEs vedúce k prerušeniu liečby

- Pneumonitída (n=2; 2.6%)
- Encephalitída, hepaitída, zvýšenie AST, pneumónia, proktitída (každá n=1; 1.3%)

Data cut-off date: Sept 20, 2018 (Group 1); Oct 10, 2018 (Group 2)
CSCC, cutaneous squamous cell carcinoma; TEAE, treatment-emergent adverse event.
1. Guminski et al. J Clin Oncol. 2019:37 (suppl; abstr 9526) [poster presentation]. 2. Migden MR, et al. J Clin Oncol. 2019:37 (suppl; abstr 6015) [poster presentation]. 3. Data on File, Regeneron Pharmaceuticals Inc.

ZÁVER

- Výsledky ukazujú, že cemiplimab má v liečbe CSCC významnú a dlhotrvajúcu efektivitu
- Medián trvania odpovede v dobe data cut-off nebol dosiahnutý
  - v dobe data cut-off sa stále pozorovali liečebné odpovede u väčšiny pacientov v štúdii
- Profil toxicity je porovnateľný s inými ICIs zo skupiny anti–PD-1

PD, programmed cell death.