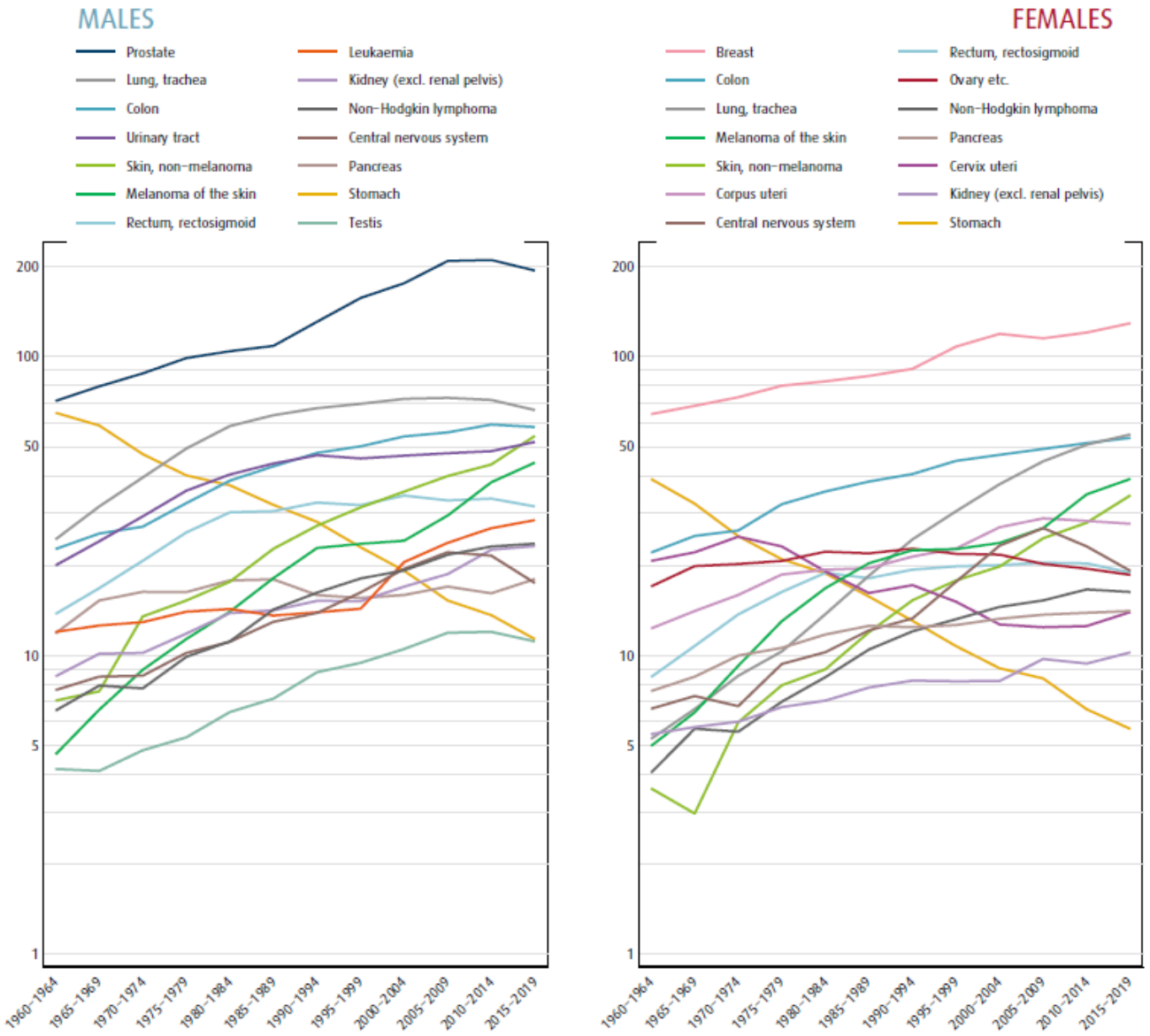
Immunbehandling av non-melanom hudkreft

Åse Bratland
Seksjonsleder, Seksjon for hode-hals kreft
AKB, Radiumhospitalet, OUS
29. januar 2021

Forekomsten av non-melanom hudkreft i Norge

ICD-10	Site	Sex	Incidence cases, 2019[1]	Incidence rate, 2015–19[2]	Change in rate (%)[3]	r
C00–96	All sites	M	18706	726.0	-0.7	
		F	16273	558.4	4.5	
C18	Colon	M	1438	58.2	-1.9	
		F	1541	53.5	4.1	
C19–20	Rectum, rectosigmoid	M	777	31.6	-5.8	
		F	539	18.9	-6.8	
C33–34	Lung, trachea	M	1659	66.3	-7.5	
		F	1661	54.9	8.2	
C43	Melanoma of the skin	M	1202	44.2	16.3	
		F	1128	39.0	12.6	
C44	Skin, non-melanoma	M	1485	54.3	24.6	
		F	1256	34.4	23.4	

Kreft i Norge, 2019



Kreft i Norge, 2019

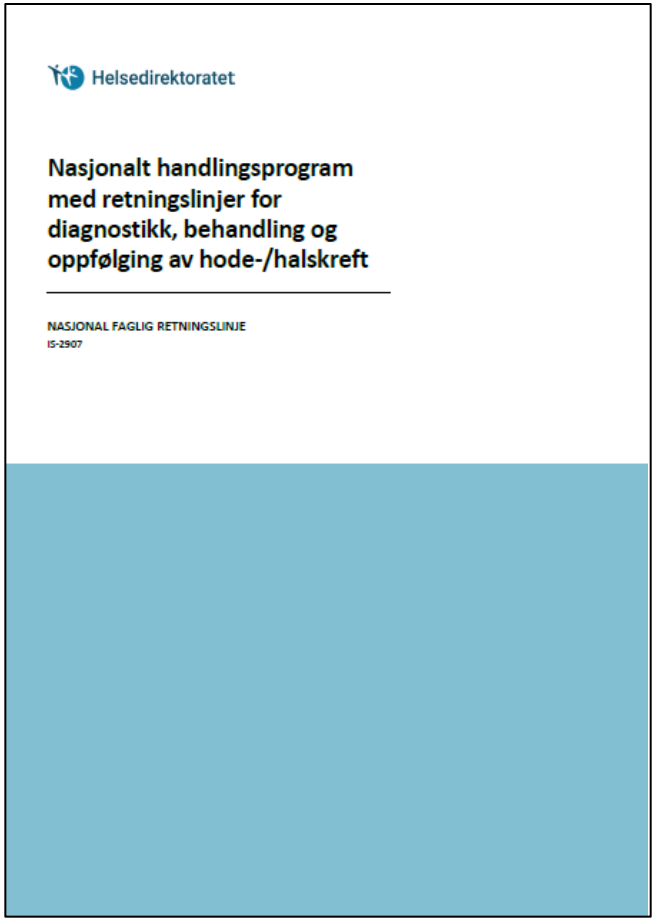
Hvorfor økning i forekomst?

- Økende levealder i befolkningen
- Soleksponering

- Flere transplanterte (immunsupprimerte)
- Flere immunsupprimerte (pga autoimmune tilstander - diverse medikamenter)
- Bruk av nye medikamenter inkl kreftmedisiner (F.eks BRAF-hemmere)
- Polyomavirus (Merkelcelle carsinom)

Handlingsprogram for hode-hals kreft – kapittel 22

Publisert av Helsedirektoratet i mai 2020



NB – ikke oppdatert med immunbehandling!

Inntil videre benytt;
www.nccn.org

Beslutningsforum 23. november 2020

Sak 106-2020 **ID2018_099 Cemiplimab (Libtayo) som monoterapi til behandling av voksne pasienter med metastatisk eller lokalavansert kutant plateepitelkarsinom som ikke er egnet for kurativ kirurgi eller kurativ strålebehandling**

Beslutning:
Beslutningen som er fattet av Beslutningsforum for nye metoder er resultat av en lang prosess og en grundig vurdering av de menneskelige konsekvenser som følger både av beslutning om innføring så vel som beslutning om ikke å innføre en metode for utredning, behandling og/eller prosedyre/organisering.

Dersom det tilkommer nye opplysninger (herunder om pasientsikkerhet, kostnadseffektivitet, pris, biotilsvarende medikamenter/generika, overlevelsestall m. m) som endrer resultatet vesentlig, vil beslutningen kunne vurderes på nytt.

1. Cemiplimab (Libtayo) kan innføres som monoterapi til behandling av voksne pasienter med metastatisk eller lokalavansert kutant plateepitelkarsinom som ikke er egnet for kurativ kirurgi eller kurativ strålebehandling.
2. Det forutsetter at prisen er lik eller lavere enn den prisen som er grunnlaget for denne beslutningen.
3. Behandlingen kan tas i bruk fra 15. desember 2020.
4. Metodevurderingen med tilhørende analyse har særskilt stor usikkerhet og skal følges opp.
5. Legemiddelfirmaet må levere en oppsummering av langtidsdata og ytterligere data som er samlet inn (samme materiale som er levert til NICE) til Statens legemiddelverk og Sykehusinnkjøp HF. I tillegg skal firmaet levere en oversikt over utviklingen av bruk i Norge etter innføring. Frist for innlevering er satt til første halvår 2023.
6. Statens legemiddelverk og Sykehusinnkjøp HF gis i oppdrag å lage en oppsummering til Beslutningsforum for nye metoder på bakgrunn av informasjonen mottatt fra legemiddelfirmaet.

Beslutningsforum 14. desember 2020

Sak 115-2020 ID2019_010

Avelumab (Bavencio) til andrelinjebehandling av metastatisk merkelcellekarsinom

Beslutning: Beslutningen som er fattet av Beslutningsforum for nye metoder er resultat av en lang prosess og en grundig vurdering av de menneskelige konsekvenser som følger både av beslutning om innføring så vel som beslutning om ikke å innføre en metode for utredning, behandling og/eller prosedyre/organisering. Dersom det tilkommer nye opplysninger (herunder om pasientsikkerhet, kostnadseffektivitet, pris, biotilsvarende medikamenter/generika, overlevelsestall m. m) som endrer resultatet vesentlig, vil beslutningen kunne vurderes på nytt.

1. Avelumab (Bavencio) innføres til andrelinjebehandling av metastatisk merkelcellekarsinom.
2. Det er stor usikkerhet ved dokumentasjon av relativ effekt sammenlignet med kjemoterapi, samtidig som en betydelig klinisk effekt er dokumentert.
3. Det forutsetter at prisen er lik eller lavere enn den prisen som er grunnlaget for denne beslutningen.
4. Legemiddelet kan tas i bruk fra 15. januar 2021.

Correlation btw tumor mutational burden and objective response rate with PD-1 inhibition in 27 tumor types[1]

The high mutation burden of advanced CSCC supports PD-1 inhibition[1]

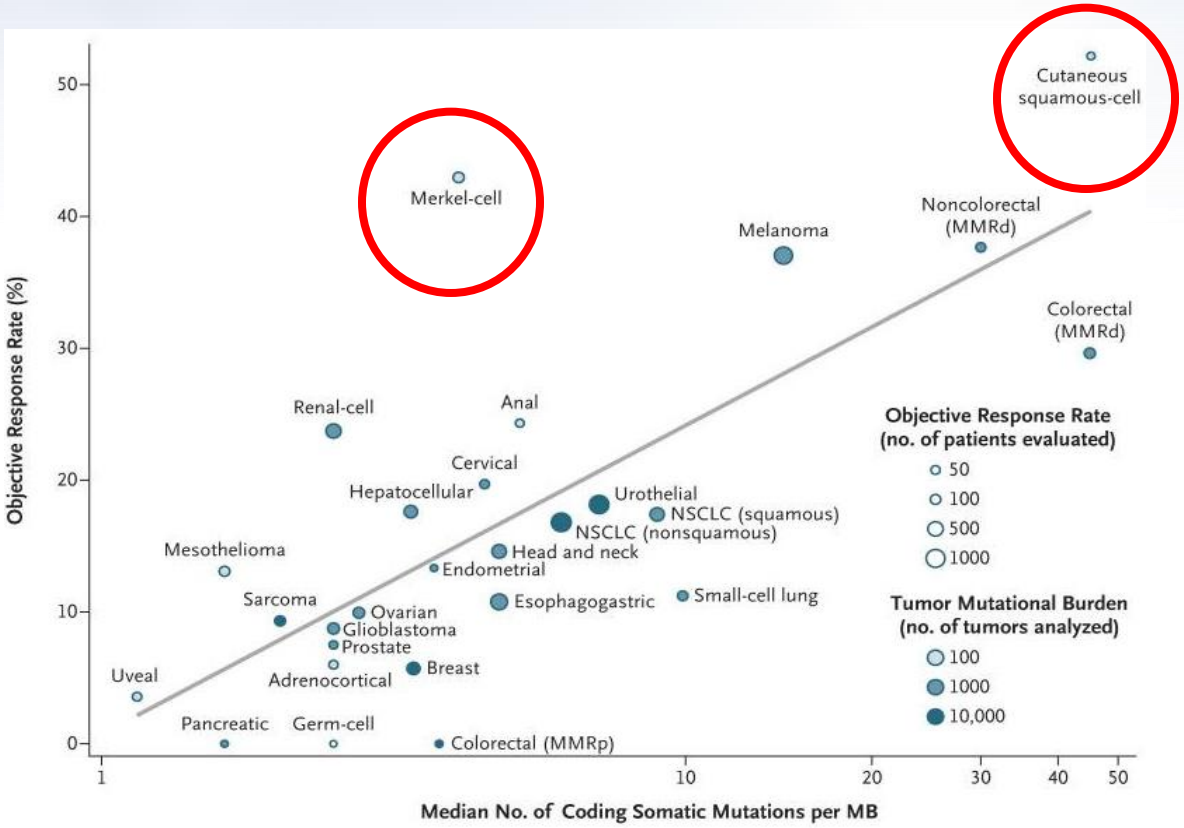


Illustration made by Sanofi

1. Yarchoan M, Hopkins A, Jaffee EM. Tumor Mutational Burden and Response Rate to PD-1 Inhibition. N Engl J Med. 2017 21;377(25):2500–1.

PLATEEPITELCARSINOM I HUD

Hvem kan få cemiplimab?

Indikasjon:

Som monoterapi til behandling av voksne med metastatisk eller lokalavansert kutant plateepitelkarsinom (mCSCC eller laCSCC) som ikke er egnet for kurativ kirurgi eller kurativ strålebehandling.

Transplanterte?

Transplantatavstøtning av solide organer er rapportert etter behandling med PD-1-hemmere. Behandling kan øke risikoen for avstøtning ved solid organtransplantasjon. Fordel med behandling vurderes opp mot risiko for mulig organavstøtning. Transplantat-mot-vert-sykdom er sett ved behandling med andre PD-1/PD-L1-hemmere i assosiasjon med allogen hematopoetisk stamcelletransplantasjon

Immunsupprimerte/pasienter med automimmune sykdommer?

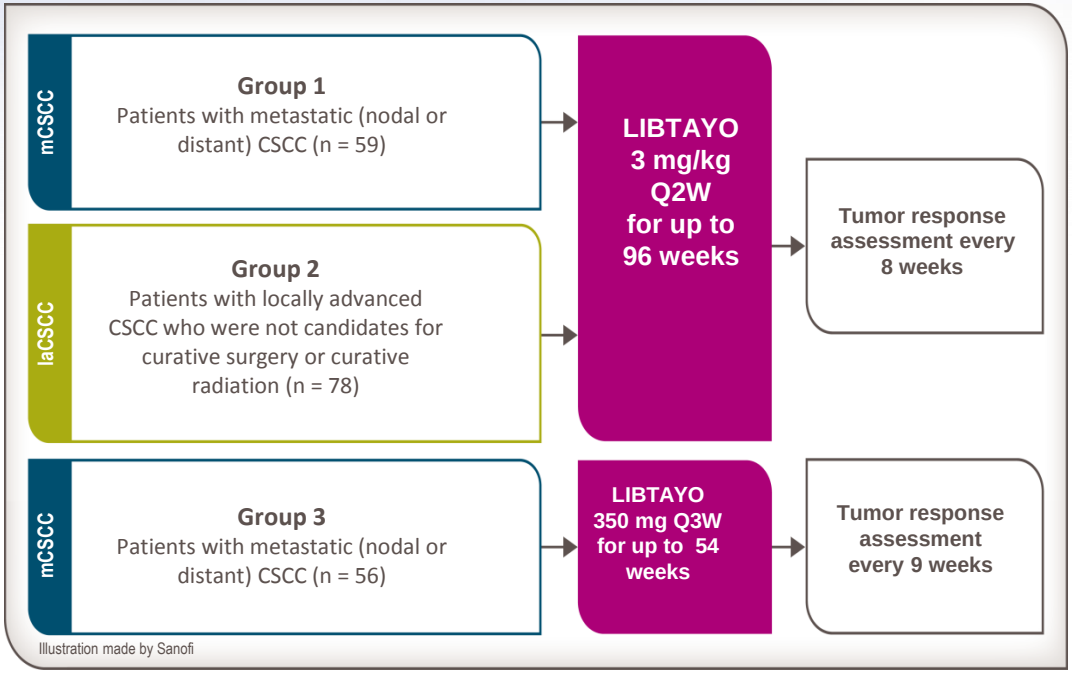
Pasienter med aktive infeksjoner eller nedsatt immunforsvar: Data mangler og cemiplimab bør brukes med forsiktighet, og etter nøye nytte-/risikovurdering.

Fra felleskatalog-omtale «Libtayo»

EMPOWER-CSCC-1 study design

LIBTAYO has been studied in a prospective trial in patients with advanced CSCC[1-3]

Open-label, multi-center, phase 2 study in 193 patients with metastatic (nodal or distant) or locally advanced CSCC who were not candidates for curative surgery or curative radiation[1,2,a]



[a] Data cut-off on 20 September 2018 for group 1 and 3, and 10 October 2018 for group 2

Tumour response assessment by ICR
(RECIST 1.1 for scans: modified WHO criteria for photographs)

To account for possible pseudoprogression, treatment could be continued beyond initial RECIST 1.1-defined progression informed by ir-related response criteria

The approved dose for LIBTAYO is 350 mg Q3W[1]

Primary endpoint

- **Confirmed ORR** (objective response rate) by **ICR** (independent central review)

Secondary endpoints included:

- Duration of response (DOR)
- ORR by investigator assessment
- Progression-free survival (PFS)
- Overall survival (OS)
- Complete response rate (CR)
- Safety profile

1. Libtayo SmPC Sept. 2020 pt. 4.2 **2.** Migden MR, Rischin D, Schmults CD, et al. PD-1 Blockade with Cemiplimab in Advanced Cutaneous Squamous-Cell Carcinoma. N Engl J Med. 2018 26;379(4):341–51. **3.** Choi FD, Kraus CN, Elsensohn AN, et al. PD-1 and PD-L1 inhibitors in the treatment of non-melanoma skin cancer: a systematic review. J Am Acad Dermatol. 2019 Jun 1; .

Patient characteristics[1]

	Advanced CSCC (N = 193)
Metastatic CSCC, n (%)	115 (60)
Distant metastasis, n (%)	88 (76.5)
Only nodal metastasis, n (%)	26 (22.6)
Locally advanced CSCC, n (%)	78 (40)
Median age, years (range)	72 (38-96)
Aged 75 years or older, n (%)	78 (40.4)
Male, n (%)	161 (83.4%)
Caucasian, n (%)	187 (96.9)
Any prior radiotherapy, n (%)	131 (67.9)
Prior cancer-related surgery, n (%)	174 (90.2)
At least 1 prior anticancer systemic therapy, n (%)	65 (33.7)

ECOG Performance Status, n (%)	
0	86 (44.6)
1	107 (55.4)

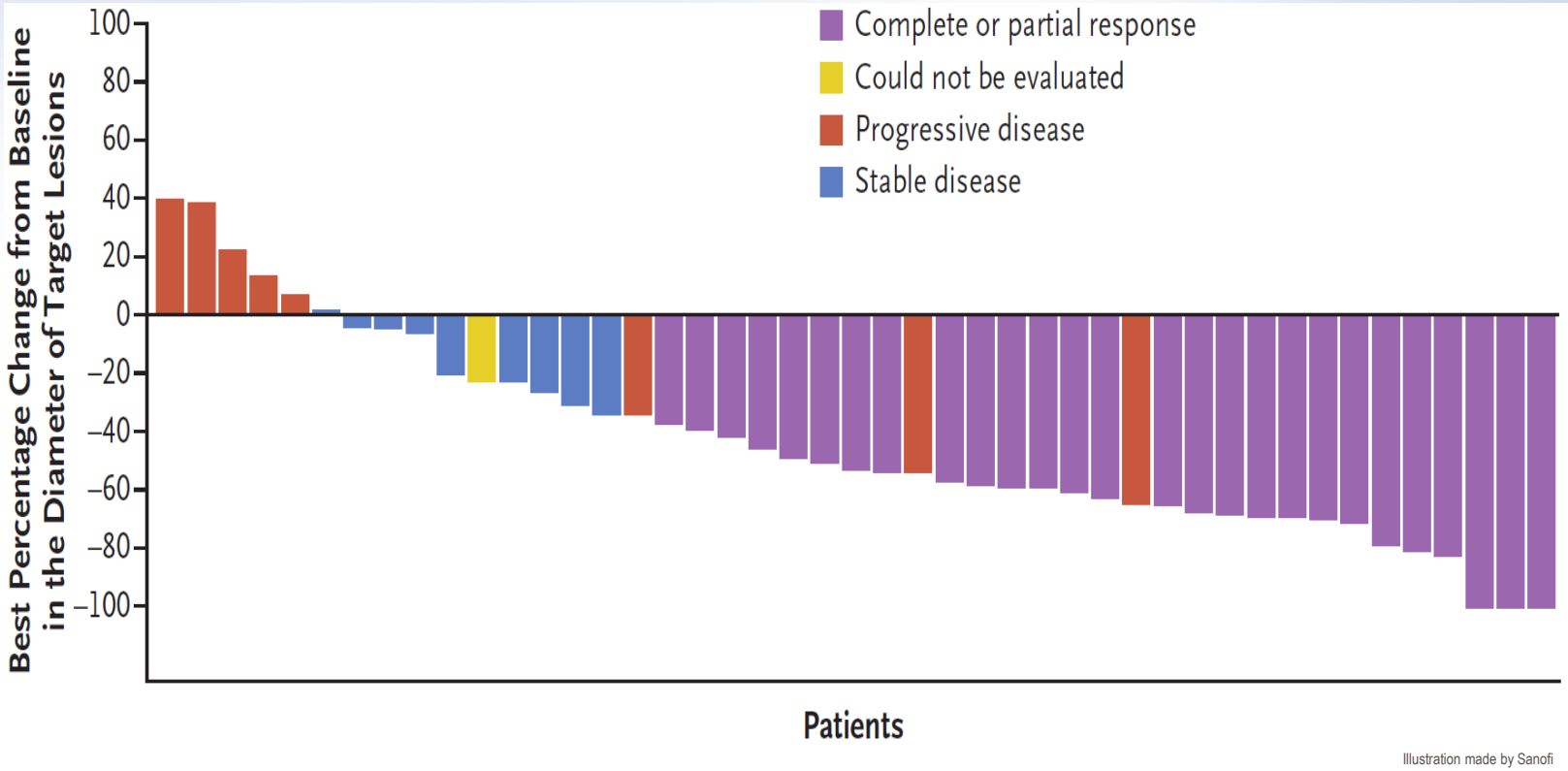
Table is made by Sanofi based on ref. 1, section 5.1, Clinical efficacy and safety.

Gjennomføring av behandling

- Ingen biomarkør-testing før oppstart
- Kan gis i «alle» linjer
- 1. linje er foretrukket?
- Fast dose 350 mg hver 3. uke til alle (lokalavanserte og metastatiske)

- Poliklinisk behandling, 30 minutter iv. infusjon

Tumor response rate for 45 patients in phase 2*[1]



*Best percentage change from baseline in the sum of the diameters of the target lesions for each of the 45 patients in the metastatic disease cohort of the phase 2 study who underwent imaging studies after the initiation of therapy, as well as the best response for each patient. Preliminary result for 59 patients with mCSCC. Enrolled May 2016 through April 2017. Median follow-up: 7.9 months (1.1 – 15.6 months).

1. Migden MR, Rischin D, Schmults CD, et al. PD-1 Blockade with Cemiplimab in Advanced Cutaneous Squamous-Cell Carcinoma. N Engl J Med. 2018 26;379(4):341–51.

Oppfølging under behandling

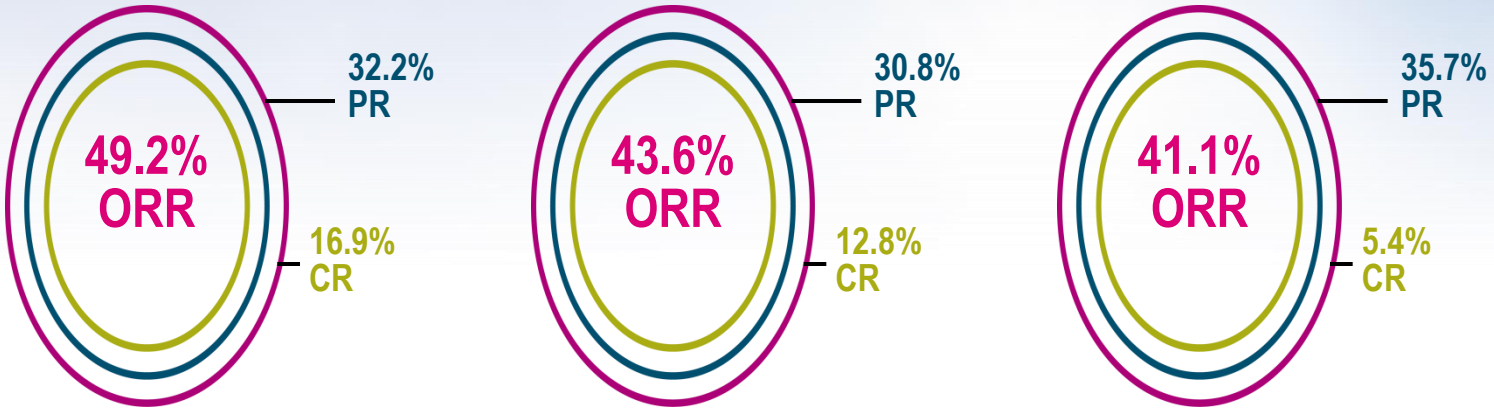
- OUS

  - sykepleierkonsultasjoner etter 2 infusjoner

    bivirkningskontroll – telefonkonsultasjon (2 sykepleiere)

  -legeevaluering etter 3-4 infusjoner – klinisk/foto hvis mulig, radiologi etter ca 6 infusjoner

Tumor responses demonstrated with LIBTAYO[1]



Group 1
mCSCC
3 mg/kg Q2W
(N = 59)

Group 2
laCSCC
3 mg/kg Q2W
(N = 78)

Group 3
mCSCC
350 mg Q3W
(N = 56)

The illustration is made by Sanofi based on ref 1, table 3.

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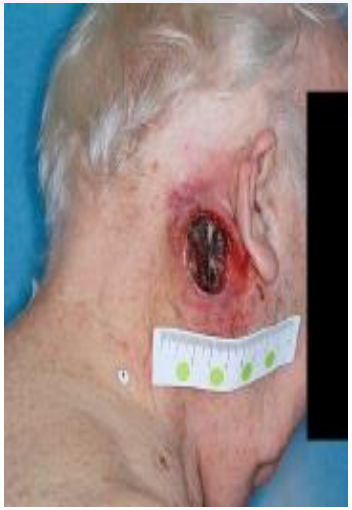
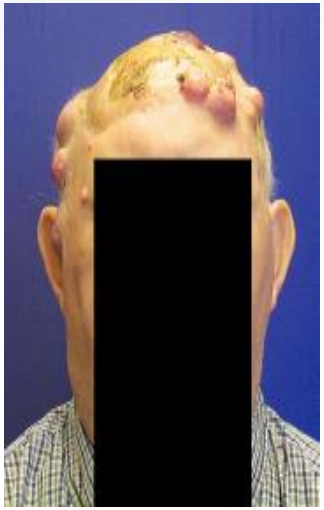
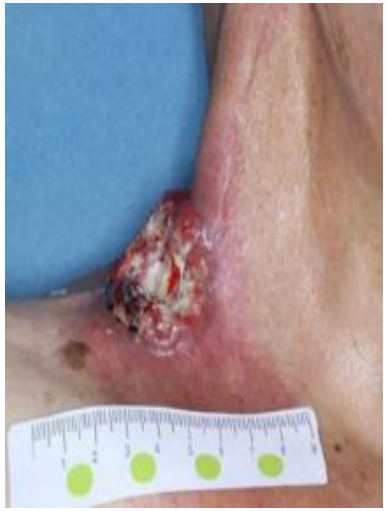
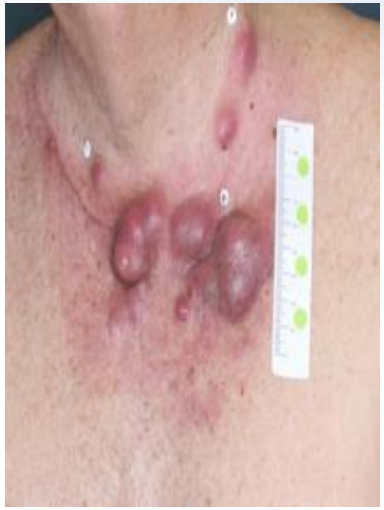
In Groups 1, 2, and 3, median durations of follow-up were 16.5 months, 9.3 months, and 8.1 months, respectively.[1]

ORR, objective response rate; PR, Partial response; CR, Complete response; laCSCC, locally advanced CSCC; mCSCC, metastatic CSCC; Q2W, every 2 weeks; Q3W, every 3 weeks.

1. Libtayo Summary of Product Characteristics. Sept. 2020

Advanced CSCC[1]

Baseline examples from cemiplimab phase 2 study

Illustration made by Sanofi

1. Migden MR, Rischin D, Schmults CD, et al. PD-1 Blockade with Cemiplimab in Advanced Cutaneous Squamous-Cell Carcinoma. N Engl J Med. 2018 26;379(4):341–51.

Bivirkninger

Cemiplimab har samme bivirkningsprofil som andre sjekkpunkthemmere

LIBTAYO adverse reactions and immune-related adverse reactions[1]

The safety was evaluated in 591 patients with advanced solid malignancies, including 219 advanced CSCC patients.[1]

Adverse reactions (ARs)[1]

- Serious ARs occurred in 8.6% of patients
- 5.8% permanently discontinued LIBTAYO due to serious ARs
- Severe cutaneous adverse reactions (SCARs) have been reported in association with LIBTAYO treatment*

Immune-related adverse reactions (irARs)[1]

- irARs occurred in 20.1% of patients
- Grade ≥ 3 irARs occurred in 8% of patients
- 4.4% permanently discontinued LIBTAYO due to irARs

LIBTAYO has a safety profile similar to other PD-1 inhibitors[1-3]

* Including Stevens-Johnson syndrom (SJS) and toxic epidermal necrolysis (TEN)

1. Libtayo SmPC Sept. 2020 pt. 4.8 **2.** Migden MR, Rischin D, Schmults CD, et al. PD-1 Blockade with Cemiplimab in Advanced Cutaneous Squamous-Cell Carcinoma. N Engl J Med. 2018 26;379(4):341–51. **3.** Libtayo SmPC Sept. 2020 pt. 5.1

Summary of immune-related adverse reactions[1]

Adverse reactions	Incidence (N=591), %	Median time to onset (range)	Median duration (range)
Pneumonitis	3.7	3.8 mo (7 d to 18 mo)	21.5 d (5 d to 6.5 mo)
Colitis or diarrhoea	1.2	3.8 mo (15 d to 6.0 mo)	30 d (4 d to 8.6 mo)
Hepatitis	1.9	1.0 mo (7 d to 4.2 mo)	15 d (8 d to 2.7 mo)
Hypothyroidism	7.1	4.2 mo (15 d to 18.9 mo)	NR
Hyperthyroidism	1.9	1.9 mo (28 d to 14.8 mo)	NR
Adrenal insuffiency	0.5	11.5 mo (10.4 mo to 12.3 mo)	NR
Hypophysitis	0.2	NR	NR
Type-1 diabetes mellitus	0.7	2.3 mo (28 d to 6.2 mo)	NR
Skin adverse reactions	2.0	1.5 mo (2 d to 10.9 mo)	4.4 mo (14 d to 9.6 mo)
Nephritis	0.5	1.8 mo (29 d to 4.1 mo)	18 d (9 d to 29 d)
Other irAR[a]	< 1 for each	NR	NR
Infusion-related reactions	9.1	NR	NR

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[a] Including meningitis (meningitis and meningitis aseptic), paraneoplastic encephalomyelitis, Guillain-Barré syndrome, central nervous system inflammation, chronic inflammatory demyelinating polyradiculoneuropathy, encephalitis (encephalitis and noninfective encephalitis), myasthenia gravis, neuropathy peripheral, myocarditis (autoimmune myocarditis and myocarditis), pericarditis, immune thrombocytopenic purpura, vasculitis, myalgia, arthritis (arthritis and polyarthritis), Sjögren's syndrome, keratitis, and stomatitis. NR, not reported. 1. Libtayo SmPC Sept. 2020 pt. 4.8

Recommended treatment modifications for the management of irAR[1]

Characteristics	Withhold LIBTAYO	Permanently discontinue LIBTAYO
Pneumonitis	Grade 2	Grade 3/4 or recurrent grade 2
Colitis	Grade 2/3	Grade 4 or recurrent Grade 3
Hepatitis	Grade 2 with AST or ALT > 3 and ≤ 5 x ULN or total bilirubin > 1.5 and ≤ 3 x ULN	Grade ≥ 3 with AST or ALT > 5 x ULN or total bilirubin > 3 x ULN
Hypothyroidism	Grade 3/4	
Hyperthyroidism	Grade 3/4	
Hypophysitis	Grade 2 to 4	
Adrenal insufficiency	Grade 2 to 4	
Type-1 Diabetes mellitus	Grade 3/4 (hyperglycemia)	
Skin adverse reaction	Grade 2 lasting longer than 1 week, Grade 3 or suspected SJS or TEN	Grade 4 or confirmed SJS or TEN
Immune-related skin reaction or other immune-related adverse reactions in patients with prior treatment with idelalisib▼	Grade 2	Grade 3/4 (excluding endocrinopathies) or recurrent grade 2
Nephritis with renal dysfunction	Grade 2 creatinine increased	Grade 3 or 4 creatinine increased
Other irAR (including but not limited to paraneoplastic encephalomyelitis, meningitis, myositis, solid organ transplant rejection, graft-vs-host disease, Guillain Barre syndrome, central nervous system inflammation, chronic inflammatory demyelinating polyradiculoneuropathy, encephalitis, myasthenia gravis, neuropathy peripheral, myocarditis, pericarditis, immune thrombocytopenic purpura, vasculitis, arthralgia, arthritis, muscular weakness, myalgia, polymyalgia rheumatica, Sjogren's syndrome, keratitis, stomatitis, thyroiditis)	Grade 2 or 3 based on type of reaction	Grade 3 based on type of reaction or Grade 4 (excluding endocrinopathies) Grade 3 or 4 neurologic toxicity, myocarditis or pericarditis. Recurrent Grade 3 immune-related adverse reaction. Persistent Grade 2 or 3 immune-related adverse reactions lasting 12 weeks or longer (excluding endocrinopathies) Inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks.
Infusion-related reaction	Grade 1/2	Grade 3/4

Illustration made by Sanofi

1. Libtayo SmPC June 2020 pt. 4.2; ALT, alanine aminotransferase, AST, aspartate aminotransferase; SJS, Stevens-Johnson syndrome; TEN, toxic epidermal necrolysis; ULN, upper limit normal Libtayo SmPC Sept. 2020 pt. 4.8

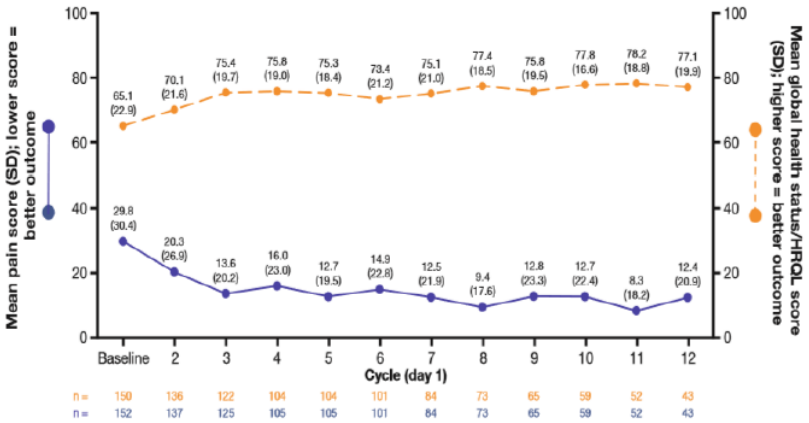
STUDIER

Health-Related Quality of Life (HRQL) in Patients with Advanced Cutaneous Squamous Cell Carcinoma (CSCC) Treated with Cemiplimab: Post Hoc Exploratory Analysis of a Phase 2 Clinical Trial

Migden et al. Poster Abstract: 10033 / Poster: 382

This post hoc exploratory analysis examined the QLQ-C30 data from the study 1540 Phase 2 clinical trial to determine the effects of cemiplimab treatment on HRQL and pain.

- **EORTC QLQ-C30 quality of life questionnaire administered at baseline and day 1 of each treatment cycle**
- **A 10 point – threshold is considered indicative of clinically meaningful improvement**



QLQ-C30 pain and global health status/HRQL scores by cycle

CONCLUSION

- The baseline pain score of patients with adv.CSCC was worse than that reported in general population or in pts with HNSCC
- By cycle 3, treatment with cemiplimab resulted in clinically meaningful reduction in pain and this effect was maintained through cycle 12
- By cycle 6, the majority of patients experienced clinically meaningful improvement or stability in global health status/HRQL and functional status

Migden, M.R., et al. J Clin Oncol; 38: Suppl, Abstr 10033 (2020)

Cemiplimab Trials in the Neoadjuvant Setti

Study (Sponsor/ Collaborator)	Intervention	Phase	Population	N	Primary endpoint	Start date
NCT03565783[1] (M. D. Anderson/ NCI)	Cemiplimab (neoadjuvant)	2	Stage III-IV CSCC of the head and neck	44	ORR	July 2018
NCT03889912[2] (Regeneron/ Sanofi)	Cemiplimab (intralesionally)	1	Recurrent CSCC	36	Safety	April 2019
NCT04315701[3] (University of Southern California/NCI)	Cemiplimab (neoadjuvant)	2	High-risk localized, locally recurrent, or regionally advanced CSCC	34	Confirmed pathologic partial response	April 2020
NCT04154943[4] (Regeneron/ Sanofi)	Cemiplimab (neoadjuvant)	2	Stage II-IV (M0) CSCC (stage II, lesion ≥3 cm)	76	pCR	March 2020

CSCC, cutaneous squamous cell carcinoma; NCI, National Cancer Institute; ORR, overall response rate
1. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT03565783. Accessed August 5,
https://clinicaltrials.gov/ct2/show/NCT03889912. Accessed August 5, 2020. 3. ClinicalTrials.gov. Availab
Accessed August 5, 2020. 4. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT0415

Keynote 629

Pembrolizumab for locally advanced and recurrent/metastatic cutaneous squamous cell carcinoma; an open label, non randomized, multicenter, phase 2 trial – *in press*

Populasjon: 159 pasienter; 54 lokalavansert, 105 tilbakefall/ metastaser

Resultat: høy responsrate, varige responser og lite bivirkninger av behandling

Adjuvant behandling

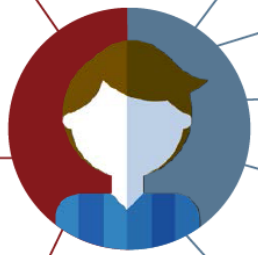
Both KEYNOTE-630 and C-POST Include Patients With High-Risk CSCC

KEYNOTE-630 (NCT03833167)[1]

Histologically involved nodal disease with extracapsular extension with:
- ≥1 lymph node >2 cm in greatest diameter, or
- ≥2 lymph nodes involved

Any index tumor with ≥2 of the following features
- Tumor ≥4 cm with a depth >6 mm
- Multifocal perineural invasion for nerves of <0.1 mm diameter (≥3 foci) or any involved nerve ≥0.1 mm diameter
- Invasion beyond subcutaneous fat
- Poor differentiation and/or sarcomatoid and/or spindle cell histology
- Recurrent disease (any CSCC that recurs within 3 years in the previously surgically or topically treated area)
- Satellite lesions (satellitosis) and/or in-transit metastases

Gross cortical bone invasion or skull base and/or skull base foramen invasion



C-POST (NCT03969004)[2]

Nodal disease with extracapsular extension, defined as extension through the lymph node capsule into the surrounding connective tissue with or without associated stromal reaction, and at least 1 node of >20 mm on the surgical pathology report[3]

In-transit metastases, defined as skin or subcutaneous metastases of >2 cm from the primary lesion but not beyond the regional nodal basin[4]

T4 lesion, including head and neck lesions and non–head and neck lesions[3,5]

Perineural invasion, defined as clinical and/or radiologic involvement of named nerves[5]

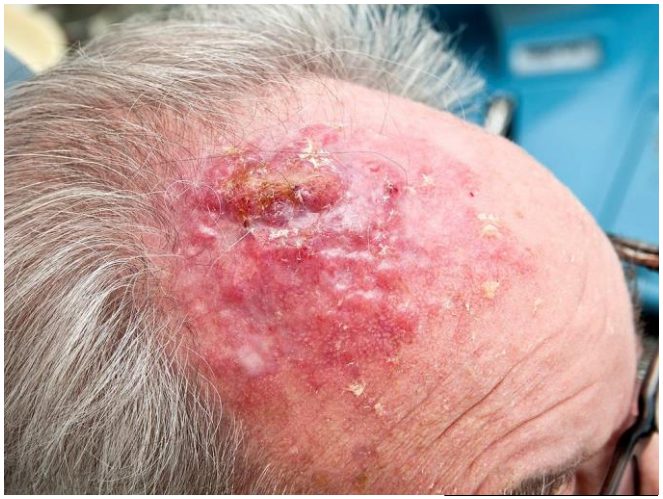
Recurrent CSCC, defined as CSCC that arises within the area of the previously resected tumor, plus at least 1 of the following additional features[3]
- ≥N2b disease associated with the recurrent lesion
- Nominal ≥T3 (recurrent lesion of ≥4 cm in diameter, minor bone erosion, or deep invasion of >6 mm measured from the granular layer of normal adjacent epithelium)
- Poorly differentiated histology and recurrent lesion of ≥20 mm diameter

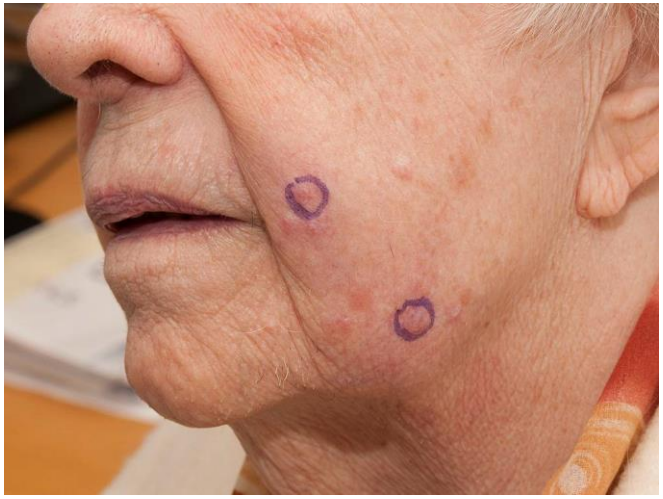
CSCC, cutaneous squamous cell carcinoma.

1. Chang ALS, et al. Presented at: AACR 2020 Virtual Annual Meeting II; June 22-24, 2020. Poster LB-138. 2. Rischin D, et al. Presented at: American Society of Clinical Oncology Annual Meeting; May 29-31, 2020. Poster 433. 3. Breuninger H, et al. *J Dtsch Dermatol Ges*. 2013;11(suppl 3):37-45. 4. Leitenberger JJ, et al. *J Am Acad Dermatol*. 2016;75(5):1022-1031. 5. Union for International Cancer Control (UICC). *Manual of Clinical Oncology*. 9th ed. UICC and John Wiley & Sons, Ltd; 2015.

MERKELCELLE CARSINOM

Merkelcellecarsinom (MCC)





- Småcellet neuroendocrin tumor
- Ved tumorutbredelse > 2 cm økt risiko for regional/metastatisk sykdom – postoperativ stråling
- Økende forekomst (større økning enn BCC og SCC)
- Assosiert med polyomavirus
- Krever mer omfattende kirurgisk behandling
- Vanligvis følsom for strålebehandling og cellegift
- Kan bruke NSE i oppfølgingen
- Immunbehandling god effekt

Schrama et al, 2012 og Wang et al, 2011

Avelumab in patients with chemotherapy-refractory metastatic Merkel cell carcinoma: a multicentre, single-group, open-label, phase 2 trial

Howard L Kaufman, Jeff ery Russell, Omid Hamid, Shailender Bhatia, Patrick Terheyden, Sandra P D'Angelo, Kent C Shih, Céleste Lebbé, Gerald P Linette,

Michele Milella, Isaac Brownell, Karl D Lewis, Jochen H Lorch, Kevin Chin, Lisa Mahnke, Anja von Heydebreck, Jean-Marie Cuillerot, Paul Nghiem

***Lancet Oncol* 2016; 17: 1374–85**

Updated efficacy of avelumab in patients with previously treated metastatic Merkel cell carcinoma after ≥1 year of follow-up: JAVELIN Merkel 200, a phase 2 clinical trial

Howard L. Kaufman[1,2*], Jeffery S. Russell[3,4], Omid Hamid[5], Shailender Bhatia[6], Patrick Terheyden[7], Sandra P. D'Angelo[8], Kent C. Shih[9], Céleste Lebbé[10], Michele Milella[11], Isaac Brownell[12], Karl D. Lewis[13], Jochen H. Lorch[14], Anja von Heydebreck[15], Meliessa Hennessy[16] and Paul Nghiem[17]

Conclusions: With longer follow-up, avelumab continues to show durable responses and promising survival outcomes in patients with distant mMCC whose disease had progressed after chemotherapy.

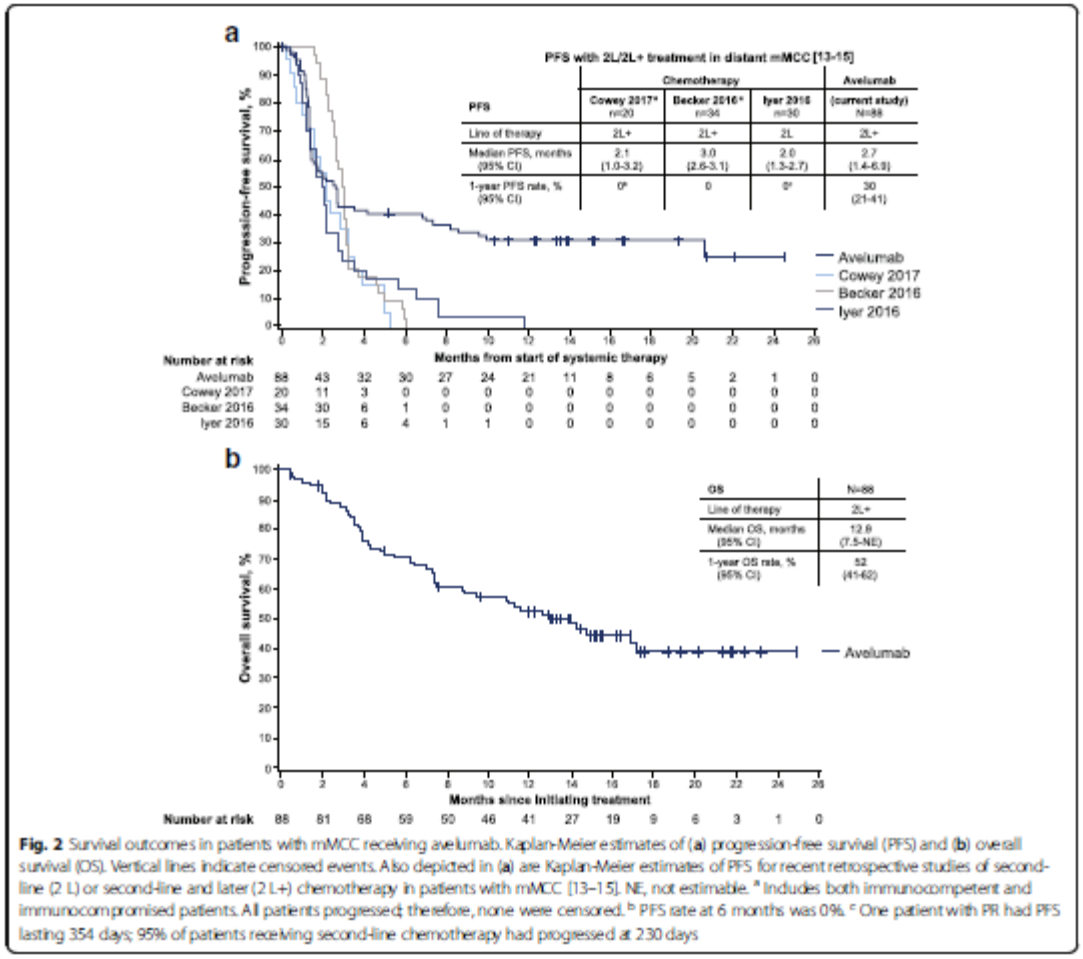


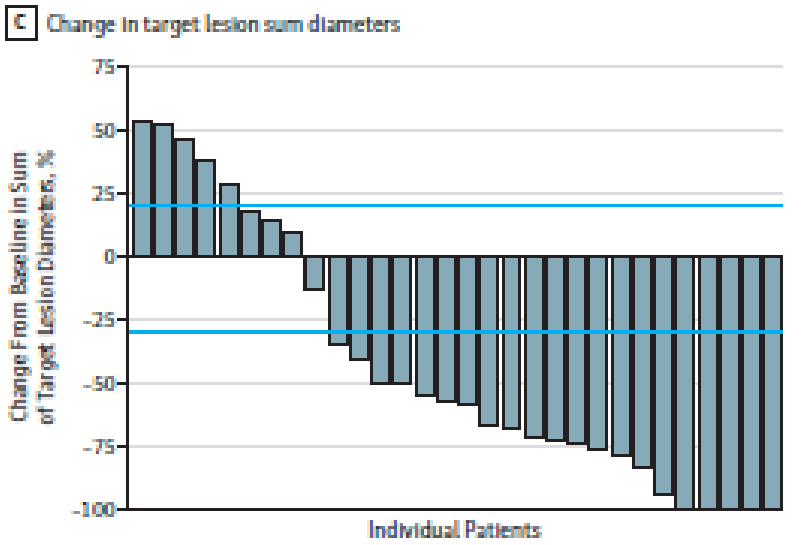
Fig. 2 Survival outcomes in patients with mMCC receiving avelumab. Kaplan-Meier estimates of (**a**) progression-free survival (PFS) and (**b**) overall survival (OS). Vertical lines indicate censored events. Also depicted in (**a**) are Kaplan-Meier estimates of PFS for recent retrospective studies of second-line (2 L) or second-line and later (2 L+) chemotherapy in patients with mMCC [13–15]. NE, not estimable. [a] Includes both immunocompetent and immunocompromised patients. All patients progressed; therefore, none were censored. [b] PFS rate at 6 months was 0%. [c] One patient with PR had PFS lasting 354 days; 95% of patients receiving second-line chemotherapy had progressed at 230 days

JAMA Oncology | Brief Report

Efficacy and Safety of First-line Avelumab Treatment in Patients With Stage IV Metastatic Merkel Cell Carcinoma
A Preplanned Interim Analysis of a Clinical Trial

Sandra P. D'Angelo, MD; Jeffery Russell, MD, PhD; Céleste Lebbé, MD, PhD; Bartosz Chmielowski, MD, PhD; Thilo Gambichler, MD; Jean-Jacques Grob, MD; Felix Kiecker, MD; Guilherme Rabinowits, MD; Patrick Terheyden, MD; Isabella Zwiener, PhD; Marcis Bajars, MD; Mellessa Hennessy, MPH; Howard L. Kaufman, MD

Resultat



A, Time to and duration of response and duration of treatment were measured in 18 patients with a confirmed response within the analysis set of patients with at least 3 months of follow-up. B and C, Change in target lesion diameters and percentage of change in target lesion sum diameters from baseline in individual patients were measured in 30 patients with a follow-up tumor assessment available. Parallel broken lines represent Response Evaluation Criteria in Solid Tumors values for progressive disease (≥20% increase in the sum of diameters of target lesions) and partial response (≥30% decrease in the sum of diameters of target lesions).

Konklusjon

1. Immunbehandling med PD1-hemmer cemiplimab er godkjent til bruk ved inoperable plateepitelcarsinomer i hud, hvor stråling ikke er mulig.
2. Immunbehandling med PD1-L1 hemmeren avelumab er godkjent i 2. linje ved avansert Merkel celle carsinom